FOCUSED REMANDS -2018

- How does it Look? SAMPLE

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council

Medic EMS, Appellant

ALJ Appeal Nos. 1-1234567890 and 7 others (see attached)
Docket No. M-12-3456

ORDER REMANDING CASE TO THE
OFFICE OF MEDICARE HEARINGS AND APPEALS

The Administrative Law Judge (ALJ) issued a decision dated April 19, 2016, concluding that Medicare should pay the appellant supplier (appellant) under Medicare Part B for ambulance transportation (HCPCS codes A0425HH, A0426HH), from one location of the G. Medical Center (West Hospital) to the other location (East Hospital), 2.3 miles away, on multiple dates of service in 2012.

By memorandum dated June 8, 2016, the Centers for Medicare & Medicaid Services (CMS) asks the Council to exercise own-motion review of the ALJ's decision. 42 C.F.R. § 405.1110. In its memo, CMS contends that the ALJ erred in ordering Medicare coverage and payment under Part B for ambulance services provided while the beneficiaries were each in a Part A inpatient hospital stay at the G Medical Center. CMS contends that in ordering this coverage and payment the ALJ made an error of law material to the outcome of the case. 42 C.F.R. § 405.1110

Smith v. Berryhill

- Petition for certiorari pending with U.S. Supreme Court.
- Challenges SSA's position that Social Security Appeals Council dismissals are not "final decisions" subject to judicial review under 42 U.S.C. § 405(g).
- Sixth Circuit Court of Appeals found in favor of SSA.
- On September 21, 2018, DOJ filed a brief in non-opposition to certiorari, stating that it now agrees with petitioner.
- Could have a direct impact on whether Medicare Appeals Council dismissals and denials of review are subject to judicial review.

Procedural Issues: Regulations Highlights

Dismissals based on abandonment

42 C.F.R. § 405.1052(a)(6) provides:

> The appellant abandons the request for hearing. An ALJ or attorney adjudicator may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

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- Council has remanded where there is insufficient evidence of the efforts to contact the appellant

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Applicability of 42 C.F.R. § 405.1062 in Part C

- 42 C.F.R. § 405.1062 provides that ALJs and the Council will give *substantial deference* to local coverage determinations and other CMS program guidance if applicable

- Pursuant to 42 C.F.R. § 422.101(b), MA plans *must* comply with NCDs, general coverage guidelines included in original Medicare manuals, and written coverage decisions of local Medicare contractors (LCDs, policy articles).

Procedural Issues: Regulations Highlights

- Applicability of 42 C.F.R. § 405.1062 in Part C (cont.)
- Because these guidelines and coverage determinations are binding on MA plans, ALJs and the Council should apply the authorities to which Plans are bound
- Council concludes that the substantial deference provisions at 42 C.F.R. § 405.1062 are inapplicable in Part C cases

Continuous Glucose Monitoring (CGM) – Legal Framework

- Issue is whether the CGM system at issue meets the definition of DME.
  - Outcome does not depend on whether a beneficiary individually shows a medical need for a particular CGM system.
  - Classifying a device as DME (or not DME) has to do with its primary function in medical treatment, not any individual's use of the device, however beneficial.

Continuous Glucose Monitoring (CGM) – Legal Framework

- Threshold inquiry for DME is whether the item is "primarily and customarily used to serve a medical purpose." 42 C.F.R. § 410.202.
  - CMS has expressed an interpretation of the definition of DME as limited to those CGM devices which are suitable for direct determination of treatment actions.
  - Effective January 12, 2017, CMS Ruling 1682-R allows Medicare coverage for *therapeutic CGM systems.*

Continuous Glucose Monitoring (CGM) – CMS Ruling 1682-R

- CMS Ruling 1682-R
  - A therapeutic CGM is one that:
    - Has been approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions;
    - Is generally not useful to the individual in the absence of an illness or injury;
    - Is appropriate for use in the home; and
    - Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.

Continuous Glucose Monitoring (CGM) – CMS Ruling 1682-R

- All CGMs that are approved by the FDA for use as an adjunctive device to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are "non-therapeutic" CGMs and would not be covered under the Ruling.
- Current FDA approved CGM systems:
  - Dexcom G5 (Dexcom, FDA approval in December 2016)
  - FreeStyle Libre System (Abbott, FDA Approval in September 2017)

Dexcom G5 Mobile CGM System components

- **A) Small sensor**
- A discrete sensor located just underneath the skin, measures your glucose levels.
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- Glucose data is sent wirelessly to either your **compatible smart device** or your receiver via Bluetooth® wireless technology.
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- Your glucose levels are shown in vivid colors so you can easily see when your glucose is trending high, low or just right. The display device can be either a **compatible smart device** with the Dexcom G5 Mobile app OR the Dexcom G5 Mobile Receiver.

FreeStyle Libre

- Discover the FreeStyle Libre system
- Get ready to make routine fingersticks a thing of the past
- **What is it?**
- The FreeStyle Libre system is a continuous glucose monitoring system consisting of a handheld reader and a sensor worn on the back of the upper arm.
- **How does it work?**
- The sensor uses a thin, flexible filament inserted just under the skin to measure glucose every minute.
- **How do you use it?**
- Use the handheld reader to scan the sensor with a painless[1], one-second scan and replace routine fingersticks.

Continuous Glucose Monitoring (CGM) – Council Position

- Dates of service prior to CMS Ruling 1682-R:
  - no change to Council position that CGM systems are not DME.
  - By its own terms, CMS Ruling 1682-R was not made retroactive to dates prior to the Jan. 12, 2017, effective date.
- Dates of service after CMS Ruling 1682-R:
  - If CGM system meets definition of DME under CMS Ruling 1682-R, then coverage may be appropriate.
  - Non-therapeutic CGM systems are not DME.
- What type of CGM?
  - Recent Remands: Record inconsistency

Continuous Glucose Monitoring (CGM) – Recurring Issues

- District court decisions not controlling.
  - *Finigan v. Burwell, 189 F. Supp.3d 201 (D. Mass 2016)*
  - *Whitcomb v. Hargan, Civ. No. 17-CV-14 (Oct. 26, 2017)*
  - *Bloom v. Azar, Civ. No. 5:16-CV-121 (Jan. 29, 2018)*
  - *Lewis v. Azar, Civ. No. 15-13530 (Apr. 5, 2018)*
- CMS has expressed a consistent interpretation of the definition of DME as limited to those CGM devices which are suitable for direct determination of treatment actions.
  - Embodied in policy articles explaining that non-therapeutic CGMs were not DME because they were precautionary.
  - The two contractors responsible for DME claims posted a joint publication explaining that CGM systems relying on confirmation from a capillary blood glucose monitor were precautionary.

Agency Referral Spotlight

Issue: whether the Secretary's designations of "inpatient only" services are applicable to providers in Medicare waiver states (i.e., the State of Maryland). *See, e.g.,* In the Case of Peninsula Regional Medical Center, Docket No. M-18-5001 (Sept. 5, 2018).

- The Secretary has designated certain procedures as inpatient only, in other words services that have been deemed inappropriate in a outpatient setting. *See* Act § 1833(t)(1)(B)(i); MCPM, Ch. 4, § 180.7

Agency Referral Spotlight

- Appellants argue that the inpatient only list is a reimbursement scheme and does not apply to providers in the State of Maryland because it is a Medicare waiver state and not subject IPPS/OPPS reimbursement guidelines
- CMS asserts that the waiver permits Maryland to have its own reimbursement system, but does not usurp the Secretary's authority to define covered services

Agency Referral Spotlight

- The Council has taken own motion review because there is an error of law and a broad issue that affects the public interest
- The Council has determined:
  - The waiver exempts Maryland hospitals from reimbursement under the national payment system, but not from the Secretary's authority to define covered services
    - Appellants conflate reimbursement and coverage. The Secretary's inpatient only list is not a component of OPPS, but an *exclusion* to payment for services that have been deemed inappropriate in an outpatient setting
  - Any procedure on the inpatient only list cannot be reimbursed under Medicare's OPPS or under Maryland's reimbursement system

Agency Referral Spotlight

- We agree with CMS that to determine otherwise would lead to a broad policy issue where only Maryland hospitals would be allowed outpatient payment for services the Secretary has deemed inpatient only
- Liability
  - Note that § 1879 does not apply because the denial is based § 1833(t)(1)(B)(i) of the Act. *See also* 65 Fed. Reg. 18442-18443.
    - Bene should be joined as a party for the hearing.
  - The beneficiary is financially responsible for non-covered services
- Maybe a good candidate for precedential designation
  - These cases present a discrete legal issue
  - If adjudicators are bound to the Council's holding, then it's possible these types of cases won't enter the appeals system

2018 Judicial Education Symposium: View from the Council

October 16, 2018

Topics

- Medicare Appeals Council Overview
- Precedential Final Decisions of the Secretary
- Focused Remands
- Hot Topics: Dismissals/ Denials of Review
- Procedural Issues/Regulations Highlights
- Continuous Glucose Monitoring (CGM)
- Key Council Decisions/AR Spotlight

Medicare Appeals Council (Council)

- Council performs a *de novo* review of ALJ actions

The Council:

- Chair, Deputy Chair,
- A Chief Administrative Appeals Judge
- 6 (AAJs)
- and select Board Members

- The Authority of Council decisions
  - Cohesion and Consistency
- Weekly meetings, Policy memoranda,
- informal consultation…

Precedential Final Decisions of the Secretary

- **Medicare Appeals Council Precedent Rule**
- 42 C.F.R. § 401.109(a)-(d) **(effective March 20, 2017)**
  - Chair of the DAB may designate a final decision issued by the Council of the Secretary as precedential.
  - Precedential effect from the date made available to the public. Notice published in the Federal Register.
  - Binding on all CMS, HHS, and SSA components that adjudicate matters under the jurisdiction of CMS.
  - Legal analysis and interpretation of a Medicare authority or provision is binding as well as factual findings (for same parties if same facts unchanged).

Precedential Final Decisions of the Secretary

- Medicare Appeals Backlog Measure.
- Goal is to increase consistency at all levels of appeal, thereby reducing improper payments and unnecessary appeals.
- No precedential decisions yet.
- Stakeholder outreach is underway, and initial designations are expected to be announced in early 2019.

FOCUSED REMANDS -2018

- What is It?
  - A streamlined approach for remanding cases to OMHA
  - The Council issues a shortened, focused action document.
  - Eliminating lengthier action documents
    - Case background/Procedural history
    - Legal discussions/Legal analysis
- Intended to apply to most remands based on ALJ error in Parts A and B, and Part C.
- Part D Cases– cases where ALJ made a legal error in deciding the case (also no hearing cases).

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U.S. Department of Health & Human Services
Office of Medicare Hearings and Appeals

Judicial Education Symposium (JES):
PART D TIERING EXCEPTIONS

AUGUST 2018

Learning Objectives

- Provide an overview of the Existing Part D Legal Framework applicable to Part D Tiering exceptions
- Highlight regulatory changes to Part D Program due to the final rule on the Medicare Prescription Drug Benefit Program, applicable January 1, 2019 (83 Fed. Reg. 16440)
- Review subtopics identified by the training cadre survey
- Identify trends in Medicare Appeals Council decisions and Program Advisor updates from FY2014 to FY2018

Why Medicare Part D?

- As of January 1, 2018, 43.8 million people were enrolled in Medicare Part D Prescription Drug coverage.

  Source: CMS, Enrollment Dashboard, March 2018

- As of September 5, 2017, there were 42,426 distinct versions of plans (1,860 plans) offering Part D coverage.
  - 28,485 versions offered enhanced alternative benefits.
  - 6,225 versions offered the defined standard benefit.

  Source: CMS, 2018 Plan and Premium Information for Medicare Plans Offering Part D Coverage

Why Medicare Part D Tiering Exceptions?

- While tiering exception requests are a small percentage of overall case volume, they are consistently associated with significantly lower approval rates than all other types of coverage and exception requests.
- CMS has made a number of changes to Part D formulary tier models for non-defined standard benefit plans, including changes to tier labeling, which has resulted in brand and generic drugs being placed on the same tiers more frequently.
- Changes in the prescription drug landscape, including the considerable impact of high-cost drugs on the Part D program, have resulted in increasingly complex plan benefit packages and more variation in type and level of cost-sharing.

Training Survey

- In April 2018, the national training cadre solicited input on topics requiring further substantive training.
- OMHA Employees self-selected Part D Tiering Exceptions as one of the most important topics needing further instruction.

- Specific subtopics of interest included:
  - Preferred Drugs
  - Generic Drugs
  - Compendia Analysis
  - Physician Statements
  - Corrected Prescriptions
  - Exhibiting

Pre-Assessment

Pre-Assessment

Scenario 1:

- On January 10, 2018, Lyrica (100mg) was prescribed for the treatment of the enrollee's post-herpetic neuralgia, included as an indication on the FDA label. The formulary contains coverage for Lyrica (25mg, 50mg, 75mg, 150mg) and lists the drug as a tier 3 drug. A prescriber statement has been submitted saying lower tier alternatives on tier 1 and 2, which both include brand drugs, would cause adverse effects. Can the enrollee receive a tiering exception?

Pre-Assessment

Scenario 2:

- The enrollee was provided rhinocort allergy spray (budesonide) to treat her allergic rhinitis in 2017. The drug is on tier 3 of the plan's formulary, not a specialty tier. She seeks a tiering exception to lower the cost. There is an alternative medication on tier 2. An appropriate physician statement has been provided. Can the enrollee receive a tiering exception?

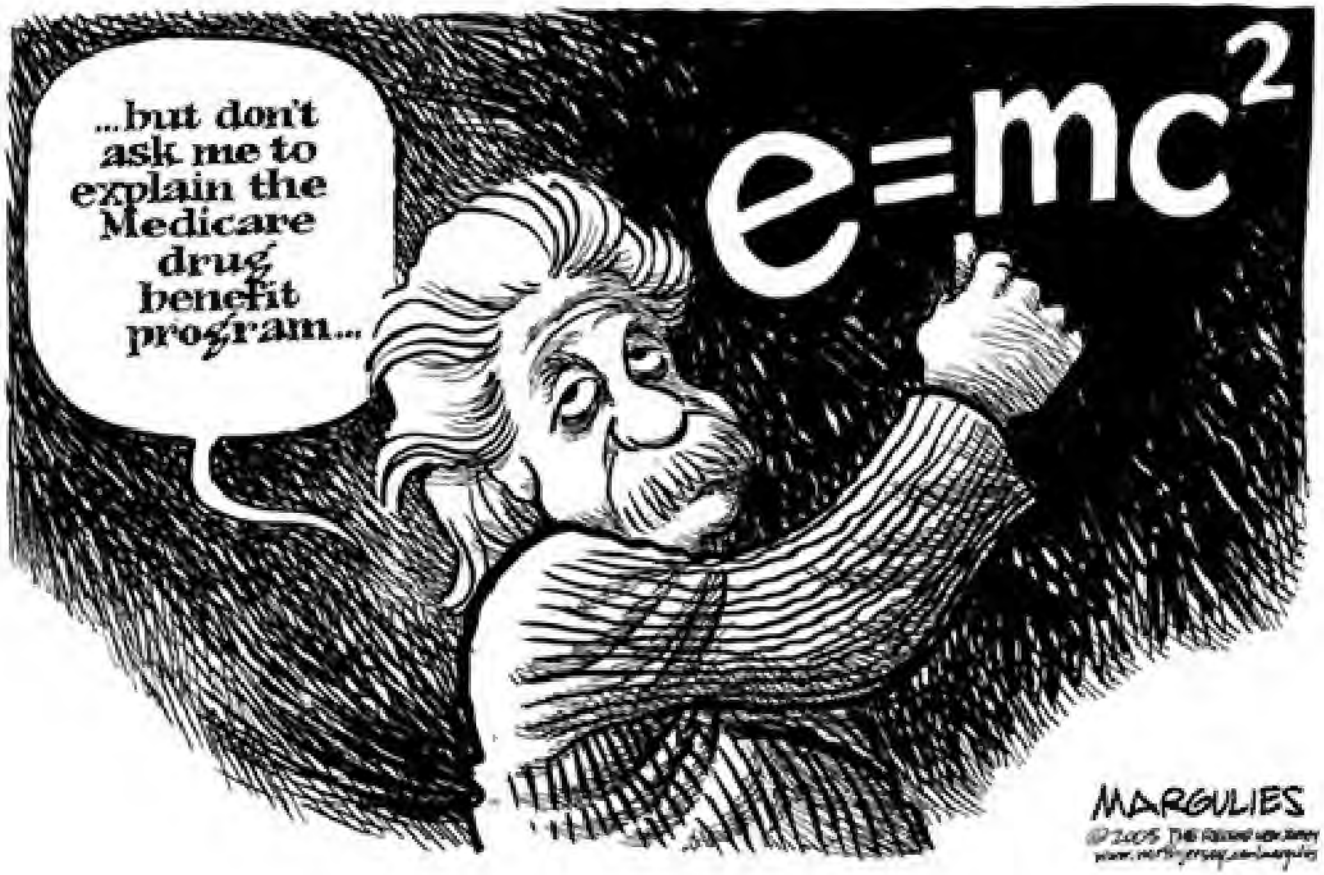
Pre-Assessment

Scenario 3:

- The enrollee was prescribed the brand drug Zestril (10mg) for the treatment of hypertension, an FDA approved indication, on March 10, 2018. Zestril, and all other brand drugs, are listed on tier 3 of the plan's formulary. Zestril is not a specialty drug. Enalapril, a therapeutically equivalent generic, is listed on Tier 1 of the formulary, which does not exclusively contain generics. The prescriber provided an appropriate physician statement. Can the enrollee receive a tiering exception?

Existing Part D Legal Framework

Judicial Education Symposium



Part D Tiering Exceptions Legal Framework

- Statute
  - § 1860D of the Act
    - **Subpart 1: Part D Eligible Individuals & Prescription Drug Benefits**
    - Subpart 2: Prescription Drug Plans; PDP Sponsors; Financing
    - Subpart 3: Application to Medicare Advantage Program and Treatment of Employer-Sponsored Programs and Other Prescription Drug Plans
    - Subpart 4: Medicare Prescription Drug Discount Card and Transitional Assistance Program
    - Subpart 5: Definitions and Miscellaneous Provisions

Part D Tiering Exceptions Legal Framework

- Statutes
  - **§ 1860D of the Act, Subpart 1**
    - » 1860D-2(e)(1) – **Covered Part D Drug** Definition
      - 1927(k)(2) – FDA Approval & Grandfathered Language
    - » 1860D-2(e)(2) – **Exclusions**
    - » 1860D-2(e)(4) – **Medically Accepted Indication** Defined
      - 1927(k)(6)- General
      - 1927(g)(1)(B)(i) – General Compendia Citation
      - 1861(t)(2)(B) – Cancer
      - 1927(g)(1)(B)(i)-(ii) – Cancer Compendia Citation

Part D Tiering Exceptions Legal Framework

- Statutes **§ 1860D of the Act, Subpart 1**
  - 1860D-4(g)(2) – Tiering Exceptions:
    - In the case of a prescription drug plan offered by a PDP sponsor that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, a part D eligible individual who is enrolled in the plan may request an exception to the tiered cost-sharing structure.
    - Under such an exception, a **nonpreferred drug** could be covered under the terms applicable for preferred drugs if the **prescribing physician** determines that the preferred drug for treatment of the same condition either **would not be as effective** for the individual or would have **adverse effects** for the individual or **both**.
    - Denial of such an exception shall be treated as a **coverage denial**.

Part D Tiering Exceptions Legal Framework

- Statutes **§ 1860D of the Act, Subpart 1**
  - 1860D-4(h) – Formulary exceptions
    - A part D eligible individual who is enrolled in a prescription drug plan offered by a PDP sponsor may appeal under paragraph (1) a determination not to provide for coverage of a covered part D drug that is not on the formulary under the plan only if the **prescribing physician** determines that **all** covered part D drugs on any tier of the formulary for treatment of the same condition **would not be as effective** for the individual as the nonformulary drug, would have **adverse effects** for the individual, or **both.**

Statutory Recap

- Part D Coverage
  - § 1860D-2(e): Definitions & Exclusions
  - § 1860D-4: Formulary and Tiering Exceptions

- Medically Accepted Indication
  - § 1927(k)(6)
  - § 1861(t)(2)(B) - Cancer

- Compendia
  - § 1927(g)(1)(B)(i)
  - § 1927(g)(1)(B)(i)-(ii) – Cancer

Existing Part D Regulations Definitions (Part 423)

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Definitions 42 C.F.R. § 423.4**
    - Formulary: the entire list of Part D drugs covered by a Part D plan.
    - PDP sponsor: a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans.
    - Prescription drug plan or PDP: prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in § 423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part
    - Tiered cost-sharing: a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Definitions 42 C.F.R. § 423.4**
    - Brand name drug: a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).
    - Generic drug: a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Definitions 42 C.F.R. § 423.100**
    - Covered Part D drug: a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §§ 423.566, 423.580, and 423.600, 423.610, 423,620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124
    - Part D drug means—
      - (1) Unless excluded under paragraph (2) of this definition, any of the following if used for a **medically accepted indication** (as defined in section 1860D-2(e)(4) of the Act)—
      - (i) A drug that may be dispensed only upon **a prescription** and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.
      - (ii) A **biological product** described in sections 1927(k)(2)(B)(i) through (iii) of the Act.
      - (iii) **Insulin** described in section 1927(k)(2)(C) of the Act.

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Definitions 42 C.F.R. § 423.100**
    - Part D drug means—
      - (iv) **Medical supplies** associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.
      - (v) A **vaccine** licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.
      - (vi) **Supplies that are directly associated with delivering insulin** into the body, such as an inhalation chamber used to deliver the insulin through inhalation.
      - (vii) A **combination** product approved and regulated by the FDA as a **drug, vaccine, or biologic** described in paragraphs (1)(i), (ii), (iii), or (v) of this definition.

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Definitions 42 C.F.R. § 423.100**
    - Part D drug —

      (2) Does not include any of the following:

      » (i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under **Part A or Part B** (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).

      » (ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections **1927(d)(2) or (d)(3) of the Act**, except for smoking cessation agents.

      » (iii) **Medical foods**, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Definitions 42 C.F.R. § 423.100**
    - Preferred drug: a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.
    - Therapeutically equivalent: refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."
  - **Definitions 42 C.F.R. § 423.560**
    - Other prescriber: a health care professional other than a physician who is authorized under State law or other applicable law to write prescriptions.

Existing Part D Tiering Exception Regulation

42 C.F.R. § 423.578

Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Exceptions 42 C.F.R. § 423.578**
    - (a) The Part D plan sponsor grants an exception whenever it determines that the **non-preferred drug** for treatment of the enrollee's condition is **medically necessary**, **consistent with the physician's or other prescriber's statement** under paragraph (a)(4) of this section.

      - (a)(4): A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug for the treatment of the enrollee's conditions—
        - (i) Would not be as effective for the enrollee as the requested drug;
        - (ii) Would have adverse effects for the enrollee; or
        - (iii) Both paragraphs (a)(4)(i) and (a)(4)(ii) of this section apply

Part D Tiering Exceptions Legal Framework

Tiering Exception Elements

- Prescription;
- FDA Approved or Grandfathered drug;
- Not Excluded from Part D Coverage;
- Prescribed for a Medically Accepted Indication;
- The Desired Drug must be Nonpreferred;
- There must be a Physician or Other Prescriber Statement; AND
  - Drug is not as effective
  - Would have adverse effects, or
  - Both
- Therapeutically Equivalent Lower Tier Alternative

➢ Prescription

- M-16-5895: Section 1860D-2(e) of the Act defines a "covered part D drug" as "a drug that may be dispensed only upon a prescription"

➢FDA Approved or Grandfathered drug

- **§§ 1927(k)(2)(A)(i) - (iii)**

  – It is FDA-approved for safety and effectiveness under the New Drug Application (NDA) process in § 505 or the Abbreviated New Drug Application (ANDA) process in § 505(j) of the FD&C Act, pursuant to § 1927(k)(2)(A)(i) of the Act;

  – (2) It is exempted from the FDA approval process through a grandfathering provision in § 1927(k)(2)(A)(ii); or

  – (3) It is exempted from the FDA approval process through the Secretary's determination provision in § 1927 (k)(2)(A)(iii).

➢FDA Approved or Grandfathered drug

- **Where do you look to determine?**
  - Drugs@FDA (FDA Website)
  - Electronic Orange Book (FDA Website)
  - List of Pre-1938 Drugs (OMHA SharePoint)
    - » United States Pharmacopoeia Drug Index (USPDI), Volume III, "Approved Drug Products and Legal Requirements," Part 1, Section III

➢ FDA Approved or Grandfathered drug

- M-15-1877: The Council found that the ALJ erred in focusing on whether the drug was prescribed for a medically accepted indication without first analyzing whether the drug was FDA-approved or exempt from approval as a grandfathered drug.

- M-14-657: Congress cross-referenced section 1927(k)(2) in defining "covered part D drug[s]" in section 1860D-2(e) of the Act. That section specifically included the reference to drugs commercially sold or marketed prior to the Drug Amendments of 1962; grandfathered drug provisions of section 1927(k)(2)(A)(ii).

- M-17-7198: a drug authorized through the investigational new drug (IND) application process under § 505(i) is not equivalent to an FDA-approval for safety and effectiveness under the NDA process in § 505 or the ANDA process in § 505(j) to meet the definition of a Part D drug…IND application drugs are authorized to be investigated for safety and effectiveness, rather than approved for safety and effectiveness as a prescription drug under §§ 505 and 505(j).

➢ FDA Approved or Grandfathered drug

- M-16-256: the Part D plan is not required to cover a drug categorized as a less-than-effective (LTE) Drug Efficacy Study and Implementation (DESI) drug by the FDA because it is not a Part D drug.

- M-16-1179: LTE DESI drugs are not Part D drugs because they are categorized as less than effective and not FDA approved for any indication in accordance with current FDA requirements. the formulary exceptions process cannot be used to obtain drugs that do not meet the definition of a Part D drug. *See* § 423.578(e)

- M-16-219: Drug products compounded from bulk chemical powders are not grandfathered drugs. The grandfather exemptions apply to commercially available drug products that are identical to commercially available drug products marketed prior to 1938 or 1962 . By their nature and definition, compounded drug products tailored to the needs of an individual patient are not commercially available and are not identical to previously marketed drugs.

➢FDA Approved or Grandfathered drug

- M-16-7312: Part D drug benefit is limited to items or substances that are FDA approved as drugs. Euflexxa injections are classified by the FDA as a "device," and devices are not covered under Part D.

- M-18-10: the FDA has made a final determination that drugs in extended-release dosage forms are not new drugs. Accordingly, it does not fall within the category of a "grandfathered" drug pursuant to § 1927(k)(2)(ii).

Not Excluded from Part D Coverage

- Section1860D-2(e)(2)(A) says:
  - In general.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section **1927(d)(2)**, other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines) or under section **1927(d)(3**), as such sections were in effect on the date of the enactment of this part.
  - Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

Not Excluded from Part D Coverage

- 1927(d)(2) lists a variety of drug classes and uses that are excluded.

- The 1927(d)(2) exclusions include:
  - Drugs for anorexia, weight loss, or weight gain;
  - used to promote fertility;
  - cosmetic purposes or hair growth;
  - the symptomatic relief of cough and colds;
  - Used to promote smoking cessation;
  - Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations;

Not Excluded from Part D Coverage

- The 1927(d)(2) exclusions (cont.):
  - Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A)
  - Agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation;
  - Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee;
  - for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

Not Excluded from Part D Coverage

- The 1927(d)(2) exclusions (cont.):
  - Barbiturates;
  - Benzodiazepines

- 1927(d)(3) allows the Secretary to modify this list by regulation.

  - Effective January 1, 2013, Part D began covering **benzodiazepines** for any medically-accepted indication (as defined in § 1927(k)(6) of the Act), as well as **barbiturates** for the treatment of certain conditions (epilepsy, cancer, or a chronic mental health disorder). § 1860D-2(e)(2)(A) of the Act, as amended by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)

  - Effective January 1, 2014, **barbiturates** that meet the definition of a Part D drug may be covered under Part D for any medically-accepted indication. ACA amended § 1927(d)(2) of the Act to remove the limitation of certain conditions for coverage of barbiturates.

Not Excluded from Part D Coverage

- M-15-612 & M-16-5895: Drugs available **without a prescription**, and **over-the-counter drugs** are excluded from Medicare Part D coverage. You have to look to "Rx only" marking on the product label, in accordance with § 503(b)(4) of the Act and as indicated in chapter 6, section 10.1, MPDBM

- M-17-6574: immunosuppressive drugs enjoy Part B coverage even if Medicare did not pay for the transplant so long as the beneficiary was enrolled in Part A at the time of the transplant. If a drug is eligible for **Part B payment**, the Council determined that drug does not meet the definition of a Part D drug. See Act, § 1860D-2(e)(2)(B) ; see also 42 C.F.R. § 423.100

- M-13-4494: experimental, investigational drugs

Not Excluded from Part D Coverage

- M-17-8297: probiotics / medical food
- M-17-6620: drugs used for anorexia, weight loss, or weight gain
- M-15-5317, M-15-1877 & M-17-2835: vitamins and minerals, except prenatal vitamins and fluoride preparations
- M-16-138 & M-17-365: drugs used for the treatment of sexual or erectile dysfunction, unless such drugs are used to treat a condition, other than sexual or erectile dysfunction, for which the drugs have been approved by the FDA.

➢ Prescribed for a Medically Accepted Indication

- M-17-437: even drugs that may be medically necessary and effective are not covered under Part D if they are not being prescribed to treat a medically accepted indication, as defined by the Act.

- What to Review
  - FDA Label
  - Compendia
  - Peer Reviewed Medical Literature (Chemo Drugs)

Recognized Compendia (CMS Transmittal 212)

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- **Truven Health Analytics Micromedex DrugDex**
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

➢ The Desired Drug must be Nonpreferred

- M-18-1481: The Act and its implementing regulations limit tiering exception requests to non-preferred drugs on a Part D plan's formulary . See Act § 1860D-4(g)(2); 42 C.F. R. § 423.578(a). Part D plans are not required to award tiering exceptions for preferred drugs

- M-17-8538: Part D plans are not required to grant tiering exception requests for preferred drugs because tiering exception requests are limited to non-preferred drugs on a Part D plan's formulary. See Act § 1860D-4(g)(2); 42 C.F.R. § 423.578(a)

- M-17-3358: Under 42 C.F.R. § 423.578(a), tiering exception requests are limited to non-preferred drugs on a Part D plan's formulary. Thus, Part D plans are not required to grant tiering exception requests for preferred drugs

- M-15-2720: Part D plans are not required to grant tiering exception requests for preferred drugs

➢ Physician or Other Prescriber Statement

- If the prescriber's supporting statement does not sufficiently demonstrate the medical necessity of the requested drug and the plan determines it needs more information to make the decision, **the plan must contact** the prescriber and clearly identify what is needed. MPDBM, Chapter 18, § 30.2

- It is **incumbent upon the plan** to determine, in light of the supporting statement, whether there is another alternative to the prescribed drug that is in a lower tier than the preferred drug(s) addressed in the prescriber's supporting statement. CMS, 2018 Final Call Letter (April 3, 2017)

➢ Physician or Other Prescriber Statement

- M-13-4494: Medicare does not recognize the **"treating physician rule**," and a physician's recommendation or order for an item or service does not establish Medicare coverage for that item or service.

- M-16-11128: A prescriber's statement in support of a formulary exception request "is entitled to **great weight** when reviewing the exception or other coverage determination request." Medicare Prescription Drug Benefit Manual (MPDBM), Ch. 18, § 30.2.2.

- M-18-1481: Physician statements are **not controlling** when an enrollee is requesting a tiering exception for a preferred drug, and not a nonpreferred drug

- M-16-11100: The ALJ found that the enrollee's prescribing physician did not specifically list and address which lower tiered drugs on the formulary had been tried, how they were not as effective, and/or how these drugs would have adverse effects. The Council found that the enrollee was not eligible for a tiering exception because the record did not include an **adequate supporting statement** by the prescribing physician

➢ Physician or Other Prescriber Statement

- M-17-11062: Enrollee **need not try alternative drug**. Declaration submitted by the prescribing physician satisfies the exception requirement.

- M-16-6812: the ALJ's assertion that the prescribing physician's "opinion …**outweighs a label contraindication**" was legally incorrect and insufficient to compel Medicare coverage.

- M-15-1139: the Plan is not required to grant a cost-sharing tiering exception for a drug when the prescribing physician failed to identify a **lower cost-sharing alternative drug** to treat the enrollee's condition. 42 C.F.R. § 423.578(a)(4).

➢ Physician or Other Prescriber Statement

- M-17-654: A tiering exception **must be granted** when the prescribing practitioner provides a supporting statement that the plan's preferred drug for the treatment of the enrollee's condition would not be as effective as the non-preferred drug and/or would have adverse effects for the enrollee." See Medicare Prescription Drug Benefit Manual (MPDBM), Ch. 18, § 30.2.1; 42 C.F.R. § 423.578(a)(4). Although the appellant argues that the other drugs available, specifically Morphine, cause adverse side effects, the regulations require a statement by the prescribing physician.

- M-16-11102: A tiering exception **must be granted** when "the preferred drug for treatment of the enrollee's condition would not be as effective for the enrollee as the requested non-preferred drug and/or would have adverse effects." The record does not contain evidence from the enrollee's physician as to whether all available lower tier alternatives would not be as effective or would have adverse effects on the enrollee.

➢ Physician or Other Prescriber Statement

- M-16-2074: Throughout the appeals process, the enrollee and her physician have affirmatively asserted that the enrollee has tried generic medications without success. However, those **assertions are not supported by documented identification of these alternative drugs or the corresponding courses of treatment for such drugs**. Unsupported and generalized assertions of compliance with the regulatory requirements are insufficient bases for finding compliance. Without documentation, there is no support for the enrollee's arguments for coverage.

- M-15-513: Without a statement from the enrollee's prescribing physician that includes information addressing lower tiered formulary drugs that treat the same condition, the Plan is not required to provide a tiering exception.

- M-14-2259: The Council adopted the ALJ's decision, finding that the enrollee's new physician, who provided a prescriber statement to the Part D QIC, was not able to provide the **detail and specificity** required under 42 C.F.R. § 423.578(b)(5)(iii) to support an exception

➢ Therapeutically Equivalent Lower Tier Alternative

- M-16-9298: the Council found that the ALJ had overlooked the requirement that a tiering exception must be based on the fact that the Part D prescription drug plan has a **therapeutically equivalent drug at a lower tier**, but that drug will not work for the enrollee because it is not effective or has problematic side effects. The Council noted that in this case there was no equivalent drug on a lower tier in the plan's formulary for treating the appellant's condition; therefore, there was no basis under section 1860D-4(g)(2) of the Act and 42 C.F.R. section 423.578(a) for granting a tiering exception.

- M-18-1481: The regulations expressly require that exceptions criteria of a Part D plan sponsor "must include, but are not limited to . . . "[c]onsideration of whether the requested Part D drug that is the subject of the exceptions request is the **therapeutic equivalent**, as defined in § 423.100, of any other drug on the plan's formulary." 42 C.F.R. § 423.578(a)(2)(ii). Therefore, **there must be another drug (and a lower cost-sharing one) on the Plan's formulary that is available to treat the enrollee's condition**. The lower cost-sharing drug must either be not as effective or have adverse effects on the enrollee, or both, as stated by the prescribing physician, in order for the Plan to grant a tiering exception . 42 C.F.R. §§ 423 .578(a), 423.578(a)(4); MPDBM, Ch. 18, § 30.2.1 .4.

➢ Therapeutically Equivalent Lower Tier Alternative

- M-17-8361: Drug was not eligible for a tiering exception because there were **no lower cost drugs** in the Plan's formulary to treat the appellant's condition

- M-16-11102: While the record does establish that there are no lower tiered alternatives that are FDA-approved for interstitial cystitis, it does not contain sufficient information to determine whether there are **any lower tiered alternatives that are supported by recognized compendia** for the treatment of the enrollee's condition.

- M-16-9893: The ALJ found that the appellant was not entitled to a tiering exception because there are **no drugs in the lower tiers** to treat the appellant's condition which would allow for a lower copayment

- M-16-10723: The manual indicates that **there must be a drug on the lower tier that is approved to treat the condition on the higher tier**. MPDBM Ch. 18, § 30.2.1.4.

➢ Therapeutically Equivalent Lower Tier Alternative

- M-15-3913: Medicare regulations provide that an enrollee may only receive a tiering exception for a drug if there is **another drug on a lower tier** of the formulary that could also be prescribed for the enrollee's condition. 42 C.F.R. §§ 423.100, 423.578.

- M-15-5164: The enrollee argued that colchicine should be on a lower tier because it was not a brand name drug. An enrollee may request a tiering exception when there is a drug on a plan's lower tier that is approved for treating the same condition that the requested higher tier drug is being used to treat. See MPDBM, ch. 18, § 30.2.1.4. The Council found that colchicine was not eligible for a tiering exception because there was **not a lower tier drug** to treat the appellant's condition.

- M-15-1139: the Plan is not required to grant a cost-sharing tiering exception for a drug when the **prescribing physician failed to identify a lower cost-sharing alternative** drug to treat the enrollee's condition. 42 C.F.R. § 423.578(a)(4).

- M-16-5311: there was no lower cost-sharing preferred drug to treat the enrollee's condition. Act, § 1860D4(g)(2); § 423.578.

Part D Tiering Exceptions Legal Framework

Tiering Exception Elements (Recap)

- Prescription;
- FDA Approved or Grandfathered drug;
- Not Excluded from Part D Coverage;
- Prescribed for a Medically Accepted Indication;
- The Desired Drug must be Nonpreferred;
- There must be a Physician or Other Prescriber Statement; AND
  - Drug is not as effective
  - Would have adverse effects, or
  - Both
- Therapeutically Equivalent Lower Tier Alternative

What Tier Do you Cover the Drug?

- Chapter 18, § 30.2.1.4, MPDBM
  - When a tiering exception is approved, the plan sponsor must provide coverage for the drug in the higher cost-sharing tier at the cost-sharing level that applies to the drug in the applicable lower cost-sharing tier.

- CMS, 2018 Final Call Letter (April 3, 2017)
  - Where the requested drug has alternatives in multiple lower tiers and the plan sponsor has approved the request for a tiering exception, the plan must apply the cost-sharing for the **lowest applicable cost-sharing tier** that contains alternatives for the requested drug.

Bright-Line Rules

➢ No Tiering Exceptions if:

- **Formulary Exception has been granted**: 42 C.F.R. § 423.578(c)(4)(iii) An enrollee may not request a tiering exception for a non-formulary prescription drug approved under § 423.578(b).
  - M-17-7927: The regulations specifically do not allow for a tiering exception for drugs covered through a formulary exception. See § 423.578(c)(4)(iii).
  - M-14-2541: Plan changed. Removed drug from formulary. Did not provide notice of change. Council held tiering exception for a drug for which the Part D plan had already approved a formulary exception was explicitly precluded both by regulation and by the Plan's EOC.
  - M-17-6110: If the formulary does not list the particular **drug strength** and the drug is covered, the Plan has granted a formulary exception, which makes the enrollee ineligible for a tiering exception.

➢ No Tiering Exceptions if:

- Drug on Specialty Tier: 42 C.F.R. § 423.578(a)(7): If a Part D plan sponsor maintains a formulary tier in which it places **very high cost and unique items**, such as genomic and biotech products, the sponsor may design its exception process so that very high cost or unique drugs are not eligible for a tiering exception.

- **No Tiering Exceptions if:**
  - **Drug on Specialty Tier**
    - M-17-5797: if a plan maintains a formulary tier for unique and high-cost drugs, the plan may design its exception process so that drugs in that tier are ineligible for a tiering exception. § 423.578(a)(7).
    - M-17-519: Under 42 C.F.R. § 423.578(a)(7), if a Part D plan maintains a formulary tier in which it places very high cost and unique drugs, the plan may redesign its exception process that drugs in that tier are ineligible for a tiering exception. Thus, the Part D plan is not required to grant a tiering exception for any Tier 5 specialty drugs.
    - M-17-7514: the plan was permitted to create a specialty tier of drugs that are ineligible for a tiering exception and that this drug was in their specialty tier. 42 C.F.R. § 423.578(a)(7).

➢ No Tiering Exceptions if:

- **Drug on Specialty Tier**

  – M-16-166: Neither the Council nor an ALJ has **authority to review** the plan's placement of any particular drug on a particular tier. 42 C.F.R. § 423.120

  – M-14-3559: Part D Plan was not required to provide a tiering exception for a drug because the drug was in the "Specialty" cost-sharing tier and a Part D Plan may design an exception process that makes very high cost or unique products ineligible for a tiering exception

Specialty Tiers

- Only Part D drugs with sponsor-negotiated prices that exceed an established dollar-per-month threshold are eligible for specialty tier placement.
- The cost threshold of $670 was established for CY 2017 as a result of applying the annual percentage increase used in the Part D benefit parameter updates to the previous threshold of $600.
- The proportion of Part D expenditures for specialty tier eligible drugs is increasing and is now near 20%. CMS will maintain the **$670 threshold for CY 2018**, but we will continue to investigate these and other trends in order to shape future analyses involving the specialty tier.

➢ Scenario 4:

- **On July 1, 2015, the plan removed the Vivelle-Dot Transdermal Patch (0.1 mg/24 hr) from their formulary and replaced it with the generic drug, Estradiol Transdermal Patches. The generic drug was approved by the FDA in December 2014. The enrollee asserts she cannot use the generic alternative due to a skin allergy. Prior to the formulary change, the Vivelle-Dot drug was provided by the plan to the enrollee as a tier 3 drug and the enrollee was responsible for a $95.00 co-pay. After the drug was removed from the formulary, the plan granted the enrollee a formulary exception and filled the drug on July 22, 2015 at a cost of $222.50. The enrollee contacted the plan stating that she should be able to obtain the drug at the tier 3 copay. Can a tiering exception be granted?**

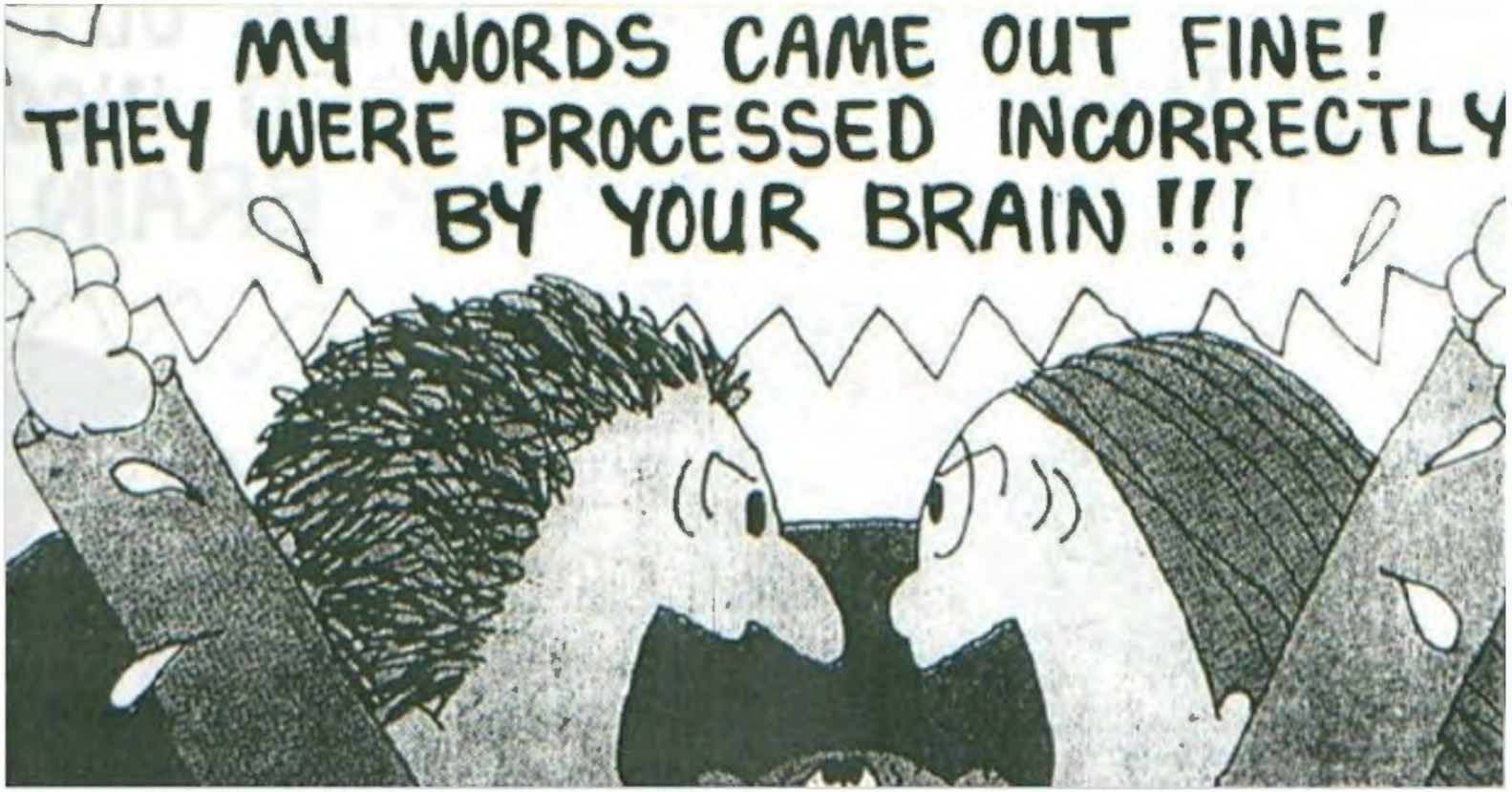
➢ Scenario 5:

- **The enrollee was prescribed CellCept for an autoimmune disease that affects her eyes. Without the drug, the enrollee's condition could lead to blindness. In 2012, the drug was covered as Tier 2 on the Plan's formulary and she paid $5 for a month supply. In 2013, the drug was moved to tier 3 and the enrollee received a tiering exception to cover the drug at $5.00. During the 2014 open enrollment period, the enrollee contacted the Plan and verified the drug remained on Tier 3 for 2014 plan year. The plan also sent the Enrollee a formulary showing the drug remained on Tier 3. Based on representations of the Plan and the formulary, she reenrolled. Upon filling her first prescription for the plan year she discovered the Plan representatives misinformed her of the tier placement and the cost was now $946 per month, as the Plan reclassified the drug to Tier 5, its specialty tier. She did not receive notice of the change until April 2014. Can the Enrollee be granted a tiering exception in 2014?**

- **No Tiering Exceptions based on:**
  - Prior Plan Coverage: M-17-7336; M-17-6810; M-16-134; M-16-3312; M-15-1524; and M-14-1383
  - Deficient Notice of Plan or Formulary Changes: M-16-524; M-16-306; M-16-100; M-16-65; M-16-261; M-14-2541; and M-14-178
  - Plan Misinformation: M-16-9518; M-16-5311; M-15-758; and M-14-178
  - Non-precedential District Court Case Law: M-14-1228; M-15-1720; M-15-1420; and M-15-1470

Not So Bright-Line Rules

Judicial Education Symposium



Part D Tiering Exceptions Legal Framework

- Regulations - **Part 423**
  - **Bright-Line (Or Not so Bright) Rules:**
    - Tiering exceptions are only available for **nonpreferred drugs.** 42 C.F.R. § 423.578(a)
    - 42 C.F.R. § 423.578(a)(6): In no case is a Part D plan sponsor required to cover a non-preferred drug at the generic drug cost-sharing level if the plan maintains a **separate tier dedicated to generic drugs**.
    - 42 C.F.R. § 423.578(e): Nothing in this section may be construed to allow an enrollee to use the exceptions processes set out in this section to request or be granted coverage for a prescription drug that does not meet the **definition of a Part D drug**.

When preferred doesn't mean preferred

Preferred vs. Non-Preferred drugs

- Regulations at 42 C.F.R. § 423.100 define a preferred drug as a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

- CMS expects sponsors to apply the correct definitions for preferred and non-preferred drugs. CMS, 2018 Final Call Letter (April 3, 2017)

- CMS' position is that
  - § 1860D-4(g)(2) of the Act plainly contemplates that a preferred drug is a drug with more favorable cost-sharing for the beneficiary; and
  - Eligibility for a tiering exception is based on whether the alternative drug is on a formulary tier that has lower cost-sharing than the tier on which the requested drug resides, thereby making it a "preferred" drug.
  - Eligibility should not be based on the label of the tier with the alternative drug(s)

Preferred vs. Non-Preferred drugs

➢ Key Points:

- Preferred drugs are not eligible for tiering exceptions
- If there is a lower cost therapeutically equivalent alternative drug on a lower tier than the desired drug, the desired drug is not preferred regardless of the tier label.

When generic doesn't mean generic

Generic vs. Non-Generic Drugs

- Current tier labels for non-defined standard Part D plans allow plans to label a tier as "generic" when that tier may contain brand drugs.
- The regulation at 42 C.F.R. § 423.578(a)(6) states that a plan sponsor is not required to cover a non-preferred drug at the generic cost-sharing if the plan maintains a separate tier dedicated to generic drugs.
- Chapter 18, § 30.2.1.4 of the MPDBM currently states that the limitation on approval of tiering exceptions at the cost-sharing that applies to generic drugs refers to tiers that include only generic drugs, not mixed tiers (that contain both brand and generic drugs) that are labeled generic.

Generic vs. Non-Generic Drugs

- M-17-7911: A tiering exception cannot be granted because Medicare rules provide that a plan is not required to approve a tiering exception for a drug in a higher cost-sharing tier at the generic tier cost-sharing level if the plan maintains a separate tier that only includes generic drugs. See 42 C.F.R. § 423.578(a)(6); MPDBM, ch. 18, § 30.2.1.4

Generic vs. Non-Generic Drugs

- In the CMS, 2018 Final Call Letter (April 3, 2017), Plan sponsors requested to be able to treat "authorized generics" as generic drugs for purposes of tiering exceptions

- CMS determined the concept of a tier "dedicated to generic drugs" can be interpreted to mean a tier dedicated to generics and other drugs that are comparable to generics such as "authorized generics."

- CMS reasoned
  - To the extent a formulary tier is made up of only generic drugs or authorized generics, such a tier is considered dedicated to generics whether or not specific authorized generic drug products are adjudicated at the cost sharing applicable to such tier and a plan sponsor may exclude that tier from the tiering exception process.

What is a Generic Drug?

- A generic drug, as that term is commonly understood and referred to by health care providers and insurers, is a copy of a brand-name drug that is developed and made by a company other than the company that makes the brand-name drug.

- A generic drug is the same as the brand-name drug in active ingredient, conditions of use, dosage form, strength, route of administration, and (with certain permissible differences) labeling. However, a generic drug may have certain minor differences from the brand-name product, such as different inactive ingredients.

- To obtain approval of a generic drug, a company must submit an Abbreviated New Drug Application (ANDA) to FDA and prove that its product is the same as the brand-name drug in the ways described above, and that it is "bioequivalent," meaning it gets to the part of the body where the drug works at the same time and in the same amount. A generic drug must also meet the same standards of quality and manufacturing as the brand name drug. An ANDA applicant is not required to provide independent evidence of the safety and effectiveness of a proposed generic drug. Instead, the applicant relies on FDA's finding that a previously approved drug product is safe and effective.

What is an "authorized generic" drug?

- Definition of authorized generic. 42 C.F.R. § 447.502

  - Authorized generic drug: any drug sold, licensed, or marketed under a new drug application (NDA) approved by the Food and Drug Administration (FDA) under section 505(c) of the Federal Food, Drug and Cosmetic Act (FFDCA) that is marketed, sold or distributed under a different labeler code, product code, trade name, trademark, or packaging (other than repackaging the listed drug for use in institutions) than the brand name drug.

  - FDA explains the term "authorized generic" as an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product.

What is an "authorized generic" drug?

- An authorized generic drug is the exact same in all aspects as a brand-name drug, with the exception of not using the brand name on the label. Because an authorized generic drug is marketed under the brand name drug's New Drug Application (NDA), it is not listed in FDA's Approved Drug Products With Therapeutic Equivalence Evaluations (the Orange Book).

- An authorized generic is considered to be therapeutically equivalent to its brand-name drug because it is the same drug. This is true even if the brand-name drug is "single source," meaning there are no ANDAs approved for that product, or coded as non-equivalent (e.g., BN) by FDA in the Orange Book. While a separate NDA is not required for marketing an authorized generic, FDA requires that the NDA holder notify the FDA if it markets an authorized generic. The NDA holder may market both the authorized generic and the brand-name product at the same time.

Generic vs. Non-Generic Drugs

- M-17-8538: The appellant-enrollee was prescribed Livalo, a Tier 4 drug, and sought a tiering exception to allow him to pay a lower copayment for the drug at the tier 1 level. Medicare rules provide that a plan is not required to approve a tiering exception for a drug in a higher cost-sharing tier at the generic tier cost-sharing level if the plan maintains a separate tier that only includes generic drugs. See 42 C.F.R. § 423.578(a)(6); MPDBM, Ch. 18, § 30.2.1.4. The ALJ issued a favorable decision concluding the plan was required to grant the tiering exception because the Plan's tiers 1 and 2 "are not exclusively dedicated to generic drugs."

- The Council found the plan is not required to provide a tiering exception under the regulations or the EOC. Although the ALJ found some "brand name" drugs in the Plan's tiers, "brand name" drugs are defined under the regulations as "a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)). § 423.4.

- The IRE provided evidence in its referral that the "brand name" drugs noted by the ALJ were either generic drugs with Abbreviated New Drug Application numbers (indicating they are marketed as generic drugs) or are listed as dietary supplements. The Council determined that the ALJ erred by not determining whether the plan's tiers had "generic" or brand name" drugs in accordance with the applicable regulations. Finally, the Council noted that the tiering exceptions process allows for tier 4 drugs to be lowered to the tier 3 cost-sharing amount and there was no benefit in the EOC that allows for a tier 4 drug to receive a cost-sharing amount at the tier 1 level.

How do these concepts impact OMHA?

- CMS collects Part D plan formularies based on the National Library of Medicine RxNorm concept unique identifier (RXCUI), and not at the more specific National Drug Code (NDC) level.

- CMS does not have a process to clearly identify whether the tier includes authorized generics. CMS, 2018 Final Call Letter (April 3, 2017).

- FDA publishes a list of authorized generics and updates that list quarterly.

Generic vs. Non-Generic Drugs

- Key Take Aways:
  - Tiering exceptions are not allowed to the generic tier if the plan maintains a separate tier dedicated to generic drugs.
  - The generic tier restriction applies, even if the tier has generic and authorized generic drugs on the tier.
  - The generic tier restriction does not apply if the tier includes generic and brand drugs, even if the tier is labeled as a generic tier on a plan formulary.

When not "meeting the definition of a Part D drug" doesn't mean the drug cannot be covered by Part D

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Supplemental Part D Coverage

- If drug does not meet the definition of a Part D drug, then a plan cannot be required to cover the drug or grant a tiering exception. 42 C.F.R. § 423.578(e).

- However, a Plan can provide optional drug coverage for certain **excluded drugs** as an enhanced benefit.

Authority for Supplemental Part D Coverage

- Section1860D-2(a)(2)(A): Qualified prescription drug coverage may include supplemental prescription drug coverage consisting of …

  (ii) Optional drugs—Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

- 42 C.F.R. § 423.104 allows coverage of drugs specifically excluded as Part D drugs as an enhanced alternative benefit.

What May Be Covered as a Supplemental Benefit

Supplemental Part D Coverage

- M-15-1792: While a Plan may offer supplemental drug coverage, coverage authorities limit the classes of drugs that may be covered as enhanced, supplemental benefits. See 42 C.F.R. §§ 423.100 ("Part D drug"), 423.104(f); Act, § 1927 (d)(2)-(3); MPDBM, Ch. 6 § 20.3. These authorities do not provide for supplemental coverage of drugs that are not used for a medically accepted indication.

- M-16-134: Part D plans can only offer supplemental coverage for drugs that would otherwise meet the definition of a Part D drug.

Supplemental Part D Coverage

- M-15-1524: Medicare Part D allows a plan to offer supplemental (or optional) drug coverage for "any product that would be a covered part D drug but for the application of subsection (e)(2)(A) ..."
- Subsection (e)(2)(A), in turn, excludes certain drugs and categories of drugs from coverage, including, for example, fertility drugs and prescription vitamins. Id., cross-referencing section 1927(d)(2) of the Act; see also 42 C.F.R. § 423.104(f)(1)(ii).
- However, CMS manual authority states that a Medicare Part D plan may provide supplemental coverage for "drugs that would meet the definition of a Part D drug" if they had not otherwise been excluded. MPDBM Ch. 6, § 20.3. Defining supplemental drugs, the manual provides that "such drugs must have otherwise qualified as covered Part D drugs.

Supplemental Part D Coverage & Exceptions

- M-16-138: Under the law, erectile dysfunction drugs are excluded from coverage regardless of whether they are or are not also considered to be "performance enhancing" drugs. For these reasons, the Council may not require the Plan to cover or reimburse for the drug unless the Plan has agreed to cover the drug as a supplemental benefit. Here, the Plan offers such supplemental coverage, but limits that coverage to a quantity of six tabs every thirty days. The Plan is providing the enrollee with coverage for Cialis at the quantity that it has agreed to cover. **The Council may not require the Plan to cover or reimburse for the drug at a larger quantity than it has agreed to cover as a supplemental benefit**. While the regulations allow for a formulary exception process when certain requirements are met, the enrollee does not qualify for such an exception. See 42 C.F.R. § 423.578. **As pertinent to this case, as stated above, Cialis does not meet the definition of a Part D drug because it is an excluded erectile dysfunction drug. The formulary exception process may not be invoked to cover a drug that is not a Part D drug. 42 C.F.R. § 423.578(e).** Thus, there is no basis on which the Plan may be directed to grant the enrollee a formulary exception for the prescribed quantity of Cialis.

Supplemental Part D Coverage

- M-17-1852: The Plan's Evidence of Coverage does not identify any supplemental coverage for drugs that are excluded from Medicare Part D definition and coverage under the enhanced alternative coverage provision of 42 C.F.R. § 423.104(f).

- M-15-1115: the enhanced drug coverage benefit was for drugs excluded under § 1927(d)(2)–(3) of the Act, such as drugs used for anorexia, weight loss, or weight gain; drugs to promote fertility; and drugs when used for symptomatic relief of cough and colds

- M-13-1886 & M-13-2849: The exceptions process may not be invoked to cover a drug that does not meet the definition of a Part D drug. 42 C.F.R. § 423.578(e)

Supplemental Part D Coverage

- Key Point:
  - Tiering exceptions cannot be required for drugs covered as supplemental benefits on Medicare Part D Plans. Generally, the EOC and Formulary control in these cases.

Break

Learning Objectives (Recap)

- Provide an overview of the Existing Part D Legal Framework applicable to Part D Tiering exceptions
- Highlight regulatory changes to Part D Program due to the final rule on the Medicare Prescription Drug Benefit Program, applicable January 1, 2019 (83 Fed. Reg. 16440)
- Review subtopics identified by the training cadre survey
- Identify trends in Medicare Appeals Council decisions and Program Advisor updates from FY2014 to FY2018

- **Regulatory Changes to Part D Program**
  83 Fed. Reg. 16440 (Apr. 16, 2018)

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Regulatory Changes to Part D Program (83 Fed. Reg. 16440)

- CMS admitted existing tiering exception policy was confusing for beneficiaries and acknowledged they were making significant changes to existing tiering exceptions policy through the final rule

- Changes are applicable as of **January 1, 2019**

- **What did the Final Rule do?**
  - Modified regulatory definitions
  - Implemented permissible limitations to tiering exceptions
  - Modified the "dedicated to generic tier" exclusion
  - Clarified what constitutes an alternative drug

Regulatory Changes to Part D Program (83 Fed. Reg. 16440)

What did the Final Rule do?

- Affirmed Tier Level designation for Approved Exceptions
- Re-Affirmed Tiering Exception Exclusion for Formulary Exceptions
- Changed Transition Supply Requirements
- Modified Notice Requirements
- Allowed for more Mid-year Formulary Changes

Other Notable Changes

- Created new expedited OMHA workload for "at-risk beneficiaries" for "frequently abused" controlled substances
- Established a preclusion list for Part D Prescribers

Regulatory definitions

- § 423.100:
  - definition of **"other authorized prescriber"** has been removed

- § 423.560:
  - **Appeal** means any of the procedures that deal with the review of adverse coverage determinations made by the Part D plan sponsor on the benefits under a Part D plan the enrollee believes he or she is entitled to receive, including delay in providing or approving the drug coverage (when a delay would adversely affect the health of the enrollee), or on any amounts the enrollee must pay for the drug coverage as defined in § 423.566(b). Appeal also includes the review of at-risk determinations made under a drug management program in accordance with § 423.153(f). These procedures include redeterminations by the Part D plan sponsor, reconsiderations by the independent review entity, ALJ hearings, reviews by the Medicare Appeals Council (Council), and judicial reviews.

- § 423.560:
  - **Grievance** means any complaint or dispute, other than one that involves a coverage determination or at-risk determination, expressing dissatisfaction with any aspect of the operations, activities, or behavior of a Part D plan sponsor, regardless of whether remedial action is requested.
  - **Specialty tier** means a formulary costsharing tier dedicated to very high cost Part D drugs and biological products that exceed a cost threshold established by the Secretary.

➢ Definition of Generic Drug

- CMS proposed to change the definition of generic drug to include biosimilar and interchangeable biological products approved under section 351(k) of the PHSA, but declined to do so on the basis of comments received.
  - Although we attempted to clarify that we were not equating biosimilar and interchangeable biological products to generic drugs for any other purpose than cost sharing intended to encourage utilization of lower-cost alternatives, we are persuaded by comments that our proposed approach to include biosimilar and interchangeable biological products in our definition of generic drug still could be misinterpreted and create further confusion about the broader treatment of biosimilar and interchangeable biological products under the Part D program
- In its discussion of a generic drug it also discussed biosimilar products and interchangeable biological products.
- Multi-source drugs are not to be treated similar to generics or authorized generic drugs

➢ Definition of Biosimilar Product

- A biosimilar product is a biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products

  – Biological products approved under section 351 of the PHSA (42 U.S.C. 262) are listed in the FDA's Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations

➢ Definition of Interchangeable Biological Product

- An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.

New Part D Tiering Exception Regulation

42 C.F.R. § 423.578

Overarching Responses in Final Rule

- CMS believes applying rules based on FDA approval type is the best way to limit confusion and create a consistent policy.
- The statutory basis for approval of a tiering exception request is the presence of an alternative drug(s) on a lower costsharing tier of the plan's formulary
- CMS encourages plans to accept oral prescriber supporting statements for exceptions
- Plans are not required to treat the specialty tier as a preferred cost-sharing tier for purposes of tiering exceptions
- Tiering exceptions do not apply to low income subsidy (LIS) beneficiaries.

- § 423.578
  - (a) Requests for exceptions to a plan's tiered cost-sharing structure. Each Part D plan sponsor that provides prescription drug benefits for Part D drugs and manages this benefit through the use of a tiered formulary must establish and maintain reasonable and complete exceptions procedures subject to CMS' approval for this type of coverage determination. The Part D plan sponsor grants an exception whenever it determines that the requested nonpreferred drug for treatment of the enrollee's condition is medically necessary, consistent with the physician's or other prescriber's statement under paragraph (a)(4) of this section.
    - (1) The tiering exceptions procedures must address situations where a formulary's tiering structure changes during the year and an enrollee is using a drug affected by the change.
    - (2) Part D plan sponsors must establish criteria that provide for a tiering exception, consistent with paragraphs (a)(3) through (6) of this section.

- § 423.578
  - (a)(4) A prescribing physician or other prescriber must provide an oral or written supporting statement that the preferred drug(s) for the treatment of the enrollee's condition—…
  - (a)(5) If the physician or other prescriber provides an oral supporting statement, the Part D plan sponsor may require the physician or other prescriber to subsequently provide a written supporting statement. The Part D plan sponsor may require the prescribing physician or other prescriber to provide additional supporting medical documentation as part of the written follow-up.

§ 423.578

- (a)(6): Limitations on tiering exceptions: A Part D plan sponsor is permitted to design its tiering exceptions procedures such that an exception is not approvable in the following circumstances:
  - » (i) To cover a brand name drug, as defined in § 423.4, at a preferred costsharing level that applies only to alternative drugs that are—
    - (A) **Generic drugs**, for which an application is approved under section 505(j) of the Federal Food, Drug, and Cosmetic Act; or
    - (B) **Authorized generic drugs** as defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act.
  - » (ii) To cover a **biological product** licensed under section 351 of the Public Health Service Act at a preferred costsharing level that does not contain any alternative drug(s) that are biological products.
  - » (iii) If a Part D plan sponsor maintains a specialty tier, as defined in § 423.560, the sponsor may design its exception process so that Part D drugs and biological products on the specialty tier are not eligible for a tiering exception.

§ 423.578

- (c)(3): When a tiering exceptions request is approved. Whenever an exceptions request made under paragraph (a) of this section is approved—
  - (i) The Part D plan sponsor may not require the enrollee to request approval for a refill, or a new prescription to continue using the Part D prescription drug after the refills for the initial prescription are exhausted, as long as—
    - (A) The enrollee's prescribing physician or other prescriber continues to prescribe the drug;
    - (B) The drug continues to be considered safe for treating the enrollee's disease or medical condition; and
    - (C) The enrollment period has not expired. If an enrollee renews his or her membership after the plan year, the plan may choose to continue coverage into the subsequent plan year.
  - (ii) The Part D plan sponsor must provide coverage for the approved prescription drug at the cost-sharing level that applies to preferred alternative drugs. If the plan's formulary contains alternative drugs on multiple tiers, cost-sharing must be assigned at **the lowest applicable tier**, under the requirements in paragraph (a) of this section.

New Tiering Exception Framework

- The "dedicated to generic tier" exclusion is gone. However, a tiering exception for a brand or biological to the cost sharing of generic alternatives is still not required.

- Plans are required to grant tiering exceptions for nonpreferred generic drugs at the cost of preferred generic alternatives even when the tier is dedicated to generics or has a mix of brand and generic drugs

- Plans are permitted to limit the availability of tiering exceptions for brands and biologicals to a preferred tier that contains the same type of alternative drug(s) for treating the enrollee's condition:
  - Brand to Brand Alternatives;
  - Biological to Biological Alternatives; and
  - Nonpreferred Generic to preferred Brand or Generic Alternative

Alternative Drugs

- While our proposal did not include regulation text specific to the meaning of an alternative drug, we clarified in the preamble that we interpret this language to refer to the condition as it affects the enrollee,
  - Taking into consideration the individual's overall clinical condition, including the presence of comorbidities and known relevant characteristics of the enrollee and/or the drug regimen, which can factor into which drugs are appropriate alternative therapies for that enrollee.
- Plans must apply reasonable clinical judgment, based on sound medical and scientific evidence and acceptable standards of practice, in adjudicating exception requests, including consideration of alternative drugs on the plan's formulary.

Alternative Drugs

- Drugs not prescribed for a medically accepted indication are not alternative drugs
- Alternative drugs need not be in same therapeutic class as the nonpreferred drug
- Mechanisms of action or route of administration may be relevant to whether the drug is alternative

Approved Exceptions

- Cost sharing for an approved tiering exception request is assigned at the lowest applicable tier when preferred alternatives sit on multiple lower tiers

Prior Formulary Exception

- We did not propose to revise the existing requirement set forth at § 423.578(c)(4)(iii) which establishes that an enrollee may not request a tiering exception for a non-formulary drug approved under the formulary exceptions rules at § 423.578(b).

- Under the proposed changes to tiering exceptions rules, which we are finalizing as proposed, an enrollee may not obtain a tiering exception for an approved non-formulary drug.

Transition Supplies

- Section 423.120(b)(3) used to require that a Part D sponsor provide certain enrollees access to a temporary supply of drugs within the first 90 days of a new plan enrollment by ensuring a temporary fill when an enrollee requests a fill of a non-formulary drug during this time period. In the outpatient setting, the supply required at least 30 days of medication. In the long-term care (LTC) setting, this supply required at least 91 days and up to 98 days, consistent with a 14-day-or-less dispensing increment for brand drugs.

- Now an "approved month's supply" is required for both outpatient and LTC, unless the prescription is written by the prescriber for less and means a month's supply approved in a plan's bid.

- The transition process is not applicable in cases in which a Part D sponsor substitutes a generic drug for a brand name drug as specified under paragraph § 423.120(b)(3)(iv).

Notice & Midyear Formulary Changes

- Section 1860D–4(b)(3)(E) of the Act requires Part D sponsors to provide "appropriate notice" to the Secretary, affected enrollees, authorized prescribers, pharmacists, and pharmacies regarding any decision to either: (1) Remove a drug from its formulary, or (2) make any change in the preferred or tiered cost-sharing status of a drug

- Three types of midyear formulary changes effect notice requirements:
  - Substitutions of newer generics that meet the requirements of § 423.120(b)(5)(iv);
  - Drugs removed from formularies on the basis that they are deemed unsafe by the FDA or withdrawn by their manufacturer consistent with current § 423.120(b)(5)(iii); and
  - All other midyear formulary changes that do not fall into one of the first two types, which are governed by § 423.120(b)(5)(i)

Notice & Midyear Formulary Changes

- 423.120(b)(5)(iv): Permits Part D sponsors meeting all requirements to immediately remove brand name drugs (or to make changes in their preferred or tiered costsharing status), when those Part D sponsors replace the brand name drugs with (or add to their formularies) newly approved generics rated therapeutically equivalent by the Food and Drug Administration (FDA) to the brand name drug—rather than having to wait until the direct notice and formulary change request requirements have been met.

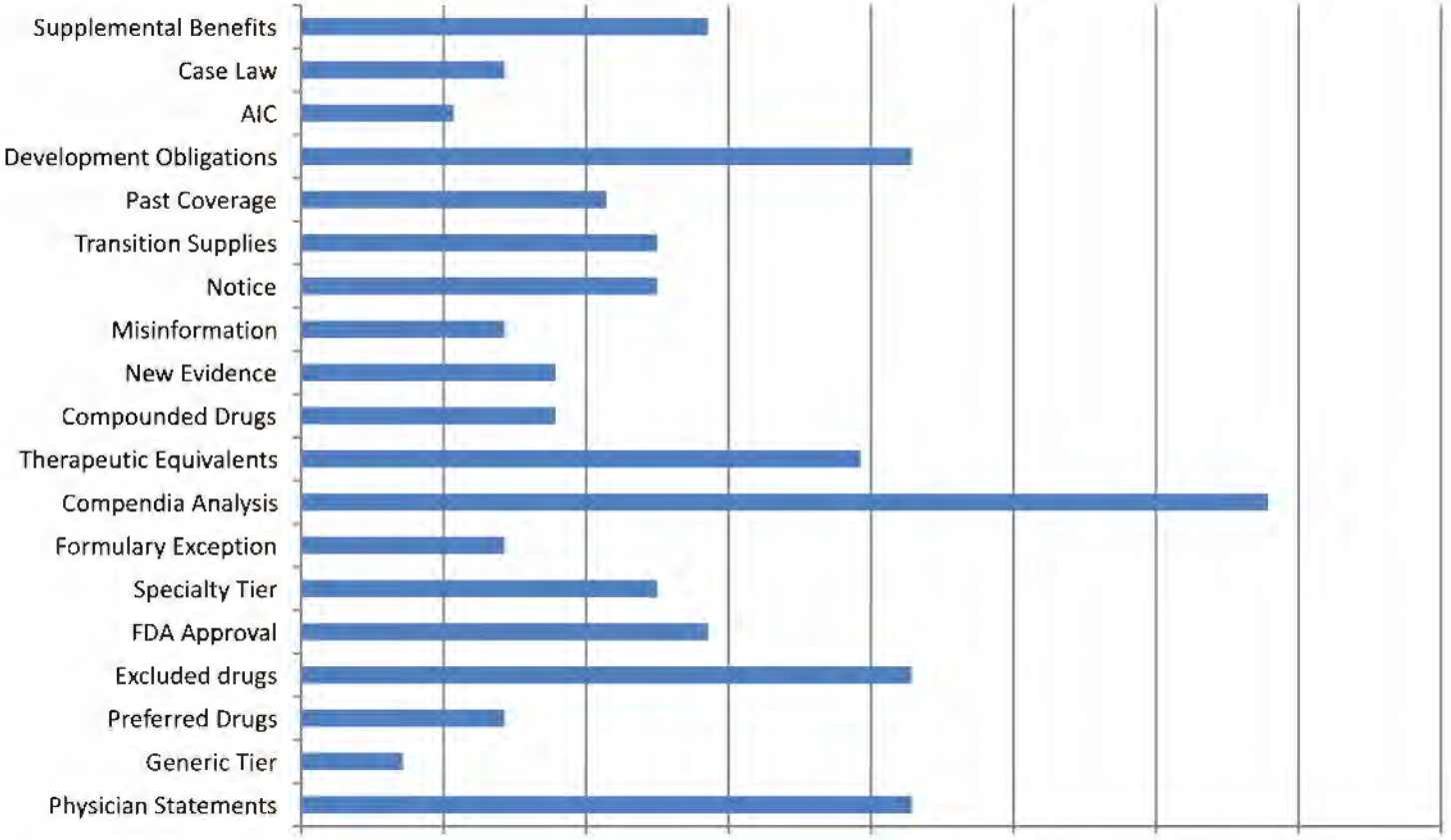
- Revises § 423.120(b)(6) to allow sponsors to make those specified generic substitutions at any time of the year rather than waiting for them to take effect two months after the start of the plan year.

Notice & Midyear Formulary Changes

- § 423.120(b)(5)(i) changes the notice requirement when (aside from expedited generic substitutions and drugs deemed unsafe or withdrawn from the market) drug removal or changes in cost-sharing would affect enrollees.
  - Changes the minimum notice to at least 30 days' to all entities prior to the effective date of changes and at least 30 days' direct notice to affected enrollees or a one month refill upon the request of an affected enrollee.
  - Amends the refill amount to months (namely a month) rather than days (it was 60 days previously) to conform to a proposed revision to the transition policy regulations at § 423.120(b)(3)

Medicare Appeals Council Trends (FY14-FY18)

Overall Council Trends (FY2014-2018)



Topics

- Compendia analysis
  - Appropriate Compendia
  - Similarity of Diagnoses to Covered Uses
  - Compendia Interpretation
  - Considering Other Sources
  - CMS Transmittal 212
- ALJ's Part D obligations to develop the record
- Miscellaneous Part D Issues
  - New Evidence / Change in Condition / Corrected Prescriptions
  - Transition Supplies
  - Compounded Drugs

Compendia Analysis

Compendia Analysis

Recognized Compendia (CMS Transmittal 212 & MPDBM)

- **American Hospital Formulary Service-Drug Information (AHFS-DI)**
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- **Truven Health Analytics Micromedex DrugDex**
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

➢ Compendia Analysis

- **CMS Transmittal 212 & MPDBM**

- In general, a use is **medically accepted** if the:
  1. indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or,
  2. narrative text in AHFS-DI or Clinical Pharmacology is supportive, or
  3. indication is listed in Lexi-Drugs as "Use: Off-Label" and rated as "Evidence Level A"

- A use is **not medically accepted** by a compendium if the:
  1. indication is a Category 3 in NCCN or a Class III in DrugDex; or,
  2. narrative text in AHFS or Clinical Pharmacology is "not supportive," or
  3. indication is listed in Lexi-Drugs as "Use: Unsupported"

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Compendia analysis

Appropriate Compendia

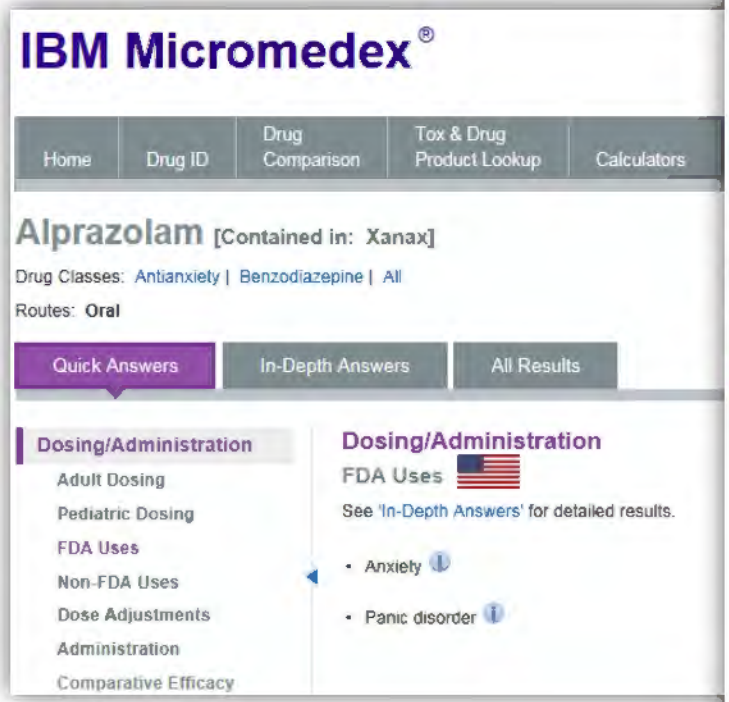
- M-16-3563: The only current sources that may be consulted to determine whether the drug at issue was prescribed for a medically accepted indication are the FDA label, AHFS-DI, and DrugDex
- M-17-7756: DrugPoints is not a Medicare-approved compendium
- M-17-6570: Cannot use outdated compendia
- M-15-1265: Although the use was listed in the 2010 DrugDex compendium, the use is no longer listed in current compendium

Cancer Compendia

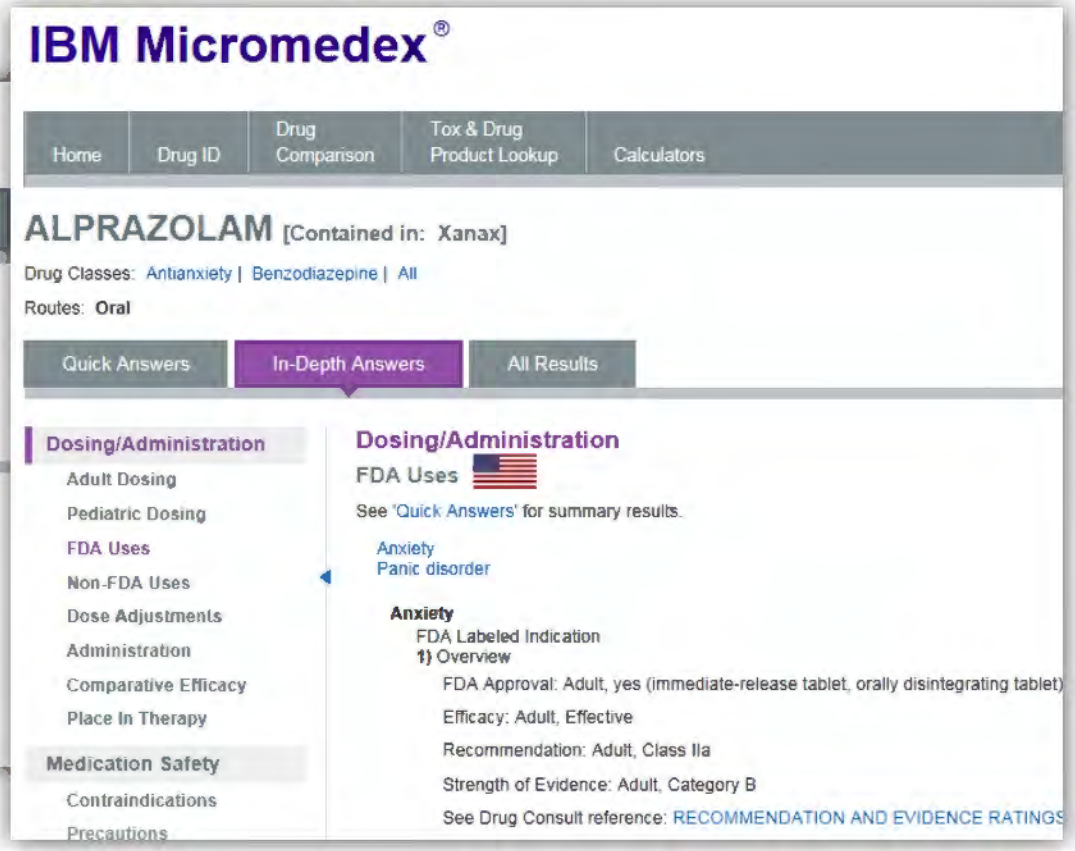
- M-16-2402 & M-16-2397: Clinical Pharmacology is only indicated as an approved compendium for chemotherapy drugs
- M-17-8168: Cannot use Clinical Pharmacology Compendia for non-chemo drugs, even if "sufficient nexus" to cancer.
- M-16-496: Clinical Pharmacology is not an approved compendium, except with regard to chemotherapy drugs

Appropriate Compendia

DrugPoints



DrugDex



Compendia analysis

Compendia Interpretation

- **Similarity to Covered Uses**

  - M-16-922: the ALJ had no authority to grant coverage based on the condition's **similarity to a covered indication**, or equitable principles due to the **severity** of the enrollee's condition
  - M-17-6813: Compendia support for "**substantially similar condition**" is not enough for MAI
  - M-16-220: Compendia support for an **"analogous condition"** is not enough for MAI
  - M-15-1420: the **similarity of a diagnosis** to a covered use was not a basis upon which to direct Part D coverage
  - M-15-1362: Similar to covered use

- **Compendia analysis**
  - **Compendia Interpretation**
    - M-17-6570: A statement of the "effect of drug" is not enough to find the compendia supports the prescribed indication.
    - M-16-1631: Compendia support for one formulation of the drug (gel) does not give rise to a medically accepted indication for another formulation (liquid) of the same drug.
    - M-16-314: A diagnosis in heading of compendia does not give rise to a medically accepted indication, where the text under the heading discusses a different diagnosis for which 60% of the people with the heading diagnosis also suffers.
  - **Other Sources**
    - M-16-1631: the ALJ erred in consulting sources other than the approved compendia and the FDA label to determine whether the drug was prescribed for a medically accepted indication.
    - M-13-1685: the ALJ erred by considering peer-reviewed medical literature in the determination

ALJ's Obligations to Develop the Record

ALJ Development Obligations

- M-17-8416: the ALJ has the **obligation to develop the record** and should have requested copies of the **FDA label** and relevant **compendia** entries
- M-15-1045: Obligation **to hold a hearing**, unless (1) the decision is wholly favorable to the enrollee or (2) the enrollee indicates in writing or, for expedited appeals, orally or in writing, that she does not wish to have a hearing. 42 C.F.R. § 423.2038.
- M-16-11128: A **plan's EOC and formulary** for the relevant year(s) must always be admitted into the record whenever there is any allegation that a drug was not on the formulary, or a case involves any dispute as to whether a drug meets the criteria for a formulary exception, what cost sharing provisions are in place based on the appropriate tier for the drug, and whether a tiering exception can be granted.
- M-16-10553: When there is no **appointment of representation form** in the record and physician appears at hearing, the Enrollee has had no opportunity to participate in the hearing in accordance with section 423.2036(a). ALJ must admit AOR form, **FDA Label, and compendia** in accordance with 42 C.F.R. § 423.2042.
- M-16-9167: Must admit **correct year of the evidence of coverage**.

ALJ Development Obligations

- M-17-533: the claim file did not contain a copy of the FDA label, the AHFS-Drug Information compendium, or the Micromedex DrugDex Information System compendium. **ALJ must compile a complete record**.
- M-16-11102: obligation to **clarify physician statement** and obtain approved compendia
- M-17-7315: Obligation to **contact the physician or enrollee** to ascertain if the enrollee had appointed the physician as her representative.
- M-15-2531: Obligation to develop the record concerning the **cost** (if any) to the enrollee for the compounded pain management cream, including refills, for plan year 2015 and **AIC**

ALJ Development Obligations

- M-14-5657: ALJ obligation to develop record:
  - provide to the enrollee a complete copy of any documentation in the current record to which the enrollee does not have access prior to any scheduled hearing and prior to issuance of any new decision;
  - provide the enrollee with an opportunity to respond to the documents submitted by the Plan representative or any other documents of record that the enrollee was not previously provided;
  - obtain primary evidence from the compounding pharmacy as to whether the GHRP-2, GHRP-6, or other portions of the drug meet the definition of a Part D drug and provide that evidence to all parties and proffer to all parties with a meaningful opportunity to respond
  - Obtain medical records from the enrollee and review the enrollee's diagnoses, the medical condition for which the compounded drug was prescribed, and whether the drug was prescribed for a "medically accepted indication" within the meaning of the statute

ALJ Development Obligations

- M-15-1616: the ALJ did not admit the compendium citation into the record. The Council found that the ALJ erred as a matter of law in relying on evidence outside of the record in determining that the drug was covered. 42 C.F.R. § 423.2046(a)(2)

- M-15-1792: Record lacked compendia and FDA label. Instead of remanding, the Council received DrugDex entry from IRE, and IRE sent compendia to Plan and Enrollee. The Council entered FDA label into record sua sponte and included it with its decision to the Enrollee, Plan, and IRE.

Miscellaneous Part D Issues

Miscellaneous Part D Topics

New Evidence / Change in Condition / Corrected Prescriptions

- M-17-417: Remand was necessary because the appellant submitted, through physician testimony for the first time at the OMHA level of review that Exelon was being prescribed for Alzheimer's disease. See § 423.2018(a)(1)

- M-17-1222: The enrollee's physician submitted a preauthorization request noting a diagnosis of osteoarthritis of the hip and that the Lidoderm patches were not prescribed for an FDA approved indication. During the ALJ hearing, the enrollee and her son testified that she previously used Lidoderm patches after she was diagnosed with shingles years ago.

- M-16-10734: By regulation, an ALJ or the Council may not consider any new evidence regarding a change in condition of the enrollee after a coverage determination is made. 42 C.F.R. §§ 423.2018(a)(2) and 423.2122(a)(3); see also 42 C.F.R. § 423.2126(b).

Miscellaneous Part D Topics

New Evidence / Change in Condition / Corrected Prescriptions

- M-15-1982: By regulation, an ALJ or the Council will remand a case to the Part D IRE if an ALJ or Council determines that an enrollee wishes to have evidence on her change in condition considered after the coverage determination.

- M-15-1000: the case should have been remanded to the Part D IRE because the enrollee had submitted evidence to the ALJ of a new diagnosis, bursitis of the leg, that was not considered in the initial determination.

Miscellaneous Part D Topics

Transition Supplies

- M-16-524: Regulations requiring a transition supply apply only to covered Part D drugs.
- M-15-1524: Part D authority for coverage of transition drugs only applied to medications that met the definition of a Part D drug
- M-15-1389: CMS authority provides that the transition drug process does not apply to a drug that is not covered under Medicare Part D. MPDBM Ch. 6, §§ 30.4, 30.4.1, 30.4.4.3.
- M-16-261: Regulations requiring a transitional supply applied only to covered Part D drugs. Moreover, the change in coverage requiring preauthorization occurred prior to the start of the plan year, and the enrollee received notice of the new formulary with the annual notice of change.

Miscellaneous Part D Topics

Transition Supplies

- M-16-100: 42 C.F.R. § 423.120(b)(5), as well as section 30.3.4.1 of chapter 6 of the MDPBM, require that a plan must provide notice to the enrollee when there is a change in the formulary or provide a 60 day supply of the drug at the next refill together with notice of the change. The manual provision states that its applicability is limited to covered Part D drugs.

- M-16-765: Replacing a brand name drug with a new generic drug is considered to be a maintenance change. Enrollees are not exempt from maintenance changes as provided in the MBPDM, Ch. 6, § 30.3.3.1. Non-maintenance formulary changes for which relief is available include removing drugs from the formulary, moving covered drugs to a less preferred tier, or adding utilization management requirements.

- M-16-306: the provisions in 42 C.F.R. § 423.120(b)(5) and in Chapter 5, Section 6.2, only address formulary changes that take place during the plan year (i.e., mid-year formulary changes)

Miscellaneous Part D Topics

- Compounded Drugs

  - M-17-90: Plan was not required to cover the compounded drug because it was made from non-FDA approved bulk pharmaceutical powders which do not meet the definition of a Part D drug

  - M-16-219: Drug products compounded from bulk chemical powders are not grandfathered drugs.

  - M-14-5657: Under 42 C.F.R. § 423.120(d)(1)(ii), compounds that contain at least one ingredient that independently meets the definition of a Part D drug may be considered a Part D compound. The portions of the compounded drug may be eligible for Part D coverage and an enrollee cannot be billed for the non Part D ingredients. 42 C.F.R. § 423.120(d)(2)(ii)

Miscellaneous Part D Topics

Compounded Drugs

- M-17-7700: the ALJ erred by determining the inclusion of one drug component that met the definition of a Medicare Part D drug permitted the entire compound to be covered.

- M-15-855: The ALJ issued a decision for a compounded drug product that consists of levocarnitine, Coenzyme Q10 (CoQ10), Creatine, and Folic Acid. The Plan is required to cover only the levocarnitine portion of the compounded drug at issue, as this component drug has been verified to be an FDA-approved drug based on the current record. The Council adopts that aspect of the ALJ's decision finding that the Creatine, Folic Acid, and CoQlO are not covered Medicare Part D drugs and are not subject to reimbursement.

Post-Assessment

Post-Assessment

Scenario 6:

- On February 20, 2019, the brand drug Hytrin (1mg) was prescribed for the treatment of the enrollee's hypertension, included as an indication on the FDA label. The formulary covers hytrin as a nonpreferred drug on tier 4 of its 5 tier formulary. A prescriber statement has been submitted saying lower cost brand alternatives are included on the specialty tier of the Plan's formulary. Can the enrollee receive a tiering exception up to the specialty tier?

Post-Assessment

Scenario 7:

- The enrollee was prescribed the brand name drug Tagrisso for the treatment of a medically accepted indication. The drug is on tier 4 of the plan's formulary, not a specialty tier, and includes step therapy requirements, to which the enrollee received an exception. She now seeks a tiering exception to lower the cost to tier 3, which includes a lower cost brand drug alternative appropriate for her condition. An appropriate physician statement has been provided. Can the enrollee receive a tiering exception?

Post-Assessment

Scenario 8:

- The enrollee was prescribed the generic drug Sumatriptan (100mg) for the treatment of migraine headaches, an FDA approved indication in January 2020. Sumatriptan is listed on tier 3 of the plan's formulary. Tier 1 of the formulary exclusively contains generics and authorized generics, one of which is a therapeutically equivalent alternative drug that would cause adverse effects. The prescriber provided an appropriate physician statement. Can the enrollee receive a tiering exception?

Questions?

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia

Appeal of:	**ARRIVA MEDICAL LLC**	OMHA Appeal No.:	**1-1111111111(Combined)**
		QIC Appeal No.:	**MULTIPLE (951)**
Beneficiary:	**MULTIPLE (946)**	Medicare	**Part B**
Medicare No.:	**MULTIPLE (946)**	Before:	**Leslie B Holt** Administrative Law Judge

DECISION

Medicare Part B does not cover the diabetic/glucose testing supplies furnished by the Appellant because the records failed to establish medical reasonableness and necessity and satisfy coverage and documentation requirements set forth in LCDs, Policy Articles, CMS Manuals, and Title XVIII §§ 1862(a)(1)(A) and 1833(e) of the Social Security Act. Furthermore, the statistical sample methodology and extrapolation utilized in for this appeal comports with Title XVIII § 1893 of the Act, HCFA Ruling 86-1 (Jan. 8, 2001), and the Medicare Program Integrity Manual, Pub. 100-8, Chapter 8. The Attachment specifies the beneficiaries, the services provided, the dispositions, and the dates of service involved in this appeal. Accordingly, an **UNFAVORABLE** decision is entered for **ARRIVA MEDICAL LLC** (the "Appellant" or "Supplier").

PROCEDURAL HISTORY

The Appellant submitted multiple claims for monthly diabetic/glucose testing supplies furnished to 946 Beneficiaries on various dates of service. The claims were initially denied by Medicare. The Contractors issued multiple unfavorable or partially favorable redetermination decisions. The Contractors issued multiple unfavorable redetermination decisions. The Appellant requested that a Qualified Independent Contractor ("QIC") reconsider the Contractor's denials. Subsequently, the QIC issued multiple unfavorable reconsideration decisions denying all appealed claims.

The Office of Medicare Hearings and Appeals ("OMHA") received the Appellant's timely requests for Administrative Law Judge (ALJ) hearings. (*See generally* Beneficiary Folders, Exh. 1, pp 1-5). Pursuant to 42 C.F.R. § 405.1006, the presenting appeal satisfies the regulatory "amount in controversy" requirement. This appeal is, therefore, properly before OMHA in accordance with 42 C.F.R. § 405.1002.

On March 27, 2015, OMHA sent the Appellant a statistical sampling offer letter indicating that a large number of the Appellant's pending claim appeals met the requirements for statistical sampling and offered the Appellant the option to proceed with statistical sampling. (Main Folder, Exh. 1, pp. 5-6). In an April 17, 2015 letter, the Appellant's representative stated that the Appellant would proceed with statistical sampling and submitted an executed, timely Consent for Statistical Sampling form. (Exh, 1, pp. 7-11).

A prehearing conference was held on May 29, 2015. Tracey Weir, Attorney, and Jessica Robinson, Counsel, represented the Appellant. The following participants were also in attendance at the conference:

Dr. Charlotte Stelly-Seitz, MD, Physician Reviewer, and Lisa Hanson, JD, General Counsel, both of C2C Solutions, Dorian Edwards, MD of CGS, Wilfred Mamuya, PhD, MD, Paul Ackerman, Compliance Office, and Robin Schneckloth, RN, with NHIC Corp. During in the conference, the requirements for participating in the statistical sampling were discussed. (Main Folder, Exh. 1, pp. 2-3). The Appellant expressed reservations regarding the data elements of the universe of appealed claims. In a June 22, 201[4] (sic) letter, the Appellant requested a second pre-hearing conference as well as a delay of the pre-hearing order, questioning whether the current data were sufficient to support use of probability sampling and estimation methodologies. The Appellant sought resolution of various data, process, and methodology issues, writing "Arriva has significant interest in participating in the Pilot, but it cannot consent to the universe, and thereby be bound to statistical sampling, without some mutually agreeable resolution…we request a second Pre-Hearing Conference to determine whether it is possible for OMHA to address these issues so that Arriva can consent to moving forward." (Main Folder, Exh. 1, pp. 26-28).

On October 20, 2015, OMHA sent the Appellant a letter and the Prehearing Conference Order summarizing the agreement and actions discussed at the May 29, 2015 prehearing conference. The letter stated that if the Appellant did not object to the order within 10 calendar days of receipt of the letter, the order would become binding and the Appellant would no longer be able to withdraw consent for statistical sampling conducted at OMHA. (Main Folder, Exh. 1, p. 25). The Prehearing Conference Order stated that the Appellant agreed to statistical sampling by a statistical expert and that the Appellant agreed to the universe of claims for statistical sampling, subject to removal of claims identified during the prehearing conference and claims identified during the adjudication process that did not meet the criteria for statistical sampling. A list of the revised universe of claims for statistical sampling was contained in a letter sent to the Appellant on August 14, 2015 and was included with the order. The Prehearing Conference Order was signed by the Deputy Chief Administrative Law Judge on October 20, 2015. (Main Folder, Exh. 1, pp. 30-31).

On February 8, 2018, 951 beneficiary ALJ appeals were combined into one ALJ appeal number in order to provide for administrative efficiency. (Main Folder, Exh. 2, pp. 5-6). On February 12, 2018, a prehearing conference was held by telephone. (Main Folder, Exh. 2, pp 5-6). Preeya Pinto, Esq. and Seth Lundy, Esq. appeared as counsel for Appellant. Stefan Boedeker, statistician, also appeared on behalf of the Appellant. Dr. John L. Adams, the statistician retained by the Office of Medicare Hearings and Appeals to provide the statistical sampling services in this matter, was present. Dr. Doran Edwards appeared on behalf of CIGNA Govt. Solutions, the DME MAC (DMAC) for DMAC Jurisdictions B and DMAC Jurisdiction C and Dr. Barbara O'Neal appeared on behalf of Noridian Healthcare Solutions, LLC, the DMAC for Jurisdictions A and DMAC Jurisdiction D. At the Prehearing Conference, it was noted that pursuant to statistical sampling methodology only the claims included in the sample receive a plenary review. The results of that review are then extrapolated to the other claims in the frame. The full hearing on the sample was scheduled and deadlines were stipulated for briefs, objections and requests for withdrawal. *Id.* The Post-Prehearing Conference Order stated that one beneficiary's claims would be removed from the universe because they did not contain any diabetic supply-related claims. They would be decided separately. Two additional requests for hearing involved claims for diabetic supplies in addition to other equipment. Those claims remained in the sampling universe for extrapolation purposes but were not included in the sampling frame. (Main Folder, Exh. 2, p. 2). The Post-Prehearing Conference Order also stipulated the Local Coverage Determination, Policy Articles, and Medicare Manuals to be used in analyzing the claims. It stated that Dr. Adams would determine a probability sample based on a one-sided, 90% confidence interval with a sample size of 30 beneficiaries and would provide the work product

documentation to the Appellant that is necessary to comply with the requirements of Title XVIII § 1893 of the Social Security Act, HCFA Ruling 86-1 (Jan. 8, 2001), and the Medicare Program Integrity Manual, Pub. 100-8, Chapter 8. (Main Folder, Exh. 2, p. 2-3).

Following the pre-hearing conference, the Appellant sent a February 20, 2018 letter requesting modifications to the Post-Prehearing Conference Order. The Appellant identified two additional claims that contained unspecified line items in addition to diabetic supplies and requested that they remain in the universe of diabetic supply claims but not be included in the sampling frame. The Appellant also requested clarification of the delineated stipulations regarding the applicability of Medicare statutes, CMS regulations, and CMS policies in the case. The Appellant again reiterated its position that CMS contractor LCDs and Policy Articles were non-binding guidance and thus ALJs were not obligated to follow the issuances when adjudicating claims appeals. The Appellant sought clarification on the stipulations for the record. (Main Folder, Exh. 2, pp. 4A-4B). On March 9, 2018, a Supplemental Post-Prehearing Order was issued indicating that the requested claims would be removed from the sampling frame but remain in the sampling universe. The Order further stated: "Appellant requests clarification of the stipulation that LCD L11520 and Policy Article A33745 will be used for analyzing the claims in the hearing and for writing the decision. To the extent that clarification is required, 42 C.F.R. § 405.1062(a),(b) and (c) apply to this case as the regulation applies to all cases before OMHA. Otherwise, LCD L11520 and Policy Article A33745 will be used for analyzing the claims in the hearing and for writing the decision." (Main Folder, Exh. 5, pp. 1A-1B).

Following the issuance of the Supplemental Post-Prehearing Order, Dr. Adams produced a random sample from the sampling frame of the remaining beneficiaries and pre-payment denied claims at issue. Dr. Adams provided a memorandum specifying a thirty-beneficiary random probability sample (hereinafter the "sample"), noting that the sampling unit was the beneficiary, which made it unnecessary to use extrapolation methods that would adjust for clustering. The memo also noted the beneficiaries/appeals that were removed from the sampling frame pursuant to previous orders. (Main Folder, Exh. 5, pp. 1-5). A simple random sample was drawn from the sampling frame to determine the 30 beneficiary random probability sample. (Main Folder, Exh. 5, pp. 1-9). Each of the thirty sample claims is analyzed below and receives full consideration. (*See* Main Folder, Exh. 5), as well as those claims/beneficiaries that were excluded from the sampling frame due to the presence of nondiabetic supply-related claims.

On March 15, 2018, the Appellant submitted a letter wherein it objected to the statistical methodology and sample drawn by Dr. Adams, as outlined in an accompanying Expert Report (*See* Main Folder, Exh. 6, pp. 5-59), and requested the casefiles of the beneficiaries who were furnished items other than diabetic testing supplies and were subsequently removed from the sampling frame. The Appellant also noted that it had not yet been provided the Contractors' screen prints of supplies provided to the respective beneficiaries from multiple suppliers over the six-months prior to and including the dates of service as required by the Post-Prehearing Conference Order. (Main Folder, Exh. 6, pp. 1-3). On March 19 and March 23, 2018, both Contractors (as non-party participants) submitted supporting documentation consisting of screen prints showing that certain claims had multiple claim submissions by other suppliers for the same dates of service at issue in the present appeal, an issue and/or reason for denial identified in multiple QIC reconsideration decisions. (Main Folder, Exh, 7, pp. 1-78).

A telephonic hearing was held in Arlington, Virginia on March 23, 2018. Preeya Pinto, Esq. and Seth Lundy, Esq. were present as representatives for the Appellant. Stefan Boedeker, statistician, also appeared

on behalf of the Appellant. Dr. John L. Adams, the statistician retained by OMHA to provide the statistical sampling services in this matter, was present. The CMS Contractors chose to send representatives to the hearing to participate as non-party participants pursuant to 42 C.F.R. § 405.1010(c). Dr. Doran Edwards appeared on behalf of CIGNA Govt. Solutions and Dr. Barbara O'Neal appeared on behalf of Noridian Healthcare Solutions, LLC. Both Dr. Adams and Dr. Boedeker were qualified as expert witnesses.
Following the hearing, the Appellant submitted additional documentation that had not previously been introduced to the record and requested the admission of the additional evidence. (Main Folder, Exh. 8, pp. 29-30). The introduction of new evidence must be evaluated pursuant to 42 C.F.R. §§ 405.1018 and 405.1028. The foregoing regulations serve the interests of orderly decision-making by providing for the proper consideration of evidence. It is recognized that timely filed and properly introduced evidence results in a more accurate case analysis at all levels of the Medicare appeals process because the medical expertise of the lower levels of claims review can fully develop a payment or non-payment rationale. Further, timely filed and properly introduced evidence reduces the incidence of fraud and abuse of the Medicare adjudicatory process and helps to eliminate mistakes that potentially occur as a result of bypassing qualified medical expertise.

Pursuant to Title 42 C.F.R. § 405.1018(a), parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 days of receiving the notice of hearing). Title 42 C.F.R. § 405.1018(c) provides that any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination constitutes new evidence and must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. Title 42 C.F.R. § 405.1018(d) permits oral testimony to be admitted as evidence as well as evidence that is submitted by an unrepresented beneficiary. Additionally, in accordance with 42 C.F.R. § 405.1028 good cause to admit new evidence can be found, for example, when the new evidence is material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

Recently, § 405.1028(a)(2)(iii) was promulgated to provide that good cause may be found when the party was unable to obtain the evidence before the QIC issued its reconsideration and the party submits evidence that, in the opinion of the ALJ, demonstrates that the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration. As explained below, in all but one instance, good cause for the late submission of the documentation is not found to be adequate to support admission.

Whether or not to routinely obtain medical records supporting medical reasonableness and necessity upon supplying medical equipment is a business decision the supplier must make. Title XVIII § 1842(p)(4) states that in the case of an item or service ordered by a physician or a practitioner but furnished by another entity, if the Secretary (or fiscal agent of the Secretary) requires the entity furnishing the item or service to provide diagnostic or other medical information in order for payment to be made to the entity, the physician or practitioner shall provide that information to the entity at the time of the item or service is ordered by the physician or practitioner. While not self-enforcing, there is no reason to expect that a supplier would not enlist the aid of the local DME Medicare Administrative Contractor for assistance in enforcing the provision of Title XVIII § 1842(p)(4). Further, there is no reason for the supplier to not obtain the assistance of the Beneficiary to assist in obtaining the medical records that are personal to the Beneficiary.

The CMS Manual System, Pub. 100-8 Medicare Program Integrity Manual ("MPIM"), Chapter 5, § 5.8 states that the documentation in the patient's medical record does not have to be routinely sent to the supplier by the physicians or by the supplier to the Medicare contractors. However, MPIM, ch. 5, § 5.8 instructs that the supplier "should also obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met." Medical progress notes, for example, *are* required by the LCDs for coverage for the various items at issue in this case. In any event, if requested by the DME MAC or other contractor, the supplier is required to obtain medical records that support that the item(s) in question meet Medicare medical necessity and statutory coverage criteria. If the information is not received when requested or the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed Advanced Beneficiary Notice ("ABN") of possible denial has been obtained.

In this case, the Appellant sought to admit physician progress notes for Beneficiary 1, a glucose testing log and physician note for Beneficiary 2, a physician progress note for Beneficiary 9, lab test results for Beneficiary 15, the phone authorization and delivery confirmation forms for Beneficiary 20, and visit progress notes for Beneficiary 30. (Main Folder, Exh, 8, pp. 32-48). The Appellant argued that it was either unable to submit the evidence prior to the QIC reconsideration decisions or was unable to confirm that the information submitted had not been misplaced or misfiled by the QIC and therefore failed to be added to the official record.

The Appellant noted that the sheer volume of denials and claims requiring appeal during the time period created multiple, competing deadlines. In many instances, the Appellant claimed that it continued its dialogue with prescribing physicians in order to obtain additional medical records to support the claims throughout the appeal process. Appellant claimed that in some instances, the physicians did not provide the documentation until such time that it was deemed late submitted. The Appellant also argued that because the case is proceeding under OMHA's Pilot Statistical Sampling Program in which the decision on 30 sample claims would be extrapolated to a universe of approximately 950 claims, the denial of admission of additional evidence that is probative to the case and supportive of medical necessity would have a highly prejudicial effect on the broader universe of claims. (Main Folder, Exh. 8, pp. 29-30; Hearing CD).

As noted above, Title XVIII § 1842(p)(4) makes clear that the physician or practitioner is obligated provide information to the supplier at the time of the service is ordered by the physician or practitioner in order for the supplier to be reimbursed. Where a supplier does not insist upon being provided with documentation of medical necessity at the time that the physician orders the item or service, it does so at its own risk. Moreover, the documentation submitted addresses issues that were noted as material issues prior to the QIC's reconsideration. The Appellant had an opportunity to acquire this evidence through the assistance of Medicare contractors or through the beneficiaries themselves but did not do so. Therefore, in accordance with 42 C.F.R. § 405.1028, good cause does not exist to permit the admission of these records, for consideration in this case.[1] All other evidence not addressed above is admitted into the record without objection from any party or Contractor.

[1] *See* Main Folder, Exh, 8, pp. 32-48.

After the conclusion of the telephonic hearing, and prior to the issuance of this decision, the ALJ ordered Dr. Adams to complete interrogatories, noting the process employed in extrapolating the dispositions of the sample as noted in this decision to the rest of the sampling universe to determine "the total dollar amount that can be reimbursed by Medicare after extrapolation." (Main Folder, Exh. 9, pp. 9-10). On July 9, 2018, Dr. Adams submitted answers to the interrogatories in the form of a memorandum explaining the statistical process used in determining the amount to be reimbursed by Medicare to the Appellant. (Main Folder, Exh. 9, p. 11). The memorandum was provided to the all parties, and on July 17, 2018, the Appellant issued a letter wherein it objected to Dr. Adams' response to the interrogatories. The Appellant stated that, as previously outlined in its Expert Report (*See* Main Folder, Exh. 6, pp. 5-59), the statistical methodology and 30-appeal sample drawn by Dr. Adams was flawed and, as such, any extrapolation based on the flawed statistical methodology and sample should not be relied upon to render a decision on the 946 appeals in the case. (Main Folder, Exh. 9, pp. 15-16).

ISSUES

Whether diabetic/glucose testing supplies provided by the Appellants on the dates of service at issue are covered under Title XVIII § 1862 of the Social Security Act, and if not, whether Title XVIII § 1879 of the Act limits the liability of the Beneficiaries or Supplier with respect to any non-covered services.

FINDINGS OF FACT

1. Each casefile contained a Doctor Order Form/Frequency Increase Request, which indicated whether or not a Beneficiary was using insulin, the relevant diagnosis code, which was always 250.00, 250.01, 250.02, or 250.03 (variations of diabetes), and the Beneficiary's testing frequency, which was always either one, two, three, or four times a day. The estimated number of strips and lancets provided for a 90 day period for testing three times a day was 300 strips and lancets, for testing one time a day was 100 strips and lancets, for testing two times a day, 200 strips and lancets, for testing four times a day, 400 strips and lancets, and for testing five times a day, 450 strips and lancets. In cases with high frequency testing (non-insulin patients testing more than one time per day or insulin treated patients testing more than three times per day), the form contained a written description for high frequency testing, although claims for Beneficiary 11 and 20 omitted such required information. The written description was usually "elevated", "uncontrolled", or "fluctuating" blood sugar or glucose levels and the indicated length of need was 99 months or lifetime. Beneficiary 2 had chronic renal failure and was on dialysis. In all instances, the form contained the prescribing physician's signature.

2. Nearly all casefiles contained progress notes for Beneficiaries' follow-up visits for ongoing treatment of diabetes with their physicians, sometimes termed as a "diabetic wellness visit." The progress notes reviewed the Beneficiaries' medical history, treatment, and prescribed medications for management of their condition(s), which, in addition to diabetes, included chronic renal failure, hypertension, hyperlipidemia, hyperthyroidism, neuropathy and other chronic comorbidities. The notes contained the Beneficiaries' diabetic related lab results, including lipid panels and glucose and glycohemoglobin (A1c) levels and/or typical ranges. The notes contained an assessment and plan related to their diabetes, hypertension, or hyperlipidemia management, which included glucose testing and medications for controlling blood glucose levels. The progress notes did not always indicate how frequently the Beneficiaries were testing or why a specific treatment plan called for excess testing and supplies. There were no physician visit or progress notes for Beneficiaries 9, 26, and 29.

3. Some casefiles contained a Supplier-produced "Glucose Testing Log" form filled out by the Beneficiary for each day of the month. In casefiles containing the form, the Beneficiary filled out his or her glucose/blood sugar level result depending on how many times a day they tested themselves. The forms were signed and dated by the Beneficiaries.

4. Some casefiles contained a physician signature log and/or physician attestation statement prepared by the treating physician indicating that they treated the Beneficiary and certifying that their signature and notations were authentic throughout a given Beneficiary's medical record.

5. Most casefiles contained the Supplier's "Patient Phone Authorization for Diabetic Supplies" form, which listed the Beneficiary's name and date of service. It contained language indicating that the Supplier's representative had spoken with the "patient" on a particular date within the preceding one to sixteen days before the date of service (one Beneficiary was contacted 23 days before the date of service). Every time, the form stated that the "patient" "confirmed running low supplies." In some instances, the written statement indicated a number of days until a "patient" expected exhaustion of the remaining test strips/lancets. Some forms[2] stated that the "patient" was "running low" or that testing supplies "on hand would be depleted." The form indicated that the Supplier scheduled the next shipment and that the "patient" acknowledged that the Supplier was their only Supplier and authorized shipment of listed supplies which included in all cases test strips and lancets. Some authorizations included control solution, lancing device and batteries.

No form indicated the name or signature of the Supplier employee that contacted the "patient" and filled out the form on behalf of the Supplier. Many files contained a Supplier-produced form with a box checked for the given scheduled ship date or confirmation to receive their "regular shipment," and an accompanying statement signed by the Beneficiary which stated that the Beneficiary authorized the Supplier to contact his or her physician, release medical information, and submit claims on his or her behalf. Further, in the cases of Beneficiaries 17 and 20, the statement included that the Beneficiary "will have less than [X] days of diabetic supplies by the scheduled ship date. My daily testing schedule is still [X] times per day." However, the forms for Beneficiaries 3, 4, 14, and 22 did not contain any language referring to the Beneficiary's specific number of days remaining or testing schedule.

6. Each casefile contained a proof of delivery printout indicating the date the equipment was shipped and the date it was delivered to the Beneficiaries.

7. Most casefiles contained a "Customer Account Form" which listed the Beneficiary's name and physician. It was signed by the Beneficiary, which acknowledged the assignment of benefits to the Supplier and that each Beneficiary had received and understood the CMS Supplier Standards and the Customer Rights and Responsibilities. Beneficiary 5's form was signed by the treating physician rather than the Beneficiary.

8. Each casefile contained Supplier-produced documents that outlined the Supplier's mission, policies and practices, customer rights and responsibilities, supplier standards, etc. One document outlined how the Supplier insured that the Beneficiary was sufficiently trained to use the equipment ("Training is confirmed by the treating physician upon completing and signing the required Doctor Order Form prior to shipping"

[2] Beneficiaries 5, 7, 8, 10, 13, 15, 16, 25, 26, 28, and 30 had such forms.

as well as product and customer service support, educational materials, and an 800-telephone number). A welcome letter stated that the Supplier only accepted customers who were eligible for their services which meant customers were diagnosed with diabetes and covered by Medicare or private indemnity insurance. The letter stated: "Medicare only allows you to receive your supplies from one provider at a time. Please be sure that you cancel your service with your previous supplier so that you can continue to receive your new supplies from Arriva Medical."

LEGAL FRAMEWORK

I. Administrative Law Judge Authority, *Jurisdiction, Scope of Review, Standard of Review,*

Medicare appeals involve a four-level process. First, individuals or organizations seeking payment under the Medicare Program submit claims to Medicare Administrative Contractors ("Contractors") who make initial determinations, and if appealed, redeterminations. 42 C.F.R. § 405.904. Second, the individual or organization may then appeal to a new reviewing entity known as Qualified Independent Contractors ("QICs"), who issue reconsideration decisions. *Id.* Thereafter, third level appeals are made to the Office of Medicare Hearings and Appeals ("OMHA") for a hearing before an Administrative Law Judge ("ALJ"). OMHA's ALJs are qualified and appointed pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 500–596 (2012), and conduct *de novo* hearings of fact and law. Title XVIII § 1869 of the Act; *see* 42 C.F.R. § 405.1000(d); 74 Fed. Reg. 65,296, 65,316 (Dec. 9, 2009). An individual or entity will be entitled to an ALJ hearing provided there is a sufficient amount in controversy and the request for hearing is timely filed. Title XVIII § 1869(b)(1)(A) of the Social Security Act. To be considered timely, a request for hearing must generally be filed within 65 days of the QIC's reconsideration decision, and the amount in controversy must meet the annual threshold established by the Secretary of the Department of Health and Human Services. 42 C.F.R. §§ 405.1002, 1006.

During the hearing process, the ALJ will consider all issues decided in the initial determination, redetermination, or reconsideration decisions that were not decided entirely in Appellant's favor. 42 C.F.R. § 405.1032(a). Further, if the evidence presented before or during the hearing causes the ALJ to question a favorable portion of the prior determination or decision, he or she will notify the Appellant and will consider it an issue at the hearing. *Id.* The ALJ may decide a case on-the-record and not conduct an oral hearing if the evidence in the hearing record supports a finding in favor of appellants on every issue or if the appellant waives their right to a hearing. 42 C.F.R. § 405.1038(a)–(b).

II. Administrative Law Judge Authority, *Statistical Sampling, OMHA Authority*

An Administrative Law Judge ("ALJ") has the duty to adjudicate appeals on his or her docket in a fair and efficient manner. Current federal regulations together with the legislative intent of Congress and CMS in creating the Office of Medicare Hearings and Appeals provide the ALJ the authority to use statistical sampling as an adjudicative technique for a more efficient administration of appeals. The Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act of 2000 ("BIPA") significantly revised the Medicare appeals process. Section 521 of BIPA, which took effect October 1, 2002, is the section that addressed the new appeals system which included the establishment of a uniform process for handling all Medicare Part A and Part B appeals and specified timeframes for filing appeals and rendering decisions. *See* Medicare, Medicaid and SCHIP Benefit Improvement and Protection Act of 2000, Pub. L. 106-554, § 521, 114 Stat 2763 (amending 42 U.S.C. 1395ff) (2000).

Subsequently, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") was passed by Congress and transferred the responsibility of conducting ALJ hearings from the Social Security Administration to the Department of Health and Human Services through the creation of the Office of Medicare Hearings and Appeals. *See* Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub .L. No. 108-173, § 931 117 Stat. 2066 (amending 42 U.S.C. 1395ff) (2003). On November 15, 2002, CMS issued a proposed rule to implement new Medicare regulations at 42 C.F.R. part 405, subpart I. *See* 67 Fed. Reg. 69312-69362 (November 15, 2002). The proposed rules were promulgated on March 8, 2005 as an Interim Rule.

The implementation of the final regulations governing ALJ adjudication of Medicare appeals is set forth in 42 C.F.R. Subpart I § 405.1000 through § 405.1066. Specifically with regard to statistical sampling of cases pending before the ALJ for pre-payment review, 42 C.F.R. § 405.1044 was implemented in the Interim Rule in 2005.[3] 42 C.F.R. § 405.1044 provides the basis for the exercise of ALJ discretion to order a statistical sampling process and to adjudicate the appeal in such a manner. Specifically, 42 C.F.R. § 405.1044 allows for an ALJ "on his or her own motion" to consolidate two or more cases where "the issues to be considered at the hearing are the same issues that are involved in another request for hearing" for purposes of "administrative efficiency." The concept of similarity among cases is reflected elsewhere in the regulations. For instance, 42 C.F.R. § 405.1006 permits aggregation of claims in order to meet the statutory jurisdictional amount in controversy requirement. A request to aggregate can be made where "common issues of fact or law" or "delivery of similar or related services" is requested. Thus, CMS explicitly recognizes that Medicare claims often involve the same or similar issues and can be addressed by aggregation and consolidation.

Where an ALJ determines that consolidation of cases for hearing is appropriate, CMS must be notified, so that it can determine how it wishes to participate. 42 C.F.R. § 405.1044(d). Pursuant to regulations at 405 C.F.R. § 1010, CMS may participate as a party, a party participant by filing position papers, providing testimony to clarify factual or policy issues or it may choose not to participate at all. Pursuant to regulations at 405 C.F.R. § 1012, CMS may participate as a party by filing position papers, providing testimony to clarify factual or policy issues, calling witnesses or cross-examining witness of other parties. Thus, the regulations not only protect the interests of CMS but also fully integrate the discretionary determination of the ALJ to consolidate cases with other regulatory provisions found in 42 C.F.R. part 405, subpart I.

The Medicare Program Integrity Manual ("MPIM"), Pub. 100-08, Chapter 8, § 8.4.1.5 mandates that the sampling methodology used to project overpayments must be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically valid sample is drawn and that statistically valid methods for projecting overpayments are followed. *Id.* It requires that, at a minimum, the statistical expert shall possess a master's degree in

[3] All of the claims in this case were denied three times (initially, on redetermination and upon reconsideration). Thus these claims are not "overpayments" but are "underpayments." It is important to note that although the guidance outlined in the Medicare Program Integrity Manual ("MPIM") IOM 100-08, Chapter Eight generally addressees "overpayments," the statistical sampling *principles* noted in the MPIM are applicable to both "overpayments" and "underpayments." For example, MPIM Chapter 8, § 8.4.4.4.4 notes that the process of establishing both the net underpayment and the net overpayment must be thoroughly documented. Similarly, MPIM Chapter 8, § 8.4.6.3 directs contractors conducting their review to document the amount of all overpayments and underpayments and how they were determined. Accordingly, the principles outlined in the MPIM for determining a statistically valid sample and extrapolation process are applicable to both underpayments, such as those involved in this pre-payment review, and to overpayments.

statistics or have equivalent experience. *Id.* In this case, the Appellant did not challenge the qualifications of Dr. Adams, the statistical expert hired by OMHA for this case.

With respect to simple random sampling, the MPIM, Ch.8, § 8.4.2 states that simple random sampling involves using a random selection method to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if the number of possible distinct samples is large - possibly billions. It merely means that if one had unlimited time, one could in theory, write down the samples and the sampling units contained therein, and based on the probabilities, that each sampling unit in each distinct possible sample must have a known probability of selection. In statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

For a procedure that satisfies these properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment. MPIM, Ch.8, § 8.4.2.

The relevant question is therefore whether the sample at issue qualifies as a probability sample. In order for any sample, including a simple random sample, to qualify as a "probability sample," the MPIM, Ch.8, § 8.4.2 sets forth two requirements. First, in principle, it must be possible to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Secondly, each sampling unit in each distinct possible sample must have a known probability of selection. *Id.*

III. Administrative Law Judge Authority, *Statistical Sampling, Due Process Concerns*

The duty of an ALJ to adjudicate appeals on his or her docket in a fair and efficient manner does not include the requirement that each claim filed necessitates an individualized hearing in order to reach a determination of the claim. Federal courts have long held that a determination of procedural due process involves balancing three factors: (1) "private interest that will be affected by official action; (2) risk of erroneous deprivation of such interest through procedures used, and probable value, if any, of additional or substitute procedural safeguards; and (3) government's interest, including function involved and fiscal and administrative burdens that additional or substitute procedural requirements would entail." *Mathews v. Eldridge,* 424 U.S. 319, 335 (1976).

When considering a provider's property interest in the payments due from Medicare, federal courts have long held that if a sample is representative and statistically significant, the risk of error to a provider is fairly low. The District of Columbia Circuit has stated that, in the context of statistical sampling, "HHS

has not, in fact, suspended individualized determinations and substituted sample adjudication on initial review of payment claims … instead, the Department has supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review of providers suspected of overbilling. We cannot find a statutory preclusion to such post-payment auditing nor to the method used to accomplish such objective." *Chaves County Home Health Servs. v. Sullivan*, 931 F.2d 914, 919-22 (D.C.Cir. 1991).

In State of Ga. v. Califano, 446 F.Supp. 404, 409-10 (N.D.Ga. 1977), a federal district court stated in a Medicaid recoupment action that ("[A]udit on an individual claim-by-claim basis of the many thousands of claims submitted each month by each state would be a practical impossibility as well as unnecessary."). In a federal bankruptcy proceeding, the court stated that "the statutory scheme of individualized review of claims on pre-payment review can be reconciled with a sample adjudication procedure on post-payment review. Such an interpretation is reasonable given the logistical imperatives recognized by courts in other comparable circumstances." *Rataenasen v. Cal., Dep't of Health Servs.*, 11 F.3d 1467, 1471-73 (9th Cir. 1993). While the "gold standard" of individualized hearings is the preferred method of claims adjudication, statistical sampling can be undertaken where necessary to protect the interests of the appellant and the Medicare Trust Fund. The use of statistical sampling outweighs an Appellant's interest in individualized adjudication of claims.

While statistical sampling performed at the ALJ level in this case is a "pre-payment" review, each claim in the frame received individual consideration on multiple occasions by Medicare contractors. The basis for the appeal of each of the claims in this case arises from its denial by Medicare contractors on at least three occasions. The denials occurred initially, upon redetermination and reconsideration of the claim. The Court in *Chaves* noted that a Provider's due process right to "individual coverage determinations" is protected during the statistical sampling process because each claim in the post-payment audit was initially reviewed by a HHS contractor and the Department merely "supplemented individualized pre-payment review of claims with a sampling procedure on post-payment review." *Chaves*, 931 F.2d at 916-917. Further, Courts have emphasized that a Provider continues to have adjudicatory rights to challenge the sampling and each determination made by the ALJ. *See, Rataenasen*, 11 F.3d at 1468, 1472-73; *See also, Bayer Corp. v. U.S.*, 850 F.Supp.2d 522, 544 (W.D.Pa. 2012).

IV. Principles of Law, *Statistical Sampling, Policy Guidance*

The manuals issued by the Centers for Medicare and Medicaid Services (CMS) administering the Medicare program also are considered. Although not binding on the ALJ, the respective manuals provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995), the United States Supreme Court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it.

The **Medicare Program Integrity Manual ("MPIM"), Chapter 8** outlines the policies regarding accepted statistical sampling principles.[4] Chapter 8, § 8.4.1.5 mandates that the sampling methodology used to project overpayments be reviewed by a statistician, or by a person with equivalent expertise in probability sampling and estimation methods. This is done to ensure that a statistically valid sample is drawn and that statistically valid methods for projecting overpayments are followed. *Id.* It requires that, at a minimum, the statistical expert shall possess a master's degree in statistics or have equivalent experience. *Id.*

[4] *See* footnote 2 regarding a discussion of statistical principles in the MPIM regarding "overpayment" vs. "underpayment" cases.

One of the important safeguards for Providers being subjected to the statistical sampling process is the use of a "one-sided 90 percent confidence interval estimation" when calculating the final overpayment or underpayment in a case. The details of the calculation of this lower limit involve subtracting some multiple of the estimated standard error from the point estimate, thus yielding a lower figure. Thus confidence interval estimation incorporates the uncertainty inherent in the sample design and is a conservative method that works to the financial advantage of the provider or supplier. That is, it yields a demand amount for recovery that is very likely less than the true amount of overpayment [or a higher amount of underpayment] and it allows a reasonable recovery without requiring the tight precision that might be needed to support a demand for the point estimate. *See* MPIM, ch. 8, § 8.4.5.1.

In simple random or systematic sampling the total overpayment [or underpayment] in the frame may be estimated by calculating the mean overpayment, net of underpayment, in the sample and multiplying it by the number of units in the frame. In this estimation procedure, which is unbiased, the amount of overpayment or underpayment dollars in the sample is expanded to yield an overpayment or underpayment figure for the universe. The method is equivalent to dividing the total sample overpayment or underpayment by the selection rate. The resulting estimated total is called the point estimate, i.e., the difference between what was paid and what should have been paid. *Id.*

Other methods of obtaining the point estimate are discussed in the standard textbooks on sampling theory. Alternatives to the simple expansion method that make use of auxiliary variables include ratio and regression estimation. Under the appropriate conditions, ratio or regression methods can result in smaller margins of error than the simple expansion method. It is noted that one should exercise caution in using alternatives such as ratio or regression estimation because serious biases can be introduced if sample sizes are very small. (The term bias is used here in a technical sense and does not imply a finding that treats the provider or supplier unfairly. A biased estimator is often used rather than an unbiased estimator because the advantage of its greater precision outweighs the tendency of the point estimate to be a bit high or low.). *Id.*

With respect to simple random sampling, the MPIM states that simple random sampling involves using a random selection method to draw a fixed number of sampling units from the frame without replacement, i.e., not allowing the same sampling unit to be selected more than once. The random selection method must ensure that, given the desired sample size, each distinguishable set of sampling units has the same probability of selection as any other set - thus the method is a case of "equal probability sampling." An example of simple random sampling is that of shuffling a deck of playing cards and dealing out a certain number of cards (although for such a design to qualify as probability sampling a randomization method that is more precise than hand shuffling and dealing would be required.). *Id.* at § 8.4.4.1.1.

Regardless of the method of sample selection used, the process must result in a probability sample. For a procedure to be classified as probability sampling the following two features must apply:

- It must be possible, in principle, to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Although only one sample will be selected, each distinct sample of the set has a known probability of selection. It is not necessary to actually carry out the enumeration or calculate the probabilities, especially if

> the number of possible distinct samples is large - possibly billions. It is merely meant that one could, in theory, write down the samples, the sampling units contained therein, and the probabilities if one had unlimited time; and
>
> • Each sampling unit in each distinct possible sample must have a known probability of selection. For statistical sampling for overpayment estimation, one of the possible samples is selected by a random process according to which each sampling unit in the target population receives its appropriate chance of selection. The selection probabilities do not have to be equal but they should all be greater than zero. In fact, some designs bring gains in efficiency by not assigning equal probabilities to all of the distinct sampling units.

For a procedure that satisfies these bulleted properties it is possible to develop a mathematical theory for various methods of estimation based on probability sampling and to study the features of the estimation method (i.e., bias, precision, cost) although the details of the theory may be complex. If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." Because of differences in the choice of a design, the level of available resources, and the method of estimation, however, some procedures lead to higher precision (smaller confidence intervals) than other methods. A feature of probability sampling is that the level of uncertainty can be incorporated into the estimate of overpayment. *Id.* at § 8.4.2.

Thus, the relevant question is therefore whether the sample at issue qualifies as a probability sample. As stated above, in order for any sample, including a simple random sample, to qualify as a "probability sample," first, in principle, it must be possible to enumerate a set of distinct samples that the procedure is capable of selecting if applied to the target universe. Secondly, each sampling unit in each distinct possible sample must have a known probability of selection. *Id.*

V. Principles of Law, *Durable Medical Equipment, Statutes and Regulations*

The Social Security Act Amendments of 1965 (Pub. Law 89-97, 79 Stat. 286) created the Medicare Program, a federal health insurance program for the elderly (65 years of age and older), disabled, and individuals with specific illnesses, found in Title XVIII of the Social Security Act (the "Act"). 42 U.S.C. § 1395 et seq.; Title XVIII § 1811 of the Act. Medicare was originally comprised of two parts: Medicare Part A, the Hospital Insurance program, found at Title XVIII §§ 1811 to 1821 of the Act, and Medicare Part B, the Supplementary Medical Insurance program, found at Title XVIII §§ 1831 to 1848 of the Act. Part B provides enrolled beneficiaries insurance coverage for a variety of "medical and other health services" and supplies furnished by physicians or by others in connection with physicians' services, outpatient hospital services, and a number of other specific health-related items and services as set forth in Title XVIII § 1832 of the Act. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium. Title XVIII §§ 1839–1840 of the Act.

Coverage under Part B entitles a beneficiary to have payments made on his or her behalf for reasonable and necessary items of durable medical equipment ("DME"). Title XVIII § 1832 (a)(2)(G) (covering "covered items" which are defined in Title XVIII § 1834(a)(13) to mean durable medical equipment);

Title XVIII § 1832(a)(1)(covering "medical and other health services," which in Title XVIII § 1861(s)(6) includes durable medical equipment). Title XVIII § 1861(n) of the Act defines DME to include a variety of equipment and supplies including, but not limited to, oxygen tents, hospital beds, wheelchairs, and blood glucose monitors and test strips.

As a condition for payment, Section 6407 of the Patient Protection and Affordable Care Act of 2010, (Pub. Law 111–148, 124 Stat. 119) created Title XVIII § 1834(a)(11)(b) of the Act, which requires documentation that a physician, PA, NP or CNS has had a face-to-face encounter examination with a beneficiary in the six (6) months prior to the written order for certain items of DME. The specific list of items of DME affected by this requirement was listed in 77 Fed. Reg. 44798 (July 30, 2012). The face-to-face requirement is effective for dates of service beginning in October 2013. Note this section does not apply to Power Mobility Devices ("PMDs") as these items are covered under a separate requirement. CMS, Medicare Learning Network (MLN) Matters: MM8304 (Eff. July 1, 2013).

Services that are "not reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are specifically excluded from Medicare coverage pursuant to Title XVIII § 1862(a)(1)(A) of the Act. Further, payment to any provider of services is precluded under Title XVIII § 1833(e) of the Act unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider."

The Medicare program found in Title XVIII of the Act is administered through the Centers for Medicare and Medicaid Services ("CMS"), a component of the United States Department of Health and Human Services ("HHS"). CMS promulgates regulations found at Title 42 of the Code of Federal Regulations for administration of the Medicare program. Medicare Part B pays for the rental or purchase of durable medical equipment, if the equipment is used in the patient's home or in an institution that is used as a home. 42 C.F.R. §§ 410.38(a), 410.10(h). DME is defined as equipment furnished by a supplier or home health agency that (1) can withstand repeated use, (2) has an expected life of at least 3 years, (3) is primarily and customarily used to serve a medical purpose, (4) generally is not useful to an individual in the absence of an illness or injury, and (5) is appropriate for use in the home. 42 C.F.R. § 414.202.

VI. Principles of Law, *Durable Medical Equipment, Policy Guidance*

The manuals issued by the Centers for Medicare and Medicaid Services administering the Medicare program also are considered. The respective manuals provide guidance in the administration of the Medicare program. In *Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87, 102 (1995), the United States Supreme Court concluded that an agency manual section is a valid interpretive rule and that it is reasonable for the agency to follow it. The manuals represent CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies use the manuals to administer CMS programs. Under 42 C.F.R. § 405.1062, ALJs are not bound by the manuals, but must give them substantial deference if they apply to a particular case. If an ALJ declines to follow a policy in a particular case, the ALJ must explain the reasons why the policy was not followed.

The **MPIM, Chapter 5, § 5.2.8 states** that for DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically

ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.

The **MPIM, Chapter 5, § 5.7**, specifies that, for DME to be covered by Medicare, "[T]he patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered. However, neither a physician's order nor a CMN nor a DIF nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier."

The **MPIM, Chapter 4, § 4.26,** provides that suppliers must provide valid proof of delivery in order to verify that the beneficiary received the DMEPOS. Suppliers may deliver directly to the beneficiary or the designee. An example of proof of delivery to a beneficiary is having a signed delivery slip, and it is recommended that the delivery slip include: 1) The patient's name; 2) The quantity delivered; 3) A detailed description of the item being delivered; 4) The brand name; and 5) The serial number. The date of signature on the delivery slip must be the date that the DMEPOS item was received by the beneficiary or designee. The MPIM states that in instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service on the claim. *Id.* at § 4.26.1.

VII. Principles of Law, *Medicare Contractor's Guidance for Glucose Monitoring*

A. National Coverage Determination

A National Coverage Determination is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare. 42 C.F.R. § 405.1060. NCDs are written pursuant to Title XVIII §1862(a)(1) of the Act as well as pursuant to other applicable statutory authority. 42 C.F.R. § 405.1060(a)(3). Notably, an NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs and the MAC. 42 C.F.R. § 405.1060(a)(4). With respect to Level Three review, an ALJ may not disregard, set aside, or otherwise review an NCD. 42 C.F.R.§ 405.1060(b)(1). However, an ALJ may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

CMS Publication 100-03, Medicare National Coverage Determinations Manual, Chapter 1, § 190.20 (NCD 190.20) discusses blood glucose monitoring:

> This policy is intended to apply to blood samples used to determine glucose levels. Blood glucose determination may be done using whole blood, serum or plasma. It may be sampled by capillary puncture, as in the fingerstick method, or by vein puncture or arterial sampling. The method for assay may be by color comparison or an indicator stick, by meter assay of whole blood or a filtrate of whole blood, using a device approved for home monitoring, or by using a laboratory assay system using serum or plasma. The convenience of the meter or stick color method allows a patient to have access to blood glucose values

in less than a minute or so and has become a standard of care for control of blood glucose, even in the inpatient setting.

Blood glucose values are often necessary for the management of patients with diabetes mellitus, where hyperglycemia and hypoglycemia are often present. They are also critical in the determination of control of blood glucose levels in the patient with impaired fasting glucose (FPG 110-125 mg/dL), the patient with insulin resistance syndrome and/or carbohydrate intolerance (excessive rise in glucose following ingestion of glucose or glucose sources of food), in the patient with a hypoglycemia disorder such as nesidioblastosis or insulinoma, and in patients with a catabolic or malnutrition state. In addition to those conditions already listed, glucose testing may be medically necessary in patients with tuberculosis, unexplained chronic or recurrent infections, alcoholism, coronary artery disease (especially in women), or unexplained skin conditions (including pruritus, local skin infections, ulceration and gangrene without an established cause).

Many medical conditions may be a consequence of a sustained elevated or depressed glucose level. These include comas, seizures or epilepsy, confusion, abnormal hunger, abnormal weight loss or gain, and loss of sensation. Evaluation of glucose may also be indicated in patients on medications known to affect carbohydrate metabolism.

Effective January 1, 2005, the Medicare law expanded coverage to diabetic screening services. Some forms of blood glucose testing covered under this national coverage determination may be covered for screening purposes subject to specified frequencies. See 42 CFR 410.18 and section 90, chapter 18, of the Claims Processing Manual, for a full description of this screening benefit.

Frequent home blood glucose testing by diabetic patients should be encouraged. In stable, non-hospitalized patients who are unable or unwilling to do home monitoring, it may be reasonable and necessary to measure quantitative blood glucose up to four-times annually. Depending upon the age of the patient, type of diabetes, degree of control, complications of diabetes, and other co-morbid conditions, more frequent testing than four-times annually may be reasonable and necessary.

B. Local Coverage Determination

Title XVIII §1871(a)(2) of the Act states that no rule, requirement, or statement of policy can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS, with the only exception being national coverage determinations (NCDs). *See also* 42 CFR § 405.1060. However, in lieu of binding regulations with the full force and effect of law, CMS and its contractors have issued policy guidance describing the criteria for coverage of selected items and services in the form of manuals and local coverage determinations. A Local Coverage Determination ("LCD") is a decision whether to cover a particular service in accordance with Title XVIII § 1862(a)(1)(A) of the Social Security Act. LCDs specify under what clinical circumstances a service is considered to be reasonable and necessary for the diagnosis or treatment of illness or injury, or to improve the functioning of a malformed body member. They are administrative and educational tools to assist providers in submitting correct claims for payment. Under 42

C.F.R. § 405.1062, ALJs are not bound by Carrier LCDs, but must give them substantial deference if they apply to a particular case. If an ALJ declines to follow a LCD in a particular case, the ALJ must explain the reasons why the LCD was not followed.

The claims for glucose monitors and supplies in this appeal are governed by **LCD L11520 for Glucose Monitors[5] and Policy Article for Glucose Monitor (A33745)** issued by the DME MAC. The relevant sections are included below:

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

To be eligible for coverage of home blood glucose monitors and related accessories and supplies, the beneficiary must meet all of the following basic criteria:

> 1. The patient has diabetes (ICD-9 codes 249.00-250.93) which is being treated by a physician; and
>
> 2. The glucose monitor and related accessories and supplies have been ordered by the physician who is treating the patient's diabetes and the treating physician maintains records reflecting the care provided including, but not limited to, evidence that the prescribed frequency of testing is reasonable and necessary; and
>
> 3. The patient (or the patient's caregiver) has successfully completed training or is scheduled to begin training in the use of the monitor, test strips, and lancing devices; and
>
> 4. The patient (or the patient's caregiver) is capable of using the test results to assure the patient's appropriate glycemic control; and

[5] The sample claims in this decision are governed under multiple LCDs because the various Dates of Service span 8/3/2011 through 9/4/2011 and the claims arise in various geographical jurisdictions. The LCD sections included in the text are from LCD L11520 (Revision Effective Date: 8/5/2011), for services performed on or after 8/5/2011 through 10/31/2012. Beneficiary 3 is the only sample appeal with a Date of Service prior to 8/5/2011, and in that case, the Dates of Service were August 3, 2011 through November 2, 2011. However, the earliest appeal in the universe has a Date of Service of March 29, 2011, and the universe contains 40 Beneficiaries with Dates of Service that include Dates of Service prior to August 5, 2011. Claims with Dates of Service prior to 8/5/2011 are governed by LCD L11520 (Revision Effective Date: 2/4/2011). However, the language in both LCDs is substantively equivalent for nearly all sections, except where noted. *See also,* footnote 13.

5. The device is designed for home use.

For all glucose monitors and related accessories and supplies, if the basic coverage criteria (1)-(5) are not met, the items will be denied as not reasonable and necessary.

Home blood glucose monitors with special features (E2100, E2101) are covered when the basic coverage criteria (1)-(5) are met and the treating physician certifies that the patient has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) requiring use of this special monitoring system.

Code E2101 is also covered for those with impairment of manual dexterity when the basic coverage criteria (1)-(5) are met and the treating physician certifies that the patient has an impairment of manual dexterity severe enough to require the use of this special monitoring system. Coverage of E2101 for patients with manual dexterity impairments is not dependent upon a visual impairment.

If an E2100 or E2101 glucose monitor is provided and basic coverage criteria (1)-(5) plus the additional criteria stated above are not met, it will be denied as not reasonable and necessary.

Lancets (A4259), blood glucose test reagent strips (A4253), glucose control solutions (A4256), spring powered devices for lancets (A4258), and replacement lens shield cartridge (A4257) for use with laser skin piercing device are covered for patients for whom the glucose monitor is covered. More than one spring powered device (A4258) per 6 months is not reasonable and necessary.
The medical necessity for a laser skin piercing device (E0620) and related lens shield cartridge (A4257) has not been established; therefore, claims for E0620 and/or A4257 will be denied as not reasonable and necessary.

The quantity of test strips (A4253), lancets (A4259), and replacement lens shield cartridges (A4257) that are covered depends on the usual medical needs of the diabetic patient according to the following guidelines:

For a patient who is not currently being treated with insulin injections, up to 100 test strips and up to 100 lancets or one lens shield cartridge every 3 months are covered if criteria (a)-(c) are met:
For a patient who is currently being treated with insulin injections, up to 100 test strips and up to 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(c) are met:

For a patient who is not currently being treated with insulin injections, more than 100 test strips and more than 100 lancets or one lens shield cartridge every 3 months are covered if criteria (a)-(f) are met:

For a patient who is currently being treated with insulin injections, more than 100 test strips and more than 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(f) are met:

a. Coverage criteria (1)-(5) listed above for a glucose monitor are met.

b. The supplier of the test strips and lancets, or lens shield cartridge maintains in its records the order from the treating physician.

c. The beneficiary has nearly exhausted the supply of test strips and lancets, or useful life of one lens shield cartridge previously dispensed.

d. The treating physician has ordered a frequency of testing that exceeds the utilization guidelines and has documented in the patient's medical record the specific reason for the additional materials for that particular patient.

e. The treating physician has seen the patient and has evaluated their diabetes control within 6 months prior to ordering quantities of strips and lancets, or lens shield cartridges that exceed the utilization guidelines.

f. If refills of quantities of supplies that exceed the utilization guidelines are dispensed, there must be documentation in the physician's records (e.g., a specific narrative statement that adequately documents the frequency at which the patient is actually testing or a copy of the beneficiary's log) or in the supplier's records (e.g., a copy of the beneficiary's log) that the patient is actually testing at a frequency that corroborates the quantity of supplies that have been dispensed. If the patient is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every six months.

If criteria (a)-(c) are not met, all testing supplies will be denied as not reasonable and necessary. If quantities of test strips, lancets or lens shield cartridges that exceed the utilization guidelines are provided and criteria (d)-(f) are not met, the amount in excess will be denied as not reasonable and necessary.

For Dates of Service after August 5, 2011, the LCD includes the following three paragraphs:

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products (A4233-A4236, A4253, A4256, A4258 and A5259) that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS' Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

The following two paragraphs apply to Dates of Service from February 4, 2011 through August 5, 2011.[6]

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers should stay attuned to atypical utilization patterns on behalf of their clients and verify with the ordering physicians that the atypical utilization is, in fact, warranted. Regardless of utilization, a supplier must not dispense more than a 3-month quantity of glucose testing supplies at a time.

An order refill does not have to be approved by the ordering physician; however, a beneficiary or their caregiver must specifically request refills of glucose monitor supplies before they are dispensed. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has "authorized" this in advance. As referenced in the Program Integrity Manual (Internet-Only Manual, CMS Pub. 100-8, Chapter 4.26.1) "Contact with the beneficiary or designee regarding refills should take place no sooner than approximately 7 days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product no sooner than approximately 5 days prior to the end of usage for the current product."

Documentation Requirements

Title XVIII § 1833(e) of the Social Security Act precludes payment to any supplier of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider". It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order for home blood glucose monitors and/or diabetic testing supplies must include all of the following:

1. All item(s) to be dispensed;
2. For test strips, the specific frequency of testing;
3. The treating physician's signature;
4. The date of the treating physician's signature;
5. A start date of the order - only required if the start date is different than the signature date.

[6] *See* footnote 5.

An order that only states "as needed" will result in those items being denied as not reasonable and necessary.

REFILLS[7]

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in treating physician
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a renewal

For items that the patient obtains in person at a retail store, the signed delivery slip or copy of itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- Quantity of each item that the beneficiary still has remaining

This information must be kept on file and be available upon request.

The ICD-9 diagnosis code describing the condition that necessitates glucose testing must be included on each claim for the monitor, accessories and supplies.

If the patient is being treated with insulin injections, the KX modifier must be added to the code for the monitor and each related supply on every claim submitted. The KX modifier must not be used for a patient who is not treated with insulin injections.

If the patient is not being treated with insulin injections, the KS modifier must be added to the code for the monitor and each related supply on every claim submitted.

Additional documentation requirements apply to: 1) a diabetic patient who is not insulin-treated (KS modifier present) and whose prescribed frequency of testing is more often than once per day, or 2) a diabetic patient who is insulin-treated (KX modifier present) and whose prescribed frequency of testing is

[7] For Dates of Service after August 5, 2011, the LCD included specific requirements for refill documentation, specifically, the refill record must include the quantity of each item. To the extent that such language is not present in the LCD in effect for Dates of Service prior to August 5, 2011, the same program integrity principles and objectives apply, namely that suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. *See also,* footnote 13.

more often than three times per day. When refills for quantities of supplies that exceed the utilization guidelines are dispensed, the documentation as described in criteria (d)-(f) in the Indications and Limitations of Coverage and/or Medical Necessity section must be available upon request.

The medical necessity for E2100 or E2101 in a patient with impaired visual acuity must be documented by a narrative statement from the physician that must include the patient's specific numerical visual acuity (e.g., 20/400) and that this result represents "best corrected" vision. This information does not have to be sent in with the claim but must be substantiated in the patient's medical record and available upon request.

Similarly, claims for E2101 for patients with impaired manual dexterity must be documented by a narrative statement from the physician that includes an explanation of the patient's medical condition necessitating the monitor with special features. This information does not have to be sent in with the claim, but must be available request.

Suppliers are not prohibited from creating data collection forms in order to gather medical necessity information; however, the DME MAC or DME PSC will not rely solely on those forms to prove the medical necessity of services provided. Suppliers must not attribute any self-generated forms or data collection requests to the Medicare Program, CMS, or the DME MAC or DME PSC. Physicians are not required to fill out additional forms from suppliers or to provide additional forms to suppliers or to provide additional information to suppliers unless specifically requested by the supplier per the DME MAC or DME PSC.

Refer to the Supplier Manual for more information on documentation requirements.

Appendices

Insulin-treated means that the patient is receiving insulin injections to treat their diabetes. Insulin does not exist in an oral form and therefore patients taking oral medication to treat their diabetes are not insulin-treated. An order refill is the act of replenishing quantities of previously ordered items during the time period in which the current order is valid.

VIII. Principles of Law, *Liability*

Under Title XVIII §1879 of the Act, Beneficiary and/or Provider liability for non-covered Medicare services may be limited under particular circumstances. In pertinent part, limitation of liability may apply to items or services that are excluded under Title XVIII §§1862(a)(1)(A) and 1862(a)(9) of the Act, or by reason of a coverage denial described in subsection 1879(g).

Pursuant to Title XVIII §1879(a)(2) of the Act, Medicare will limit the Beneficiary's liability for non-covered services if he or she did not know, and could not reasonably have been expected to know, that said services were non-covered. Title XVIII § 1879(a)(2) of the Act also limits the Provider/Supplier's liability for non-covered services if it did not know, and could not reasonably have been expected to know, that said services were non-covered. When both the Beneficiary and the Provider's liability may be limited under Title XVIII § 1879 of the Act, Medicare Part B payment will be made as though Title XVIII §§1862(a)(1)(A), 1862(a)(9) or 1879(g) of the Act did not apply. Federal regulation sets forth the criteria for determining whether a beneficiary and/or provider knew that services were excluded from coverage as

custodial care or as not reasonable and necessary. 42 C.F.R. §§ 411.404 and 411.406.

CMS Publication 100-8, Medicare Program Integrity Manual, Chapter 5 – Items and Services Having Special DME Review Considerations, § 5.8 - Supplier Documentation, provides that "If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained."

ANALYSIS

a. Discussion of Statistical Sampling and Extrapolation Methodology Employed

Dr. Stefan Boedeker, the Appellant's expert, was introduced as an expert witness on statistical sampling in the initial hearing. Dr. Boedeker's impressive credentials include his current position as Managing Director at the Berkeley Research Group. He holds a Bachelor in Science in statistics and a Master of Science in statistics from the University of Dormand, Germany, as well as Master of economics from the University of California, San Diego. His has extensive experience applying economic and statistical theories and methodologies to a wide range of industries, including twenty-five years of experience in the healthcare industry. He has previous experience negotiating and presenting statistical methods with government agencies and assessing the appropriateness of claims and submission payment practices based on statistical samples. (Main Folder, Exh. 6, pp. 40-59). Dr. Boedeker was qualified as an expert in Statistics at the initial hearing by virtue of his background, education and professional training. (Hearing CD). In this case, Dr. Boedeker contends that the random sampling design is not statistically valid and is based on a flawed sample design. Based on his objections to the sample, Appellant further contends that Dr. Adams' extrapolation methodology is flawed. (Main Folder, Exh. 6, pp. 5-30; Main Folder, Exh. 9, pp. 15-16).

In this case, the Appellant's representatives challenged the probability sample, arguing that it was not statistically valid and based on a flawed sample design. (Main Folder, Exh. 8, pp. 4-5; Exh. 6, pp. 5-30). The Appellant argued that the sample design and incorrect application of statistical methodology produced numerous non-sampling errors by failing to address the complexity of the universe in its sampling design, ignoring the problem caused by a highly skewed distribution, and using formulas that did not match the sampling design. The Appellant argued that the sample design did not account for claims with different number of claim line items and that the sample size of thirty was too small to yield reliable results. The Appellant agued a probe sample should have been conducted to assess the variation in the universe and calculate a sample size necessary to achieve a desired/required level of confidence such that extrapolations to the entire universe would be reliable and accurate. Dr. Boedeker found that the distribution of the sample was not normal and therefore any extrapolation based on the lower confidence limit did not provide a 95% probability that the population mean exceeded the value computed. The Appellant further argued that the results were erroneous because there was no stratification by HCPCS codes and full or partial denials were not differentiated, making the extrapolation results not representative of the universe of claims. (*Id.*; Hearing CD).

Sampling Methodology

With respect to simple random sampling, the MPIM states that simple random sampling involves using a

random selection method to draw a fixed number of sampling units from the frame without replacement, i.e., not allowing the same sampling unit to be selected more than once. The random selection method must ensure that, given the desired sample size, each distinguishable set of sampling units has the same probability of selection as any other set - thus the method is a case of "equal probability sampling." *See* MPIM, Ch. 8, § 8.4.4.1.1.

If a particular probability sample design is properly executed, i.e., defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample and its resulting estimates are "not statistically valid" cannot legitimately be made. In other words, a probability sample and its results are always "valid." *Id.* at § 8.4.2.

The relevant question is therefore whether the sample at issue qualifies as a probability sample. Here, as noted by Dr. Adams during the hearing, simple random sampling is a valid sampling design because it is random and can be replicated as required by the MPIM. *Id.* Dr. Adams' memo notes how the universe was defined and the elements included were specifically indicated in the memorandum as required by MPIM, ch. 8, § 8.4.4.1. The sample's methodologies were adequately identified and could be replicated if one had unlimited time. (Exh. 5, pp. 1-9). Furthermore, while the MPIM acknowledges that sample size has a direct bearing on the precision of the estimated over/underpayment, it also states that it is neither possible nor desirable to specify a minimum sample size that applies to all situations. *Id.* As such, the Appellant's argument that the sample size was too small is deficient. The random sample at issue meets the requirement of a probability sample. Dr. Adams' sampling methodology is upheld.

Extrapolation Methodology

One of the important safeguards for Providers being subjected to the statistical sampling process is the use of a "one-sided 90 percent confidence interval" when calculating the final overpayment or underpayment in a case. The details of the calculation of this higher limit in underpayment cases involves adding some multiple of the estimated standard error to the point estimate, thus yielding a higher figure. This procedure, which incorporates the uncertainty inherent in the sample design, through confidence interval estimation, is a conservative method that works to the financial advantage of the provider or supplier. *See* MPIM, ch. 8, § 8.4.5.1.

Based on Dr. Boedeker's objections to the sampling methodology, Appellant contends that the extrapolation methodology is not supportable. Appellant does not challenge the mathematics of the methodology outlined in Dr. Adams' extrapolation memorandum. (Main Folder, Exh. 9, pp. 11, 15-17). Considering that the mathematics are sound, and the calculations were replicable, the Appellant's expert has provided insufficient evidence that the extrapolation process employed by Dr. Adams was improper. Accordingly, extrapolation methodology employed by Dr. Adams is upheld.

b. Discussion of Law and Facts for Beneficiaries in the Sample

Although each of the sample claims at issue received individual review and consideration, the nature of the documentation lends itself to a global analysis. Such review leads to the conclusion that the entirety of the documentation provided by the Appellant is insufficient to establish that the Appellant's claims meet Medicare billing requirements or that the services provided to the beneficiaries were reasonable and

necessary. The repetitive nature of the documentation in this case is pervasive. The concerns noted in this section are either observed in each Beneficiary's case or so consistently throughout the entire record that they are most appropriately addressed as part of a general analysis section.

At issue is Medicare Part B coverage for refills of diabetic/glucose testing supplies furnished by the Appellant to the Beneficiaries on various Dates of Service. The QIC denied all appealed claims, stating that medical necessity could not be established because either the records were lacking medical documentation that supported medical necessity, the documentation did not support or explain the need for excess testing, refill documentation regarding the quantity of items was inadequate, and/or, in some instances, Medicare records indicated that a Beneficiary had received blood glucose testing supplies from a different supplier for the dates of service in question. The Appellant was liable for the non-covered charges. The Appellant argued that the medical and refill documentation was sufficient and met Medicare requirements. (Hearing CD). It is well established that "a claimant . . . has the burden of proving entitlement to Medicare benefits." *Friedman v. Sec'y of Dept. of Health and Hum. Servs.*, 819 F.2d 42, 45 (2d Cir. 1987). Accordingly, it is the Appellant's burden to establish that the diabetic/glucose testing supplies were reasonable and necessary for treatment of the Beneficiary's condition and otherwise met Medicare coverage criteria.

The LCDs in effect for all of the sample claim's Dates of Service address the problem of unnecessary supply and reinforce underlying program integrity objectives by noting that suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Beginning August 5, 2011, all of the applicable LCDs began requiring a notated quantity of diabetic supplies that a beneficiary has remaining at the time of contact. This was done to ensure that the refilled or reoccurring items remain reasonable and necessary. As expressed in the MPIM, the goal of program integrity is to pay claims correctly. The guidelines do so by utilizing fair and firm enforcement policies such as fraud prevention, early detection and coordination of efforts. *See* MPIM, Ch. 4, § 4.1. One of the means by which CMS and its contractors protect the integrity of the Medicare program is to require uniform billing practices for DMEPOS. CMS has found that the most frequent kind of fraud arises from a false statement or misrepresentation made, or caused to be made, that is material to entitlement or payment under the Medicare program. *Id.* at § 4.2.1. Such fraud may take the form of misrepresentation of dates or quantity. Thus, requiring suppliers to assess the quantity and document the quantity in specific way allows CMS and its contractors to create systems to identify and address potentially fraudulent billing practices prior to payment.

Further, the LCDs in effect during the dates of service at issue in all of the sample claims state that there must be evidence that a beneficiary required the actual quantity of supplies provided. For DMEPOS that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14-calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10-calendar days prior to the end of usage for the current product.

In addition to national and local coverage determinations (NCDs and LCDs), there are certain principles that apply to all Medicare claims. These principles are rooted in Medicare laws and regulations. For instance, Medicare generally expects claim supporting documentation to be generated at the time of

service. Review of the Appellant's "Patient Phone Authorization for Diabetic Supplies" form is a paradigm of a proscribed system of recordkeeping known as "cloned documentation." Cloned documentation is a set of record entries which are worded exactly alike, or so unreasonably similar to previous entries within an individual's medical record or between different individual's medical records so as to make them nearly indistinguishable.[8] Cloned documentation (often from copying and pasting or by sheer repetition) threatens the integrity of the Medicare Program in that it leads to (1) inaccurate information being inserted in the record, and (2) inappropriate and fraudulent billing to CMS to inflate or duplicate claims.[9] The Medicare Contractor's published education on this subject explains:

> ... cloned documentation will be considered misrepresentation of the medical necessity requirement for coverage of services due to the lack of *specific individual information for each unique patient*. Identification of this type of documentation will lead to denial of services for lack of medical necessity and the recoupment of all overpayments made.[10]

In this case, the documentation does not establish medical reasonableness and necessity for Medicare coverage and payment. Specifically, the records pertaining to the refill requests lack documentation of the specific information identified in CMS Program Integrity Manual guidance and applicable LCDs. The LCD specifies that a valid refill request from the beneficiary is required to support the medical necessity of the refill. The LCD requires, among other things, that the refill record contain a description of each item requested, the date of the refill request, and the quantity of each item that the Beneficiary still has remaining. (LCD L11502).

The overarching problem with the Appellant's claims stems from its use of cloned documentation. Medical documentation is considered cloned when each entry in the medical record for a beneficiary is worded exactly like or similar to the previous entries. Cloning also occurs when documentation is exactly the same from beneficiary to beneficiary. The Appellant's method of cloned documentation, inserting a few pieces of alternating non-individuated stock language into a wholly generic template, prevents a reviewer from determining if an individualized refill authorization was documented in order to determine whether the records satisfied the LCD's coverage criteria. Cloned documentation is considered a misrepresentation of the medical necessity requirement for coverage of services.

Here, most casefiles contained a Supplier's "Patient Phone Authorization for Diabetic Supplies" form, which listed the Beneficiary's name and date of service. The form contains language indicating that the Supplier's representative spoke with the "patient" on a particular date within the preceding one to sixteen days before the date of service. It should be noted that suppliers such as the supplier here, do not have "patients." They have customers who in these cases happen to be Medicare enrollees that will hereafter be referred to as a "Beneficiary." One Beneficiary was contacted 23 days before the date of service. The form stated that a Beneficiary was "confirmed running low on supplies." In some instances, the written statement indicated a number of days until a Beneficiary's expected exhaustion of test strips/lancets. Other

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[8] See University of Alabama Health Services Foundation: Navigating Compliance Landmines in Electronic Health Record ("HER") Documentation, at https://www.healthlawyers.org/events/programs/materials/documents/fc13/406_bates_slides.pdf

[9] Report: U.S. Department of Health and Human Services, Office of the Inspector General: CMS and its Contractors Have Adopted Few Program Integrity Practices to Address Vulnerabilities in EHRs (January 2014), at http://oig.hhs.gov/oei/reports/oei-01-11-00571.pdf.

[10] National Government Services: Cloned Documentation Could Results in Medicare Denials for Payment, at https://ngsmedicare.com, Policy Education Topics. (*emphasis added*)

versions of the form stated only that a Beneficiary was "running low" or that testing supplies "on hand would be depleted."[11] The form indicated that the Supplier scheduled the next shipment and that the Beneficiary acknowledged that the Supplier was their only Supplier and authorized shipment of listed equipment (which included in all cases test strips and lancets, as well as control solution, lancing device, and batteries). There was no name or signature to indicate who contacted the Beneficiary and filled out the form on behalf of the Supplier. There was never a named caregiver or other designee for refill requests for which a Beneficiary might not be able to personally provide the information required to fulfill the request. While a Beneficiary's name appears on the face of the document, no individual person's name was ever used in the corpus of the form to identify the person purportedly contacted.

In other cases, the file contained a Supplier-produced form with a box electronically checked for the Beneficiary's given scheduled ship date or to indicate confirmation to receive their "regular shipment," and an accompanying statement signed by the Beneficiary which stated that the Beneficiary authorized the Supplier to contact his or her physician, release medical information and submit claims on his or her behalf.[12] In the cases of Beneficiaries 17 and 20, the statement included that the Beneficiary "will have less than [X] days of diabetic supplies by the scheduled ship date. My daily testing schedule is still [X] times per day." The statement for Beneficiaries 3, 4, 14, and 22 did not contain any language referring to the Beneficiary's specific number of days remaining or testing schedule.

In both authorization document formats, the limited information on the document does not indicate how the Supplier assessed the quantity of each item or provide any specific notation regarding the actual number or quantity of items that the individual Beneficiary had on hand for any of the supplies ordered. The Appellant argued that phrasing the remaining quantity in terms of days remaining until exhaustion was sufficient to meet Medicare requirements. However, the Appellant failed to cite to any statute, regulation, coverage determination or policy manual provision to support its assertion. First, the refill authorization for Beneficiaries 3, 4, 5, 7, 8, 10, 13, 15, 14, 16, 22, 25, 26, 28, and 30 did not even provide a number of days left until the Beneficiary would run out but simply indicated that the Beneficiary was "confirmed running low on supplies," "running low," or that testing supplies "on hand would be depleted." The repetition of such stock phrases is the ultimate portrayal of "cloned documentation." Second, in the claims where a number of days is given until the expected exhaustion of test strips/lancets, the identification of the item and number is not specific enough to derive a more exacting quantity remaining. Without more information about the Beneficiary's frequency of use or testing frequency on the form itself, there is simply no calculation provided by which to establish the quantity remaining. References to days remaining are not sufficient to demonstrate compliance. The refill records are not individualized to a Beneficiary's testing frequency nor detailed in quantifying a Beneficiary's remaining supplies. There is no noted quantity of the items that the Beneficiary still has remaining, as required by the LCD. This is precisely the type of cloned documentation that Medicare has determined to be not reasonable and necessary.

The Appellant argued that their representative on the telephone call obtained the necessary and required information. The Appellant further asserted that the LCD does not specifically indicate that a quantity must be documented. The Appellant described in its submissions the steps that it takes to confirm with the beneficiaries that a refill of their medication is needed and that their current supply is nearing exhaustion.

[11] The phone authorization forms for Beneficiaries 5, 7, 8, 10, 13, 15, 16, 25, 26, 28, and 30 contained this phrasing.
[12] Beneficiaries 3, 4, 14, 17, 20, and 22 contained this style of authorization documentation.

(Hearing CD). However, the LCD requires the documentation and assessment of quantity. There is no documentation in the records of any Beneficiary that indicates the *quantity* of items that such Beneficiary had on hand at the time of the refill contact. Further, none of the Beneficiary contact records state the specific number of days until supply exhaustion. Simply assuming that the supplies were near exhaustion based on a date or passage of time does not meet the refill requirements of the LCD.

The Appellant has not sufficiently demonstrated its steps to show that it made an individualized assessment about the Beneficiaries' remaining supplies. Program and contractor guidance make clear that this information must be obtained from Beneficiaries at the time of refill request, and, therefore, the documentation of the refill request must reflect the quantity of supply remaining. Merely noting that the beneficiary is "running low" simply does not adequately provide the level of detail required by the LCD to show the specific quantity of the remaining supply.[13] Because the refill requests for the Beneficiaries lack information regarding the remaining supply, the documentation is insufficient to demonstrate that the refills were medically reasonable and necessary.

In all the cases with high frequency testing for both insulin dependent and non-insulin dependent Benenficaries,[14] the documentation indicates that the Beneficiaries were being treated by the prescribing physician for diabetes and were noted as being either an insulin dependent or non-insulin dependent diabetic. Except for Beneficiaries 11 and 20, all physician order forms contained a written description for high frequency testing, usually "elevated," "uncontrolled,", or "fluctuating" blood sugar or glucose levels (forms for Beneficiaries 11 and 20 failed to provide a description). However, pursuant to the MPIM, Ch. 5, § 5.7, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered; the order alone is not sufficient documentation. In all cases involving high frequency testing Beneficiaries, the progress notes do not specifically document the reasons for excess testing. In the majority of instances, the records contained no Beneficiary testing logs or narrative statements articulating the frequency at which a Beneficiary was actually testing. Some physicians' progress notes indicated that the Beneficiary's diabetes was controlled, managed, or doing well. In other cases, the physician notes indicated that the Beneficiary was failing to test himself or herself as ordered. Many of the plans and assessments contained no specific recommended testing regimen. The progress note documentation in all cases does not provide sufficient evidence that the physician evaluated the Beneficiaries' diabetes control nor does it provide specific reasons for the additional quantities of supplies ordered. Simply stating in an order or treatment plan that the Beneficiary should adhere to a specific testing regimen is not sufficient evidence of medical necessity for quantities of

[13] As noted, 40 Beneficiary claims in the universal frame were for Dates of Service prior to August 5, 2011 and therefore such claims were not explicitly required by the LCDs to specify a specific quantity on hand at the time of refill authorization. As Appellant notes, ALJs are not bound by LCDs but where they decline to follow policy in a specific case must explain the departure. The basis for departure from an LCD's requirements should be made only where such departure is in furtherance of the LCD's underlying policy goals. Here, the program integrity goals of fair and honest dealing with Medicare in claims submission requires departure to require provision of the quantity on hand in order to prevent program abuse and fraud. In order to be assured that a supplier has stayed attuned to changed or atypical utilization patterns on the part of the Beneficiaries, requiring that the quantity on hand be obtained prior to refilling supplies is the type of departure from the LCD's requirements that justifies the departure. By identifying changed or atypical utilization, the Appellant is best positioned to prevent abuse such as Beneficiary hoarding or medically unnecessary over-testing or worse yet, conveyance of over-supplied products to secondary markets for resale. Departure by an ALJ from the LCD to require quantity determination is precisely the type of departure envisioned by 42 C.F.R. § 405.1062.

[14] "High frequency testing" is defined as non-insulin treated patients testing more than one time per day or insulin treated patients testing more than three times per day. The physician orders for Beneficiaries 1, 2, 3, 4, 7, 8, 9, 11, 13, 14, 15, 16, 17, 19, 20, 21, 23, 25, 28, 30 indicated they were high frequency testing patients.

supplies that exceed the utilization guidelines. *See* Medicare Program Integrity Manual, Chapter 5, § 5.7. As discussed previously, the Supplier's phone authorization records do not contain a quantity remaining or list the testing frequency of a given Beneficiary. Thus there exists no further corroborating or medical documentation evidencing that the Beneficiary required the actual quantity of supplies dispensed. Without medical evidence of the specific need for excess testing, there is insufficient evidence that the Beneficiaries' conditions required high frequency testing and the corresponding quantities ordered in such cases.

In conclusion, despite ongoing notification that there were multiple suppliers shipping diabetic supplies to its customers, the Appellant did nothing to change its business practices to protect Medicare from being overbilled by the Appellant for suppling unneeded diabetic supplies. Furthermore, without medical documentation sufficient to show medical necessity for quantities of supplies that exceed the utilization guidelines, the record does not satisfy Medicare coverage criteria and the diabetic/glucose testing supplies furnished by the Appellant in all sample claims were not reasonable and necessary for the treatment of the Beneficiaries' conditions pursuant to Title XVIII § 1862(a)(1)(A) of the Act. Finally, the records for Beneficiaries 9, 26, and 29 contained no physician progress notes or medical records at all as required by the LCD and MPIM. Accordingly, Medicare Part B does not cover the items and the Appellant is not entitled to Medicare Part B reimbursement.

c. Beneficiaries with Non-Diabetic Supply Claims

Because of the non-diabetic supply claims contained in the following appeals, per the Pre-Hearing and Post Hearing Supplemental orders, these claims were excluded from the sampling frame but remain in the universe and subject to extrapolation. Below are the dispositions for the non-diabetic supply claims:

1. Beneficiary D.T. (QIC Appeal No.: 1-1111111112)
The spreadsheet contained a line item for a heating pad (E0210) with a billed amount of $100.00. (Main File, Exh. 2, p. 92). However, the Appellant's request for reconsideration did not appeal such item or service, nor did the QIC issue a reconsideration decision for such item (Bene File, Exh. 1, pp. 8, 13). Further, the Appellant's request for hearing contained no reference to any additional items for appeal. (Bene File, Exh 1, pp. 1-5). In any event, the record does not contain a physician's order for such item as required by MPIM Chapter 5, § 5.2 nor does the record contain evidence that such item was ever delivered to the Beneficiary, as required by MPIM Chapter 4, § 4.26. The only mention of a heating pad in the record is in supplier produced notes, indicating that the Beneficiary requested a heating pad. (Bene File, Exh. 1, p. 32). The documentation is insufficient to meet Medicare coverage criteria for heating pads. Therefore, the line item for this Beneficiary's heating pad (E0210) is unfavorable.

2. Beneficiary C.W. (QIC Appeal No.: 1-1111111113)
The spreadsheet contained a line item for an unspecified item with no listed billed amount. (Main File, Exh. 2, p. 68). The Appellant's request for reconsideration specifically appealed lancets (A4253) and blood glucose/reagent strips (A4259). (Bene File, Exh. 1, p. 12). The QIC's reconsideration addressed both items. (Bene File, Exh. 1, pp. 7-10). Both items were appealed to OMHA and contained on the spreadsheet (Main File, Exh. 2, p. 68), and the Appellant's request for hearing contained no reference to any additional items for appeal. (Bene File, Exh 1, pp. 1-4). Thus, while in an abundance of caution the claims were excluded from the sampling frame due to the unspecified claim connected to the diabetic supply claims listed on the spreadsheet, the record does not contain any evidence of "unspecified" non-

diabetic supply claims, nor any related medical information. Therefore, the line item for this Beneficiary's unspecified item is unfavorable.

3. Beneficiary F.C. (QIC Appeal No.: 1-1111111114)
The spreadsheet contained a line item for a heating pad (E0210) with a billed amount of $100.00 and a line item for a male vacuum erection system (L7900). (Main File, Exh. 2, p. 74). The record contains evidence that the QIC issued an unfavorable disposition for such items at reconsideration and that both items were appealed. (Bene, Exh. 1, pp. 2-4, 8-11, 13). However, the record does not contain a physician's order for such items as required by MPIM Chapter 5, § 5.2, nor does the record contain evidence that such items were ever delivered to the Beneficiary, as required by MPIM Chapter 4, § 4.26. The record contains no evidence pertaining to a heating pad or a vacuum erection system. Thus, there is insufficient documentation to meet Medicare coverage criteria for such items and the line items for this Beneficiary's heating pad (E0210) and vacuum erection system (L7900) are unfavorable.

4. Beneficiary M.J. (QIC Appeal No.: 1-1111111115)
The spreadsheet contained a line item for an "unspecified (A4253)" item with a billed amount of $100.00. (Main File, Exh. 2, p. 81). The Contractor's decision indicated that the Appellant submitted a claim for lancets and calibrator solution chips. (Bene File, Exh. 1, p. 20). The Appellant's request for reconsideration appealed lancets (A4253), calibrator solution/chips (A4256), and blood glucose/reagent strips (A4259). (Bene File, Exh. 1, p. 14). The QIC's reconsideration addressed the lancets (A4253) and calibrator solution/chips (A4256). (Bene File, Exh. 1, pp. 9-12). All items were appealed to OMHA and contained on the spreadsheet. (Main File, Exh. 2, p. 81; Bene File, Exh 1, pp. 1-6). Thus, while in an abundance of caution the claims were excluded from the sampling frame due to the irregular or seemingly non-diabetic supply-item information contained on the spreadsheet, the record does not contain any evidence of "unspecified" non-diabetic supply claims. In fact, it appears that no Contractor or QIC decision was rendered on the item, and therefore the claim for this "unspecified (A4253)" line item is improperly before OMHA pursuant to 42 C.F.R. §§ 405.1052(b)(1) and 405.1004(d). Therefore, the claim for this Beneficiary's "unspecified (A4253)" line item is dismissed.

d. Limitation of Liability

Title XVIII § 1879(a) of the Social Security Act authorizes payments to be made for services otherwise disallowed under the Medicare program because the services were not necessary or reasonable. No payment may be made under that section, however, if the provider of the services knew, or should have known, that the services were not covered under the Medicare program. The provider of services is presumed to have known the requirements for the claim. 42 C.F.R. § 411.406(e); CMS, *National Claims Processing Manual (Internet-Only Manual, Pub. 100-04),* ch. 30, § 40.1.1 and 40.1.2.

The Appellant's non-covered claims are not payable under Title XVIII § 1879(a) of the Social Security Act because the record contains no evidence to rebut the presumption that the Appellant knew, or should have known, that the services were not covered under the Medicare program. The Appellant has not presented sufficient evidence to overcome the presumption that the Appellant should have known the items denied by this decision were not covered under the Medicare program.

Under Title XVIII § 1879(b) of the Social Security Act, a beneficiary's liability for the costs incurred in providing services to the beneficiary is limited if the services are not covered under the Medicare program

because the services were not necessary or reasonable and if the beneficiary did not know, and had no reason to know, that the services were not covered under the Medicare program.

Unlike a provider of services, a beneficiary is not presumed, under Title XVIII § 1879 of the Social Security Act, to know the criteria for coverage of items or services under the Medicare program. CMS, *National Claims Processing Manual (Internet-Only Manual, Pub. 100-04)*, ch. 30, § 30.1; *See,* 42 C.F.R. § 411.404. If, however, the Beneficiary has received written notice of non-coverage under the Medicare program of a service from the provider of the service, the Beneficiary will be considered to have knowledge of the non-coverage of the service. 42 C.F.R. § 411.404.

The record contains no evidence that any of the Beneficiaries received any written notice from the Appellant that the services provided by the Appellant to the Beneficiary would not be covered under the Medicare program. The Appellant did not provide any advance beneficiary notice ("ABN") to those Beneficiaries. The record contains no evidence that any Beneficiaries knew, or should have known, that the provision of the items to each of them would not be covered under the Medicare program. Accordingly, the Beneficiaries are not liable for the expenses incurred by the Appellant in providing the non-covered items to the Beneficiaries by reason of Title XVIII § 1879(b) of the Social Security Act. The Appellant may not attempt to collect those expenses from the Beneficiaries.

The Appellant in this case is a supplier who had constructive notice of Part B DMEPOS coverage rules. This presumption is based on the widely published Medicare statute, Medicare regulations and CMS policy manuals cited in the "Principles of Law" section above. Pursuant to 42 C.F.R. § 411.406, the Appellant should have known that Medicare Part B would not cover the diabetic supplies at issue in these cases. Accordingly, pursuant to Title XVIII § 1879, the Appellant is liable for the non-covered services.

CONCLUSIONS OF LAW

The diabetic/glucose testing supplies provided by the Appellant to all Beneficiaries on the various dates of service were not reasonable and necessary pursuant to Title XVIII § 1862(a)(1)(A) of the Social Security Act because the documentation was not sufficient to establish medical reasonableness and necessity for coverage and payment pursuant to the LCD and MPIM. Furthermore, the Appellant's liability cannot be adjusted nor can the overpayment be waived pursuant to Title XVIII §§ 1879 or 1870 of the Act, and the Appellant remains responsible for the non-covered charges/items.
42 C.F.R. § 405.926 sets out the non-appealable actions that CMS or Contractors take. Specifically, 42 C.F.R. § 405.926(c) states that any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to §405.502(g), or any issue regarding the cost report settlement process under Part A are not appealable. Thus, the dollar amount determined by Dr. Adams as the result of the extrapolation method that he employed is *not* the final dollar amount of underpayment. The actual underpayment amount is to be determined by the CMS contractor charged with making such determinations. *See also* 42 C.F.R. § 405.1046(c).

Dr. Adam's extrapolation process (*see* Exh. 9) is upheld as proper in this case. Although the extrapolated dollar amount determined by Dr. Adams is not binding on the Contractor pursuant to 42 C.F.R. § 405.1046(c), the formulas used to determine the standard error are binding on the Contractor as they have

been found proper and appropriate according to Medicare guidelines. As such, the Contractor must use the methodology noted in the Expert's Extrapolation Memo in determining the exact amount of payment due to the Appellant.

ORDER

The Medicare Contractor is hereby **DIRECTED** to process the claim in accordance with this decision. Further, although the Contractor is not bound to accept the accept dollar amount of payment due to the Appellant as determined by the Expert in this case, the Medicare Contractor is **ORDERED** to adhere to the extrapolation methodology employed by the Expert as noted in the Extrapolation Memorandum found at Main Folder Exh. 9, p. 11 in its determination of the amount due to the Appellant.

SO ORDERED.

Dated: _____

_____

Leslie Holt
U.S. Administrative Law Judge

Enclosures: Form OMHA-56, Exhibit Lists
"Sample Appendix A" Excel Sheet
"Universe of Claims" Excel Sheet
Extrapolation Memorandum from Expert

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia

Appeal of:	**ARRIVA MEDICAL LLC**	OMHA Appeal No.: QIC Appeal No.:	**1-1111111111** **(Combined)** **MULTIPLE (951)**
Beneficiary:	**MULTIPLE (946)**	Medicare	**Part B**
Medicare No.:	**MULTIPLE (946)**	Before:	**Leslie B Holt** Administrative Law Judge

MAIN FOLDER EXHIBIT LIST

Exhibit #	DESCRIPTION	Page Range
1	10-20-15 Pre-Hearing Order by DC ALJ C.F. Moore & 09-29-15 Pre-Hearing Audio Recording **[CD-RoM]** OMHA ALJ Moore Exhibit List (categorized as Exhibits 1A-1J) of Proceedings and CMS Contractors' Attendance, (Re)Scheduling of Initial Pre-Hearing , Appointment of King & Spalding as Appellant Counsel & 04-21-15 Appellant Consent for Statistical Sampling Date Range: 06-22-14 through 06-22-15 follow up email from Counsel 03-28-17 OMHA Central Operations Initial Confirmation of Assignment of July 2014 ALJ RFH Sample Group to ALJ Holt	1-3 4-69 36-40
2	OMHA Directive to Statistical Expert to Create Probability Sample & Attached ALJ Holt Post-Pre-Hearing Conference Order ("PPHCO"), Sent 02-13-2018 Arriva Counsel 02-20-18 Request for Modification of PPHCO- ALJ Holt 02-08-18 Pre-Hearing Order & Enclosed Pre-Hearing Conference Notice & OMHA-102, Response to Notice of Hearing, Form Responses to Pre-Hearing Notice, to include Appellant Expert Witness, Stefan Boedeker, Ph.D, curriculum Vitae 74-Page Claims Summary, to be Used for Statistical Sampling Universe	1-4 4a-4d 5-14 15-38 39-112
3	02-07-18 Packet from Appellant Counsel, Appointing Preeya Noronha Pinto, Esq., King & Spalding LLP, as Current Owner's Representative, w/ Copy of 01-18-18 OMHA Order Discussing Methodology of Statistical Sampling	1-8
4	Notice of Hearing (NOH) w/ Enclosed Response to NOH and Exhibit Lists w/ Cert. Service of Fax Delivery to Provider Representative: 02-16-18	1-13

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia

Appeal of:	**ARRIVA MEDICAL LLC**	OMHA Appeal No.: QIC Appeal No.:	**1-1111111111 (Combined)** **MULTIPLE (951)**
Beneficiary:	**MULTIPLE (946)**	Medicare **Part B**	
Medicare No.:	**MULTIPLE (946)**	Before:	**Leslie B Holt**

MAIN FOLDER EXHIBIT LIST

Exhibit #	DESCRIPTION	Page Range
5	03-09-18 Supplemental Post-PreHearing Conference Order w/ Cert. Svc John L. Adams 03-08-18 Memo Re Arriva Medical Random Probability Sample w/ Attached OMHA Summary Claims List for 30 Benes in Sample	1A-1E 1-9
6	Supplier's Objections Statement to Statistical Methodology and Sample, and Requests for Additional Information: Dated 03-15-18, Received at OMHA Arlington FO on 03-16-18	1-59
7	CMS Durable Medical Equipment Medicare Appeals Contractors ("D-MAC") Screenshots of BUDS Database Health Claims Reimbursement History for Sample Group Members within their Jurisdictions • Noridian Healthcare Solutions D-MAC Jurisdictions A & D: Rcvd 03-19-18 • CGS Administrators – D-MAC Jurisdictions B & C: Rcvd 03-2218	1-8 9-78
8	Appellant Post-Hearing Brief w/ Attached Submissions of New Evidence, Cert. of Service to All Parties is Noticed by King & Spalding: Rcvd 04-24-18	1-48
9	06-26-18 Order for Statistical Experts' Interrogatories w/ Attached List of Claims for 30 Exemplar Beneficiaries, Cert of Service and All Responses Received 07-10-18 Order for Response to Interrogatories w/ Attached OMHA Statistician's Memo and Cert. of Service 07-17-18 Appellant Response w/ Objection and Attached Cert. of Service	1-8 9-14 15-17

Created: 04-21-2015 Last Updated 07-17-18

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington, Virginia

Appeal of:	**Via Christi Hospitals**	OMHA Appeal No.:	**1-1111111111**
		QIC Appeal No.:	**Multiple (8)**
Beneficiary:	**Multiple (8)**	**Medicare Part A**	
Medicare No.:	**Multiple (8)**	Before:	**Leslie Holt**
			Administrative Law Judge

DECISION

Medicare Part A does not cover the Appellant's claims for inpatient hospital services because, pursuant to Title XVIII §§ 1862(a)(1)(A) and 1815(a) of the Social Security Act, the documentation does not establish that the services were reasonable and necessary for treatment of the Beneficiaries' conditions. Specifically, there is insufficient evidence at the time of the physician's inpatient admission order, the physician expected the Beneficiaries to receive treatment or diagnostic testing for at least 24 hours based on the severity of the Beneficiaries' condition and the potential risk for adverse events as required by the Medicare Benefit Policy Manual ("MBPM") Chapter 1 § 10. Accordingly, an **UNFAVORABLE** decision for various dates of service identified in Attachment 1 is entered for the Via Christi Hospitals ("Appellant").

PROCEDURAL HISTORY

The Appellant submitted claims for the inpatient admission services provided to the Beneficiaries and Medicare initially paid the claims. A Recovery Audit Contractor ("RAC") reviewed the claims and determined they should have been initially denied, resulting in overpayments. The Appellant appealed the overpayment determinations, and the Contractor upheld the overpayments upon redetermination.

The Appellant requested reconsideration from the Qualified Independent Contractor ("QIC"). The QIC upheld the overpayment determinations stating that the initial level of service could have been safely performed at either the observation level of care or as an outpatient. The QIC found the Appellant liable for the cost of the non-covered services.

The Appellant then submitted timely requests to the Office of Medicare Hearings and Appeals ("OMHA") for a hearing by an Administrative Law Judge ("ALJ"). The amount in controversy meets the statutory requirements for a hearing before OMHA pursuant to 42 C.F.R. § 405.1006. Therefore, this appeal is properly before OMHA. 42 C.F.R. § 405.1002(a).

Upon receipt in the OMHA field office, the files were organized and substantively reviewed prior to the hearing. The individual appeals were combined into one appeal with one OMHA appeal number for administrative efficiency. A telephonic hearing was held on June 19, 2017. Shauna Morgan, RN

represented the Appellant and provided argument and testimony. All parties were sworn and the exhibits were entered into evidence without objection. (Hearing CD).

ISSUES

Whether Medicare Part A covers the Beneficiaries' inpatient hospital services rendered on the dates of service, and if not, whether the Appellant or Beneficiaries are liable for any non-covered services.

FINDINGS OF FACT

1. The Beneficiaries arrived at the hospital in different ways. Some elected to schedule procedures in advance. Some came through the emergency room and one came in transfer from another hospital.

2. The Beneficiaries that underwent scheduled minor surgical procedures were stabilized in the emergency room or, in the case of the transfer patient, were admitted over the objection of one of the physicians that first treated the patient in the hospital.

3. In each case, the surgical physician reported that the surgery and surgical recovery was performed without complications. The emergency room patients were stabilized in the emergency room prior to admission.

4. In one case, the Beneficiary was first admitted to the hospital as an outpatient and the admission status was later changed to inpatient without clear explanation, other than a comment that this change was a recommended by an unaffiliated physician after review of the case file.

5. In each case, the services provided during the Beneficiaries' inpatient hospital admission were consistent with the post-surgical protocol for surgical patients or for discrete treatments or diagnostic testing performed prior to discharge.

6. In each surgical case, no acute complications from the procedures or co-morbid complications arose.

7. In the emergency room or transfer case, after receiving customary treatments and testing the Beneficiaries were asymptomatic and were stable for discharge. The hospital treating physicians recommended the Beneficiaries have a follow-up with their respective physicians as outpatients.

8. In each case, the Appellant billed Medicare Part A by referencing a specific discharge diagnosis that was used to establish a Diagnostic Related Group (DRG) code based on the discharge diagnosis. No Beneficiary remained in the hospital for more than the geometric length of stay for the DRG.

9. At the hearing, each case's medical records and any related testimony were individually considered and discussed. (Hearing CD).

LEGAL FRAMEWORK

I. Administrative Law Judge Authority – ***Jurisdiction, Scope of Review and Standard of Review***

Medicare appeals involve a four-level process. First, individuals or organizations seeking payment under the Medicare Program submit claims to Medicare Administrative Contractors ("Contractors") who make initial determinations, and if appealed, redeterminations. 42 C.F.R. § 405.904. Second, the individual or organization may then appeal to a new reviewing entity known as Qualified Independent Contractors ("QICs"), who issue reconsideration decisions. *Id.* Thereafter, third level appeals are made to the Office of Medicare Hearings and Appeals ("OMHA") for a hearing before an Administrative Law Judge ("ALJ"). OMHA's ALJs are qualified and appointed pursuant to the Administrative Procedure Act, 5 U.S.C. §§ 500–596 (2012), and conduct *de novo* hearings of fact and law. Title XVIII § 1869 of the Act; *see* 42 C.F.R. § 405.1000(d); 74 Fed. Reg. 65,296, 65,316 (Dec. 9, 2009). An individual or entity will be entitled to an ALJ hearing provided there is a sufficient amount in controversy and the request for hearing is timely filed. Title XVIII § 1869(b)(1)(A) of the Social Security Act. To be considered timely, a request for hearing must generally be filed within 65 days of the QIC's reconsideration decision, and the amount in controversy must meet the annual threshold established by the Secretary of the Department of Health and Human Services. 42 C.F.R. §§ 405.1002, 1006.

During the hearing process, the ALJ will consider all issues decided in the initial determination, redetermination, or reconsideration decisions that were not decided entirely in Appellant's favor. 42 C.F.R. § 405.1032(a). Further, if the evidence presented before or during the hearing causes the ALJ to question a favorable portion of the prior determination or decision, he or she will notify the Appellant and will consider it an issue at the hearing. *Id.* The ALJ may decide a case on-the-record and not conduct an oral hearing if the evidence in the hearing record supports a finding in favor of appellants on every issue or if the appellant waives their right to a hearing. 42 C.F.R. § 405.1038(a)–(b).

II. Principles of Law –*Part A and B Coverage for Hospital Services, Statutes and Regulations*

The Social Security Act Amendments of 1965 (Pub. Law 89-97, 79 Stat. 286) created the Medicare Program, a federal health insurance program for the elderly (65 years of age and older), which was later expanded to cover the disabled, individuals with end stage renal disease ("ESRD"), and certain others, found in Title XVIII of the Social Security Act (the "Act"). 42 U.S.C. § 1395 *et seq.*; Title XVIII § 1811 of the Act. Medicare was originally comprised of two parts: Medicare Part A, the Hospital Insurance program, found at Title XVIII §§ 1811 to 1821 of the Act, and Medicare Part B, the Supplementary Medical Insurance program, found at Title XVIII §§ 1831 to 1848 of the Act.

Medicare Part A covers qualifying inpatient hospital, post-hospital extended care, post-institutional home health services,[1] and hospice services. Title XVIII §§ 1811–1812 of the Act. Part A covers up to 150 days of inpatient hospital services during any spell of illness minus 1 day for each day of such services in excess of 90 received during any preceding spell of illness. Title XVIII § 1812(a)(1) of the Act. The Act also sets forth the definition of "hospital" at Title XVIII § 1861(e) and the definition of "inpatient hospital services" at Title XVIII § 1861(b). "Inpatient hospital services" includes the following: bed and board; use of hospital facilities; nursing and other related services; medical social services; drugs, biologicals, supplies, appliances, equipment, and such other diagnostic or therapeutic items or services ordinarily furnished by a hospital for treatment of inpatients. Title XVIII § 1861(b) of the Act; *see* § 1861(e) for the definition of a "hospital;" *see also* CMS, *Medicare Benefit Policy Manual (MBPM) (Internet-Only Manual Publ'n 100-2)* ch. 1, § 10 (defining an inpatient). A "Spell of Illness" is

[1] Note the requirement that home health services be "post-institutional" applies to individuals enrolled in both Medicare Parts A and B, but does not apply to individuals only enrolled in Part A. Title XVIII § 1812(a)(3) of the Act.

a period of time beginning with the first day of covered inpatient hospitalization and ending after 60 consecutive days during which the beneficiary was not an inpatient in a hospital or skilled nursing facility. Title XVIII § 1861(a) of the Act.

Generally, hospital services are reimbursed under one of two payment models depending on whether the patient is classified as an inpatient or outpatient. Under the Part A inpatient prospective payment system ("IPPS"), CMS pays hospital costs at predetermined rates which vary according to which diagnosis-related group ("DRG") code the hospital assigns to describe the beneficiary's stay. Title XVIII § 1886(d) of the Act. The DRG payment is, with certain exceptions, payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. For beneficiary stays incurring extraordinarily high costs, Title XVIII §1886(d)(5)(A) of the Act provides for additional payments (called outlier payments).

Under Title XVIII § 1814(a)(3) of the Act, Medicare may pay for inpatient hospital services (other than inpatient psychiatric hospital services) only if a physician certifies that such services are required to be given on an inpatient basis for such individual's medical treatment, or that inpatient diagnostic study is medically required and such services are necessary for such purpose. *See* 42 C.F.R. § 424.13. As a documentary matter, the physician's certification is a condition of payment. On the other hand, the content of the certification is a condition of coverage.

Alternatively, under the Part B outpatient prospective payment system ("OPPS"), Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification. Title XVIII § 1833(t) of the Act. The OPPS was mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, and the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999, P.L. No. 106-113.

Notwithstanding any other provision of Title XVIII of the Act, no payment may be made under Part A or Part B for any expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Title XVIII § 1862(a)(1)(A) of the Act. Further, the billing party must supply sufficient information to support their claims. Title XVIII § 1815(a) of the Act.

The Medicare Program is administered by the Centers for Medicare and Medicaid Services ("CMS"), a component of the U.S. Department of Health and Human Services ("HHS"). Title 42 of the Code of Federal Regulations ("C.F.R.") sets forth regulations promulgated by CMS for implementation of the Medicare Program. See 42 C.F.R. § 400 et. seq. In pertinent part, 42 C.F.R. §§ 409.10 through 409.18 sets forth the regulations applicable to Medicare Part A inpatient hospital services. 42 C.F.R. § 409.10 repeats and expands on the statutory definition of "inpatient hospital services," by defining it as the following services furnished to an inpatient of a participating hospital: (1) Bed and board; (2) Nursing services and other related services; (3) Use of hospital or CAH facilities; (4) Medical social services; (5) Drugs, biologicals, supplies, appliances, and equipment; (6) Certain other diagnostic or therapeutic services; (7) Medical or surgical services provided by certain interns or residents-in-training; and (8) Transportation services, including transport by ambulance. 42 C.F.R. § 409.10(a).

Additionally, "Medicare Part A pays for inpatient hospital services of hospitals other than psychiatric hospitals only if a physician certifies and recertifies the continued hospitalization of the patient for medical treatment or medically required inpatient diagnostic study." 42 C.F.R. § 424.13(a)

III. Principles of Law – *Part A Inpatient Hospital Services, CMS Policy and Guidance*

CMS promulgates Medicare Manuals, which represent CMS' program issuances, day-to-day operating instructions, policies, and procedures that are based on statutes, regulations, guidelines, models, and directives. The CMS program components, providers, contractors, Medicare Advantage organizations and state survey agencies use the manuals to administer CMS programs. Under 42 C.F.R. § 405.1062, ALJs are not bound by the manuals, but must give them substantial deference if they apply to a particular case.

Medicare policy guidance defines an "inpatient" as a person who has been admitted to a hospital for bed occupancy for the purpose of receiving inpatient hospital services. A person is considered an inpatient if formally admitted as an inpatient with the expectation of remaining at least overnight and occupying a bed. Ultimately, the decision to admit a patient as an inpatient is up to the discretion of the physician or other practitioner responsible for a patient's care at the hospital.

The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis. However, the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting. Factors to be considered when making the decision to admit include such things as the (1) severity of the signs and symptoms exhibited by the patient, (2) the medical predictability of something adverse happening to the patient, (3) the need for diagnostic studies that appropriately are outpatient services (i.e., their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted, and (4) the availability of diagnostic procedures at the time when and at the location where the patient presents. *MBPM, supra* ch.1 § 10.

The beneficiary must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. Inpatient care rather than outpatient care is required only if the beneficiary's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting. Without accompanying medical conditions, factors that would only cause the beneficiary inconvenience in terms of time and money needed to care for the beneficiary at home or for travel to a physician's office, or that may cause the beneficiary to worry, do not justify a continued hospital stay. CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08) Chapter. 6, § 6.5.2.*

Quality Improvement Organizations ("QIOs") conduct review of admissions and discharges as specified in 42 C.F.R. 476.71(a)(6). Review of the medical record must indicate that inpatient hospital care was medically necessary, reasonable, and appropriate for the diagnosis and condition of the patient at any time during the stay. The patient must demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. CMS, *Quality Improvement Organization Manual (QIOM) (Internet-Only Manual Publ'n 100-10).* ch. 4, § 4110.

CMS guidance found in Health Care Financing Administration ("HCFA") (now CMS) Ruling 93-1 clarifies the weight given to the treating physician's decision to admit the Beneficiary as an inpatient in deciding Medicare coverage of inpatient hospital services. While recognizing that the physician is a "key figure" in determining utilization of health services, CMS ultimately concluded that there is no presumptive weight assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital admission under Title XVIII §1862(a)(1) of the Act. In the vast majority of cases, if the attending physician's certification of the medical need for the services is consistent with other records submitted in support of the claim for payment, Medicare covers the claim.

IV. Principles of Law – *Part B Coverage of Hospital Services, CMS Policy and Guidance*

MBPM, Chapter 6, § 20 details coverage and payment criteria for outpatient services covered under Part B. Chapter 6, § 20.2 defines a hospital outpatient as a patient registered on the hospital records as an outpatient, who has not been admitted as an inpatient, and who receives services (rather than supplies alone) from the hospital. Part B covers both the diagnostic and the therapeutic services furnished by hospitals to outpatients. Diagnostic services are defined in Chapter 6, § 20.4.1 as an examination or procedure to which the patient is subjected to obtain information to aid in the assessment of a medical condition or the identification of a disease. This includes the services of nurses, psychologists, technicians, drugs and biologicals necessary for diagnostic study, and the use of supplies and equipment. *MBPM, supra* ch. 6, § 20.4.4. Examples of diagnostic services include diagnostic laboratory testing such as hematology and chemistry, diagnostic x-rays, isotope studies, EKGs, pulmonary function studies, thyroid function tests, psychological tests, and other tests given to determine the nature and severity of an ailment or injury. *MBPM, supra* ch. 6, § 20.4.1.

Therapeutic services and supplies which hospitals provide on an outpatient basis are those services and supplies (including the use of hospital facilities and drugs and biologicals that cannot be self-administered) which are not diagnostic services, are furnished to outpatients incident to the services of physicians and practitioners, and which aid them in the treatment of patients. *MBPM, supra* ch. 6 § 20.5.2. These services include clinic services, emergency room services, and observation services. *Id.* The services and supplies must be furnished as an integral, although incidental, part of the physician or non-physician practitioner's professional service in the course of treatment of an illness or injury. *Id.*

Further, Part B covers outpatient observation services. MBPM, Chapter 6, § 20.6 defines observation care as specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. *MBPM, supra* ch. 6, § 20.6.

In the majority of cases, the decision whether to discharge a patient from the hospital following resolution of the reason for the observation care or to admit the patient as an inpatient **can be made in less than 48 hours, usually in less than 24 hours**. In only rare and exceptional cases do reasonable and necessary outpatient observation services span more than 48 hours. When a physician orders that a patient receive observation care, the patient's status is that of an outpatient. The purpose of observation is to determine the need for further treatment or for inpatient admission. Thus, a patient receiving observation services may improve and be released, or be admitted as an inpatient. All hospital

observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare. Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour).

V. Principles of Law – *Limitation on Liability, Statutes and Regulation*

Under Title XVIII § 1879 of the Act, Beneficiary and/or Provider liability for non-covered Medicare services may be limited under particular circumstances. In pertinent part, limitation on liability may apply to items or services that are excluded under Title XVIII §§ 1862(a)(1)(A) and 1862(a)(9) of the Act, or by reason of a coverage denial described in Title XVIII § 1879(g).

Pursuant to Title XVIII § 1879(a)(2) of the Act, Medicare will limit the Beneficiary's or Provider's liability for non-covered services if he or she did not know, and could not reasonably have been expected to know, that said services were non-covered. When both the Beneficiary and the Provider's liability may be limited under Title XVIII § 1879 of the Act, Medicare payment will be made as though Title XVIII §§1862(a)(1)(A), 1862(a)(9) or 1879(g) of the Act did not apply. Federal regulation sets forth the criteria for determining whether a beneficiary and/or provider knew that services were excluded from coverage as custodial care or as not reasonable and necessary. 42 C.F.R. §§ 411.404 and 411.406.

VI. Principles of Law – *Overpayments, Statute and Regulation*

If it is determined upon post-payment review that an overpayment exists, after considering all applicable coverage and payment issues, the ALJ must determine the liability for the overpayment. Pursuant to Title XVIII §1870(b), where more than the correct amount is paid under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines that the excess over the correct amount cannot be recouped from such provider of services or other person because such provider of services or other person was without fault with respect to the payment of such excess over the correct amount.

Pursuant to Title XVIII § 1870(c), for individuals, there shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to an individual who is without fault or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) would defeat the purposes of title II or title XVIII or would be against equity and good conscience.

VII. Principles of Law – *Overpayments, CMS Policy & Guidance*

The Medicare Financial Management Manual ("MFMM"), 100-06, Chapter 3, sets forth applicable CMS guidance regarding Medicare overpayment waivers. In pertinent part, § 70.3 provides that once the contractor has concluded that an overpayment exists (that is, a finding that payment cannot be made under the waiver of liability provisions) it makes a Title XVIII §1870(b) determination regarding whether the provider/beneficiary was without fault with respect to the overpayment. If a provider was without fault with respect to an overpayment it received it is not liable for the overpayment; therefore, it is not responsible for refunding the amount involved.

The MFMM, Chapter 3, § 90 further elucidates the circumstances under which a provider will be found without fault. In pertinent part, CMS provides that the Contractor considers a provider without fault if two criteria are satisfied: (1) The Provider exercised reasonable care in billing for, and accepting, the payment; i.e., it made full disclosure of all material facts; and (2) The Provider had a reasonable basis for assuming that the payment was correct or, if it had reason to question the payment, it promptly brought the question to the contractor's attention on the basis of the information available to it, including but not limited to the Medicare instructions and regulations.

The MFMM, Chapter 3, § 90.1 sets forth examples in which Providers are deemed at fault for Medicare Overpayments. For services that are medically unnecessary or custodial, CMS directs the contractor to apply the 1879 limitation on liability criteria in determining whether the Provider should have known that the services were not covered and, therefore, whether the Provider was at fault for the overpayment. For services other than those that are medically unnecessary or custodial, CMS states that the Provider should have known about a policy or rule if: (1) The policy is in the provider manual or Federal regulation; (2) The Medicare contractor provided general notice to the medical community concerning the policy or rule; or (3) The Medicare contractor gave written notice of the policy or rule to the particular provider. Generally, a provider's allegation that it was not at fault with respect to payment for non-covered services because it was not aware of the Medicare coverage provisions is not a basis for finding it without fault if any of the above conditions is met.

ANALYSIS

a. Medicare Coverage of Hospital Services

Pursuant to 42 C.F.R. § 405.1044(e) a consolidated analysis is appropriate. Upon receipt in the OMHA field office, the files were organized and substantively reviewed prior to the hearing. The individual appeals were combined into one appeal with one ALJ number for administrative efficiency. A telephonic hearing was held. All parties were sworn and the exhibits were entered into evidence without objection. At hearing each file was individually considered and discussed. (Hearing CD).

At issue is Medicare coverage for the hospital services provided to the Beneficiaries on the Dates of Service. Specifically, the question presented is whether the services rendered to the Beneficiaries met the definition of inpatient admission services which are paid under the Part A inpatient prospective payment system ("IPPS") defined in Title XVIII § 1886(d) of the Act, or were observation and related outpatient services paid under the Part B outpatient prospective payment system ("OPPS") defined in Title XVIII § 1833(t) of the Act. It has long been understood that Medicare's inpatient versus outpatient distinction primarily relates to the amount of payment and coverage under the inpatient and outpatient prospective payment systems and not the type of care required and received. See, 66 Fed. Reg. 44672, 44690-91 (Aug. 24, 2001).

Title XVIII §1886(d) of the Act established the IPPS for hospital inpatient services. Under the IPPS, CMS pays hospital costs at predetermined rates for patient discharges. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned. The DRG payment is, with certain exceptions, payment in full to the hospital for all inpatient costs associated with the beneficiary's stay. For beneficiary stays incurring extraordinarily high costs, Title XVIII §1886(d)(5)(A) of the Act provides for additional payments (called outlier payments) to Medicare-participating hospitals. Such

payments are made pursuant to the Part A - Hospital Insurance Benefits for the Aged and Disabled program.

Title XVIII §1833(t) of the Act established the OPPS for hospital outpatient services. CMS implemented the OPPS for hospital outpatient services, as mandated by the Balanced Budget Act of 1997, P.L. No. 105-33, and the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999, P.L. No. 106-113. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification. Such payments are made pursuant to the Part B—Supplementary Medical Insurance Benefits for the Aged and Disabled program.

In each case under review, the QIC issued an unfavorable decision stating that the admission did not meet Medicare criteria for payment under Part A's IPPS. In each case, the Appellant submitted several position papers wherein it argues that the condition of the patient upon admission and the actual course of the patient during the admission should result in full reimbursement under Part A for the DRG claimed by the hospital. Specifically, the Appellant averred in each case that the Beneficiaries' advanced age and significant medical history placed them at greater risk for complications. It is well established that "a claimant . . . has the burden of proving entitlement to Medicare benefits." *Friedman v. Sec'y of Dept. of Health and Hum. Servs.*, 819 F.2d 42, 45 (2d Cir. 1987). Accordingly, it is the Appellant's burden to establish that the hospital services rendered met Part A coverage criteria.

Pursuant to Title XVIII §§ 1812(a)(1) and 1861(b) of the Act, Medicare Part A recipients are entitled to coverage for inpatient hospital services for up to 150 days during any spell of illness minus 1 day for each day in excess of 90 days received during any previous spell of illness. The CMS, MBPM, Chapter 1, § 10 discusses coverage and payment criteria for inpatient hospital services covered under Part A. Chapter 1, § 10 defines an inpatient as "a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services...with the expectation that he or she will remain at least overnight." The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Physicians should use a 24-hour period as a benchmark, i.e., **they should order admission for patients who are expected to need hospital care for 24 hours or more**, and treat other patients on an outpatient basis. The decision to admit the patient should be based on such factors as:

> (1) the severity of the signs and symptoms exhibited by the patient;
> (2) the medical predictability of something adverse happening to the patient;
> (3) the need for diagnostic studies that appropriately are outpatient services (i.e. performance of such services does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and,
> (4) the availability of diagnostic procedures at the time when and at the location where the patient presents.

In sum, the beneficiary must require and receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis. *MPIM, supra* ch. 6 § 6.5.2.

Alternatively, MBPM, Chapter 6, § 20 details coverage and payment criteria for outpatient services covered under Part B. Chapter 6, § 20.2 defines a hospital outpatient as a patient registered on the

hospital records as an outpatient, who has not been admitted as an inpatient, and who receives services (rather than supplies alone) from the hospital. Part B covers both the diagnostic and the therapeutic services furnished by hospitals to outpatients. Part B also covers outpatient observation services. Observation care is a set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether patients will require further treatment as hospital inpatients or if they are able to be discharged from the hospital. *MBPM, supra* ch. 6, § 20.6. All hospital observation services, regardless of the duration of the observation care, that are medically reasonable and necessary are covered by Medicare. Observation services are reported using HCPCS code G0378 (Hospital observation service, per hour). Observation services are commonly ordered for patients who present to the emergency department and who then require a significant period of treatment or monitoring in order to make a decision concerning their admission or discharge. *MBPM, supra* ch. 6, § 20.6. In the majority of cases, the decision whether to discharge the patient or admit them to inpatient status, can **made in less than 48 hours, usually in less than 24 hours**.

HCFA Ruling 93-1 clarifies the position of the Health Care Financing Administration (now CMS) concerning the weight to be given to a treating physician's opinion in determining coverage of inpatient hospital and skilled nursing facility care. OMHA's evaluation of the reasonableness and necessity of a Part A admission is based on an evaluation of all documentation in the medical record. There is no presumptive weight assigned to the treating physician's medical opinion in determining the medical necessity of inpatient hospital admission under Title XVIII § 1862(a)(1) of the Act. A treating physician's opinion will be evaluated in the context of the evidence in the complete administrative record.[2]

Moreover, Title XVIII § 1833(t)(1)(B)(i) of the Act allows CMS to define which services may be paid under the Part B OPPS. The Secretary has determined that the services designated to be "inpatient only" services are not appropriate to be furnished in a hospital outpatient department. "Inpatient only" services are generally, but not always, surgical services that require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. The designation of services to be "inpatient-only" is open to public comment each year as part of the annual rulemaking process. CMS, *Medicare Claims Processing Manual (MCPM) (Internet-Only Manual Publ'n 100-4)* ch. 4, § 180.7.

Note when patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered outpatients for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight. *MBPM, supra* ch. 1 § 10.

[2] The "treating physician rule" was developed by case law and subsequently codified in regulations adopted by the Social Security Administration (SSA) for use in disability determinations. The current rule provides that SSA will "give more weight to opinions from…treating sources," 20 C.F.R. §§ 404.1527(d)(2), 416.927(d)(2). Friedman v. Secretary of the Dept. of HHS, 819 F.2d 42, 45 (2nd. Cir. 1987) states that "there is insufficient evidence in the instant case to put that rule in issue." Indeed, the United Sates Supreme Court has held that the "treating physician rule" is not applicable to private benefit plans deciding whether an individual is entitled to disability benefits under ERISA benefit plans. *See*, Black & Decker v. Nord, 538 U.S. 822, 123 Sup. Ct. 1965 (2003). Neither statute nor regulations extend the "treating physician rule" to Medicare coverage determinations and there is insufficient reason or evidence to place such a rule in practice in this case.

Specifically, Codes with "090" in Field 16 are major surgeries, and codes with "000" or "010" designations are either minor surgical procedures or endoscopies. *MCPM, supra* ch. 12 § 40.1.

b. Analysis of the Appellant's Claims – Minor Surgery

Some of the cases at issue involve substantially similar hospital claims for payment for scheduled, elective minor surgeries billed to Medicare Part A. As described above, the Beneficiaries arrived at the hospital for scheduled, elective surgeries. A finding that the Beneficiaries' care was appropriate for Part B, not Part A, billing is consistent with Medicare policy guidance discussing minor outpatient procedures. CMS guidance states that:

> When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered **outpatients** for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight. *MBPM, supra* ch. 1 § 10.

That is precisely the circumstances with the cases at issue here. In each surgical case, the Beneficiaries presented to the hospital with a known diagnosis for a specific procedure designated as a minor surgery according to the Medicare physician fee schedule and rules set forth in the MCPM, Chapter 12 § 40.1. The procedures were not on Medicare's inpatient only list, which lists procedures which may only be covered under Part A. [3] Based on the information above, the physician did not reasonably expect the Beneficiaries to remain in the hospital for 24 hours, and thus, inpatient admission and Part A payment are not appropriate according to the MBPM, Chapter 1 § 10.

Prior to their arrival or immediately following the procedures, the Beneficiaries were ordered admitted to the hospital as inpatients. The procedures were performed without incident, and post-procedure nursing staff observed the Beneficiaries' condition pursuant to hospital protocol procedures noted on the admission record. The record did not contain evidence that the Beneficiaries' experienced post-procedure acute signs or symptoms reflecting complications or uncontrolled comorbid conditions. The Beneficiaries' post-surgical conditions were stable, without notable complications or abnormal testing results.

Further, the Appellant has failed to establish that Part A coverage criteria were satisfied in accordance with MBPM, Chapter 1 § 10. First, the severity of the signs and symptoms displayed by the Beneficiaries at the time of inpatient admission were stable. In each case, the Beneficiaries' post-surgical recovery condition had been stabilized. Given the Beneficiaries' stable condition without evidence of abnormal acute processes at the time of inpatient admission; it is not clearly documented why the Beneficiaries could not have continued to be evaluated in an observational care setting. Accordingly, pursuant to Title XVIII § 1815(a) the documentation does not support that the physician anticipated that Part A acute or inpatient hospital-level treatment or diagnostic testing was required or received for any comorbid or acute conditions during the dates of service at issue.

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[3] Centers for Medicare and Medicaid Services: Hospital Outpatient Regulations and Notices, at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html

Based on the Beneficiaries' stable condition post-surgery without evidence of acute complications pre-admission, the Beneficiaries could have been monitored for 24–48 hours in an outpatient setting as prescribed by Medicare guidance, and then admitted to inpatient status if there was evidence of acute complications or deterioration in the Beneficiaries' condition. Such a change in circumstances would then reflect the need for 24 or more hours of inpatient hospital level diagnostic testing and treatment. *MBPM supra* ch. 6, § 20.6. Accordingly, there is insufficient evidence that the Beneficiaries required inpatient admission due to the signs and severity of symptoms displayed prior to the physician's admission order. Title XVIII § 1815(a) of the Act; *MBPM supra* ch. § 1 10. Moreover, while not immediately relevant to the physician's expectation of 24 hours of more of inpatient hospital care, it is specifically noted that the Beneficiaries' post-admission period was without incident.

The overnight monitoring or observation envisioned by the treating physicians in each minor surgery case fits squarely within the definition of outpatient observation services covered under Medicare Part B. *MBPM, supra* ch. 6, § 20.6. This conclusion is supported by the Appellants' inability to identify any service ordered by the admitting physicians that required 24-hours to perform and recover from during the hospital stays. (Hearing CD). Furthermore, when patients with known diagnoses enter a hospital for a specific minor surgical procedure that is expected to keep them in the hospital for only a few hours (less than 24 to 48), they are considered outpatients for coverage purposes. *MBPM, supra* ch. 1 § 10. The record establishes that the Beneficiaries entered the hospital to receive a minor surgical procedure that was expected to keep them in the hospital for less than 24-48 hours. As such, Part B, not Part A billing is appropriate.

In consideration of the foregoing, the inpatient admission services were not medically reasonable and necessary as required by Title XVIII §§ 1814(a)(3) and 1862(a)(1)(A) of the Act, 42 C.F.R. § 424.13(a), MPIM, Chapter 6, § 6.5.2, MBPM, Chapter 1, § 10. The services at issue are not covered under Medicare Part A.

c. Analysis of the Appellant's Claims – Outpatient-Observational Services

In the cases where the Beneficiaries arrived at the hospital through the emergency room, after receiving customary treatments and testing pursuant to the Beneficiaries' presenting signs and symptoms, the Beneficiaries were asymptomatic and were stable for discharge from the emergency room. Generally, "a patient is considered an inpatient if formally admitted as inpatient" with the expectation that he or she will remain at least overnight. Physicians should use a 24-hour period as a benchmark, i.e., **they should order admission for patients who are expected to need hospital care for 24-hours or more**, and treat other patients on an outpatient basis. *MBPM*, 100-02, Chapter 1, § 10. When a patient arrives at the facility with an unstable medical condition or a medical condition that requires further monitoring or treatment, observation services may be reasonable and necessary to evaluate the medical condition(s) and determine the need for a possible inpatient admission to the hospital. These services would include short term treatment, assessment, and reassessment. All of the Beneficiaries at issue could have safely been treated in observation to rule out an acute process.

Upon review of the records, including argument and testimony provided at hearing, the Appellant has failed to establish that Part A coverage criteria were satisfied in accordance with MBPM, Chapter 1 § 10. First, the severity of the signs and symptoms displayed by a Beneficiary can support the necessity of inpatient admission. Here, the documentation indicates that the Beneficiaries were often stabilized by the end of their respective emergency room treatments and thus were stable, without any indications of

acute processes, upon admission to the hospital. Further, in most cases, by the time of admission, all treatments and diagnostic testing was negative. Any abnormal lab or diagnostic testing did not significantly alter the plans of care or require complex intervention, and therefore were not a sufficient basis for inpatient admission. None of the Beneficiaries' medical charts clearly document why the Beneficiary could not have been further evaluated safely in a hospital outpatient setting. The Beneficiaries were no longer suffering from other acute symptoms and had stable vital signs or had returned to their baseline status upon admission. Accordingly, there is insufficient evidence that the Beneficiaries required inpatient admission for care.

Further, the documentation does not support that the admitting physicians anticipated that Part A acute or inpatient hospital-level treatment or diagnostic testing was required or received for any comorbid or acute conditions during the dates of service at issue. Upon admission, the Beneficiaries were provided such services as IV hydration, lab tests, EKGs, vital sign observations, antibiotic treatment (both oral and by IV), nebulizer treatment, medication adjustments, telemetry and physician consults. These are typically outpatient services. The Beneficiaries should have been have been admitted for observation during the treatments and diagnostic testing. In fact, the documentation demonstrates that the Beneficiaries did not receive any inpatient hospital-level diagnostic testing or treatment that would require more than 24 hours to complete and recover from during the dates of service at issue. The appearance in the hospital for Part B services and the receipt of Part B services does not create the medical need or necessity for a Part A admission. As such, admission to outpatient or observation-level care under Part B was fully justified and Part A inpatient admission was not reasonable and necessary.

Moreover, all claims were submitted to the Contractor for reimbursement under Part A using DRG billing codes. Each DRG code has an expected geometrically ascertained length of stay. No Beneficiary met or exceeded the geometric length of stay for the code billed. Considering all of the observation-type treatment received by the Beneficiaries, there is insufficient evidence that billing under Part A using a DRG code was appropriate. Therefore, inpatient admission was not medically necessary and reasonable as required by Title XVIII § 1814(a)(3), 42 C.F.R. § 424.13(a), MPIM, 100-08, Chapter 6, § 6.5.2, MBPM, 100-02, Chapter 1, § 10 and Title XVIII § 1862(a)(1)(A) of the Act.

d. Limitation of Liability

Under Title XVIII § 1879 of the Act, Beneficiary and/or Provider liability for non-covered Medicare services may be limited under particular circumstances. In pertinent part, limitation of liability may apply to items or services that are excluded under Title XVIII § 1862(a)(1)(A) of the Act. For reasons explained above the services in this case are ultimately non-covered pursuant to Title XVIII § 1862(a)(1)(A) of the Act; therefore, Title XVIII § 1879 of the Act may apply.

Pursuant to Title XVIII § 1879(a)(2) of the Act, Medicare will limit the Beneficiary's or Provider's liability for non-covered services if he, she or it did not know, and could not reasonably have been expected to know, that said services were non-covered. When both the Beneficiary and the Provider's liability may be limited under Title XVIII § 1879 of the Act, Medicare Part payment will be made as though Title XVIII §§1862(a)(1)(A), 1862(a)(9) or 1879(g) of the Act did not apply.

Under regulation, a beneficiary who receives services that are not reasonable and necessary under Title XVIII § 1862(a)(1)(A) of the Act is considered to have known that the services were not covered if written notice of non-coverage was furnished by one of the following: (1) The QIO or contractor; (2)

The group or committee responsible for utilization review for the provider that furnished the services; or (3) The provider, practitioner, or supplier that furnished the service. 42 C.F.R. § 411.404.

In this case, the hearing record contains no evidence that the Beneficiaries received written notice of non-coverage for the non-covered services at issue. The Beneficiaries therefore did not know, nor were the Beneficiaries reasonably expected to know that the services at issue were non-covered. Accordingly, pursuant to Title XVIII § 1879 of the Act, the Beneficiaries is not liable for the non-covered services.

A Provider that furnishes services that are not reasonable and necessary is considered to have known that the services were not covered if the QIO or contractor had informed the provider that the services furnished were not covered, or that similar or reasonably comparable services were not covered. 42 C.F.R. § 411.406(b). Significantly, the regulations also confer constructive knowledge of non-coverage to the provider based on any of the following: (1) Its receipt of CMS notices; (2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding non-coverage of an item or service; or (3) Its knowledge of what are considered acceptable standards of practice by the local medical community. 42 C.F.R. § 411.406(e).

The Appellant in this case is a Provider who had constructive notice of Part A inpatient hospital service coverage rules. This presumption is based on the widely published Medicare statute, Medicare regulations and CMS policy manuals cited in the "Principles of Law" section above. Pursuant to 42 C.F.R. § 411.406, the Appellant should have known that Medicare Part A would not cover the inpatient admission at issue in these cases. Accordingly, pursuant to Title XVIII § 1879 of the Act, the Appellant is liable for the non-covered services.

e. Alternative Further Actions Available to Appellant

The inpatient hospital services at issue were not reasonable and medically necessary under Medicare Part A. Pursuant to CMS Ruling 1455-R Appellant may submit Part B inpatient and/or outpatient claims. Appellant has 60 calendar days from the date of this decision to submit claims for (a) reasonable and necessary Part B inpatient services that would have been payable had the beneficiary originally been treated as an outpatient rather than admitted as an inpatient, except when those services specifically require an outpatient status, for example, outpatient visits, emergency department visits, and observation services; and/or (b) reasonable and necessary Part B outpatient services that would have normally been bundled with the inpatient stay, including observation services, which were furnished within the three calendar day payment window prior to the inpatient admission.

Alternatively, Appellant may continue to appeal the Part A claim to the Medicare Appeals Council under existing procedures in 42 C.F.R. § 405.1100. Additional information on filing a request for Medicare Appeals Council review is included with this decision. Please note that in accordance with CMS Ruling 1455-R, you may not file a Part B inpatient and/or outpatient claims while you have a pending Part A inpatient admission claim appeal. Any subsequent appeal of a Part A claim subject to CMS Ruling 1455-R filed after a Part B claim is submitted will be dismissed in accordance with the Ruling.

f. Waiver of Recovery for Overpayments

Title XVIII § 1870 of the Act governs the recovery of overpayments. Title XVIII § 1870(b) provides for a waiver of recovery of an overpayment to a supplier if it is "without fault" in incurring the overpayment. The MFMM provides that the Contractor considers a provider without fault, if it exercised reasonable care in billing for, and accepting, the payment on the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct. MFMM, *supra*, ch. 3 § 90. The Appellant was aware of the criteria for inpatient admissions as provided in Medicare statutes, regulations and guidelines. Therefore, the Appellant cannot be found without fault in creating the overpayment under Title XVIII § 1870, and a waiver of recoupment of the overpayment is not warranted.

Title XVIII § 1870(c) which provides a waiver of recoupment of overpayment where it is "against equity and good conscience" is not applicable to this case since Title XVIII § 1870(c) applies to a waiver of overpayments made to beneficiaries, and not providers that are deemed at fault.

CONCLUSIONS OF LAW

Medicare Part A does not cover the Beneficiaries' inpatient hospital services for various dates of service identified in Attachment 1 because, pursuant to Title XVIII §§ 1862(a)(1)(A) and 1815(a) of the Social Security Act, the documentation does not establish that the services were reasonable and necessary for treatment of the Beneficiaries' condition. Specifically, there is no evidence that at the time of the physician's order for inpatient admission, the Beneficiaries' signs and symptoms or the risk of adverse events gave the physician an expectation that the Beneficiaries would remain in the hospital for at least 24 hours as required for coverage under Part A pursuant to Title XVIII §§ 1814(a)(3) 1862(a)(1)(A) of the Act, 42 C.F.R. § 424.13(a), MPIM, Chapter 6, § 6.5.2, and MBPM, Chapter 1, § 10. The Appellant's liability may not be waived pursuant to Title XVIII § 1879 of the Act. Moreover, **the Appellant is responsible for the overpayment pursuant to Title XVIII § 1870(b) of the Act.**

ORDER

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: _____

_____
Leslie Holt
Administrative Law Judge

Enclosures: Form OMHA-56, *List of Exhibits*
Appendix A

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS

Arlington, Virginia

Appeal of:	**Via Christi Hospitals**	OMHA Appeal No.: QIC Appeal No.:	**1-1111111111(Combined)** **Multiple (8)**
Beneficiary:	**Multiple (8)**	Medicare **Part A**	
Medicare No.:	**Multiple (8)**	Before:	**Leslie Holt** Administrative Law Judge

MAIN FILE EXHIBIT LIST

Exhibit #	DESCRIPTION	Page Range
1	Order Combining Multiple Beneficiaries' Appeals: 06-23-17	1

Dated: June 23, 2017

noridian
Healthcare Solutions

Documentation Checklist
Oxygen and Oxygen Equipment

References: L33797, A52514

HCPCS Codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444

- ☐ Face-to-Face Examination (F2F)
  - ☐ Date stamp indicating supplier's date of receipt of F2F on or before date of delivery
- ☐ Written Order Prior to Delivery (WOPD)
  - ☐ Date stamp indicating supplier's date of receipt of WOPD on or before date of delivery

HCPCS Codes E1390, E1391, E1392, E1405, E1406, and K0738

- ☐ Dispensing Order (if applicable)
- ☐ Detailed Written Order (DWO)

All Oxygen and Oxygen Equipment

- ☐ Beneficiary Authorization
- ☐ Certificate of Medical Necessity (CMS 484 CMN)
- ☐ Proof of Delivery (POD)
  - ☐ Method 1 - Direct Delivery to the Beneficiary by the Supplier
    The date the beneficiary/designee signs for the equipment is to be the date of service of the claim.
  - ☐ Method 2 - Delivery via Shipping or Delivery Service
    The shipping date is to be the date of service of the claim.
- ☐ Continued Need
- ☐ Continued Use

Medical Records

Oxygen and Oxygen Equipment are reasonable and necessary only if all the following conditions are met:

- ☐ Treating physician determines the beneficiary has severe lung disease or hypoxia related symptoms expected to improve with oxygen therapy; **and**
- ☐ Beneficiary's blood gas study (BGS) meets the criteria noted below; **and**
- ☐ BGS was performed by a physician or qualified provider or supplier of laboratory services; and

- ☐ BGS was obtained under the following conditions:
  - ☐ If performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date; **or**
  - ☐ If not performed during an inpatient hospital stay, the reported test must be performed while the beneficiary is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease; **and**
- ☐ Alternative treatments tried or considered and deemed clinically ineffective

Group I Criteria:

- ☐ Arterial blood gas (ABG) at or below 55 mm Hg or arterial blood saturation at or below 88%
  - ☐ At rest; **or**
  - ☐ During exercise (3 tests); **or**
  - ☐ During sleep (at least 5 minutes); **or**
  - ☐ During sleep (signs of hypoxemia)
    - ☐ Decrease in ABG more than 10 mm Hg or a decrease in arterial blood saturation more than 5% from baseline for at least 5 minutes taken during sleep
- ☐ Initial coverage limited to 12 months

Group II Criteria

- ☐ ABG between 56 – 59 mm Hg or arterial blood saturation at 89%
  - ☐ Same testing requirements as Group I; **and**
- ☐ Beneficiary has one of following conditions:
  - ☐ Dependent edema, suggesting congestive heart failure; **or**
  - ☐ Pulmonary hypertension or cor pulmonale; **or**
  - ☐ Erythrocythemia with a hematocrit greater than 56%
- ☐ Initial coverage limited to 3 months

Long Term Oxygen Therapy Clinical Trials

- ☐ Beneficiary is enrolled in a clinical trial approved by CMS and sponsored by the National Heart, Lung and Blood Institute; **and**
- ☐ Beneficiary has an ABG from 56 to 65 mm Hg or arterial oxygen saturation at or above 89%

Cluster Headaches

- ☐ Beneficiary is being treated for cluster headaches (Refer to LCD for ICD codes)
  - ☐ Has had at least five severe to very severe (prevents all activities) unilateral headache attacks lasting 15-180 minutes when untreated
  - ☐ Headache is accompanied by at least one of the following:
    - ☐ Ipsilateral conjunctival injection and/or lacrimation; **or**

- ☐ Ipsilateral nasal congestion and/or rhinorrhea; **or**
- ☐ Ipsilateral eyelid edema; **or**
- ☐ Ipsilateral forehead and facial sweating; **or**
- ☐ Ipsilateral miosis and/or ptosis; **or**
- ☐ A sense of restlessness or agitation

☐ Beneficiary is enrolled in a clinical trial approved by CMS

Portable Oxygen Systems

☐ Medical records support the beneficiary is mobile within the home; **and**

☐ BGS performed at rest (awake) or during exercise

High Liter Flow – Greater than 4 LPM

☐ Group I or II BGS performed while on 4 or more LPM

Certificate of Medical Necessity (CMN)

Initial CMN

☐ 1. First claim for home oxygen; **or**

☐ 2. During the first 36 months of the rental period, when a break in medical necessity of at least 60 days, plus whatever days remain in the rental month during which the need for oxygen ended; **or**

☐ 3. Equipment is replaced because reasonable useful lifetime (RUL) has been reached; **or**

☐ 4. Equipment is replaced because of irreparable damage, theft, or loss

Situations 1 and 2 require:

☐ Most recent BGS obtained within 30 days prior to initial date; **and**

☐ Beneficiary was seen and evaluated by the treating physician within 30 days prior to date of the initial CM

Situations 3 and 4 require:

☐ Most recent qualifying value and test date (does not need to be within 30 days, can be test result reported on the most recent prior CMN)

Recertification CMN

☐ Group I - Twelve (12) months after initial CMN

- ☐ Most recent BGS prior to the thirteenth month of therapy; **and**
- ☐ Beneficiary was seen and reevaluated by the treating physician within 90 days prior to the recertification date

☐ Group II - Three (3) months after initial CMN

- ☐ Most recent BGS performed between the 61st and 90th day following the initial certification; and
- ☐ Beneficiary was seen and reevaluated by the treating physician within 90 days prior to the recertification date

- ☐ Repeat testing is not required for recertification for situations 3 and 4 above.
  - ☐ Enter the most recent qualifying test and test date

Revised CMN

- ☐ When the prescribed maximum flow rate changes from one of the following categories to another:
  - ☐ a. Less than 1 LPM
  - ☐ b. 1-4 LPM
  - ☐ c. Greater than 4 LPM; and
    - ☐ If change is from category a or b to c, a repeat BGS with the beneficiary on 4 LPM must be performed
  - ☐ BGS must be most recent study obtained within 30 days prior to initial date
- ☐ When length of need expires
  - ☐ BGS must be most recent study obtained within 30 days prior to initial date
- ☐ When portable oxygen is added subsequent to the initial CMN for stationary oxygen
  - ☐ No requirement for a repeat BGS unless the initial qualifying study was performed during sleep, in which case a repeat BGS must be performed while the beneficiary is at rest (awake) or during exercise within 30 days prior to the revised date
- ☐ When stationary oxygen is added subsequent to the initial CMN for portable oxygen
  - ☐ No BGS required
- ☐ When there is a new treating physician but the oxygen order is the same
  - ☐ No BGS required
  - ☐ Does not need to be submitted with the claim
- ☐ If there is a new supplier and that supplier does not have the prior CMN
  - ☐ No BGS required
  - ☐ Does not need to be submitted with the claim

Billing Reminders

- Long term oxygen therapy and cluster headache clinical trial claims require the "clinicaltrials.gov" identifier number of the CMS clinical trial.
- Claims that meet the coverage criteria of long term oxygen therapy or cluster headache clinical trials must include the Q0 (Q-zero) modifier.
- Claims for beneficiaries being treated in a clinical trial for cluster headaches must include the diagnosis code for the qualifying cluster headache condition and the diagnosis code for "Examination of Participant in Clinical Trial" (Refer to LCD for ICD codes).
- Maintenance and servicing of a stationary or portable concentrator or transfilling equipment will be allowed no more than every six months beginning no sooner than six months following the end of the 36 month rental period.

- Suppliers must make a visit before billing for maintenance and service.
- QE modifier must be added to all claims billed for prescribed liter flow < 1 LPM.
- QF or QG modifier must be added to all claims billed for prescribed liter flow > 4 LPM.
- QE, QF, and QG modifiers may only be used with claims for stationary gaseous (E0424) or liquid systems (E0439) or oxygen concentrators (E1390, E1391).
- When billing oxygen contents suppliers should use a date of service (DOS) that is the anniversary date of the equipment whose rental period has ended.
- A supplier does not have to deliver contents every month in order to bill every month, but must assure there are sufficient contents to last for one month following the DOS on the claim.
- CMN is not required for claims for cluster headaches.

Print Form

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Federal Administrative Law Judges
Office of Medicare Hearings and Appeals

Judicial Educational Symposium – II

The Honorable William P. Farley

The Honorable Leslie B. Holt

Best Practices --Combining Medicare Cases

October 16, 2018

PRESENTATION

- Combining a Part B case (Judge Farley)
- How to combine a Part A case (Judge Holt)

DISCLAIMER

- PEPD wants it clear that the documents we use are not templates and are not OMHA-recognized standards for adjudicators to follow.
- Feedback for improvement is highly encouraged.
- Nothing said today conflicts with the OCPM – any ambiguity would be settled by the OCPM.
- The OCPM is right.

Four Basic Parts of This Presentation

A. Beginning
B. Middle
C. End
D. Practicum Review

Beginning

A. Identify Appropriate Cases

- Same appellant
- Same item or service at issue
- Same or similar DRG Codes

Beginning (Con't)

B. Rule

- The controlling Rule/Law/Regulation is the same
- There is a common LCD
- There is more than one LCD, but they have the same requirements

Beginning (Con't)

Legal Assistants

- Discuss exhibiting
- Review Notice requirements
- Ensure the representative is still the same
- Identify if there may be PII issues
- Plan hearing schedule
- MAS/Settlement Check

Middle

- Develop/Acquire templates for writing decisions
- Train attorneys for writing decision
- Review current docket to ensure all appropriate cases will be combined
- Hold prehearing conference
- Hold consolidated hearing
  - Ensure that beneficiary PII is protected during the hearing in case a copy of the record is requested

End

- Remove cases that were dismissed at the hearing
- Send request for combination to (b)(6) @hhs.gov
- Issue Combination Order (will change with eCAPE) and send encrypted to Central Operations
- Review decision plan with attorney
- Finalize decision

End (Continued)

- Go over PII with Legal Assistant for mailing decision
- Ensure decisions are combined in MAS and closed
- Thank staff for hard work

Practicum Review

- Two documents required for combining
  - Combination Appeals Request
  - Combination Order
  - A Service Request is included, but not necessary

- Part B documents
  - Hearing Introduction and Form
  - Part B Decision
  - Contractor documents
    - LCD and Oxygen Check

REVIEW -- STEPS

- Identifying Appropriate Cases
- Reviewing
- Analyzing
- Tentatively select
- Determine need for pre-hearing conference
- Scheduling
- Hearing
- Deciding
- Closing

Judge Holt

- Part A Cases
- Part A Handouts Identification
- Overview of Part A Combination Determination
- Practical issues and concerns
- MAC Concerns
- Provider Concerns
- Results


Questions?

2018 Judicial Education Symposium

MEDICARE OPERATIONS DIVISION OVERVIEW

Topics

- FY 2018 Statistics
  - Case Production
  - Dashboard
  - Disposition Statistics
- Recent Trend in Agency Referral Workload
- Council Adjudication Timeframes
- Council Priorities for FY 2019
- Innovation Initiatives

FY 2018: Production

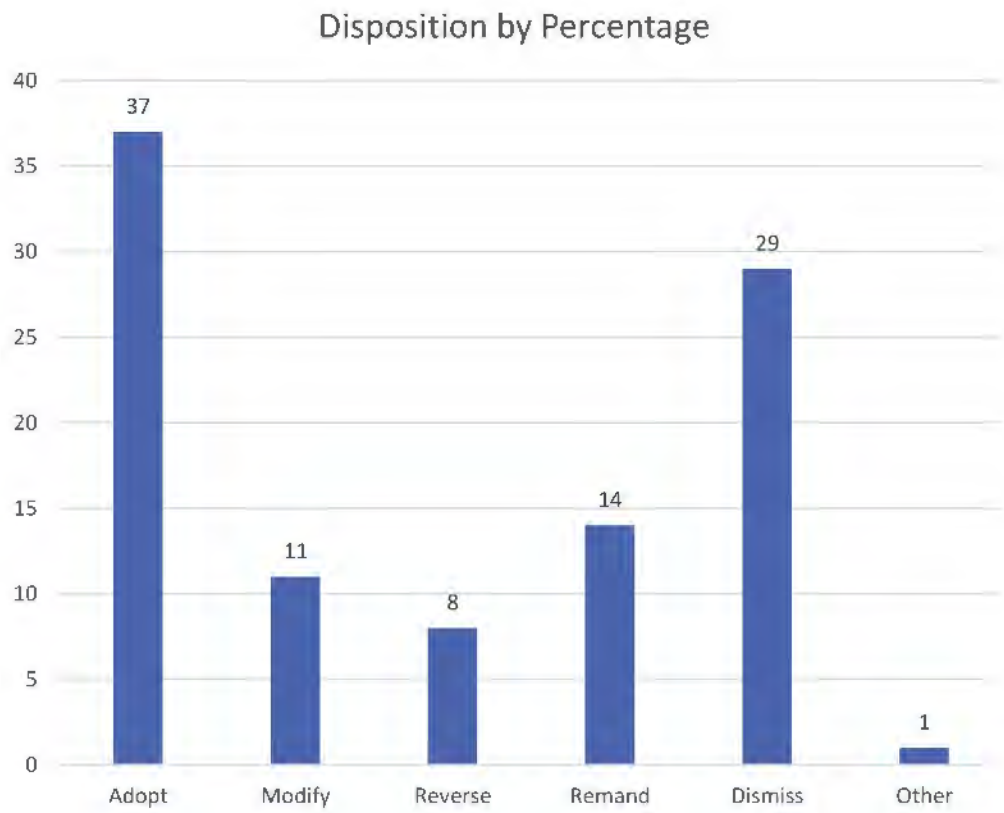
- In FY 2018, the Council closed 2,352 appeals
- FY 18 goal: 2,320
- Average processing time:
  - Part A&B: 471 days
  - Part C&D: 330 days
- FY 2018 Settlements
  - Total: 16,862
  - State Medicaid Agency: 10,869
  - Hospital Inpatient: 5,710
  - Low Volume Appeals: 283
- FY 2019 Projection: 1,317 remaining settlements

Dashboard: FY 2018

	As of September 30, 2018
Beginning Workload Balance	30,715
Receipts	6,435
Settlements	(16,862)
Closed Cases – Appeals Adjudicated	(2,352)
Ending Workload (Backlog)	17,936

Disposition Statistics: Requests for Review

- Adopt: 37%
- Modify: 11%
- Reverse: 8%
- Remand: 14%
- Dismiss: 29%
- Other: 15%

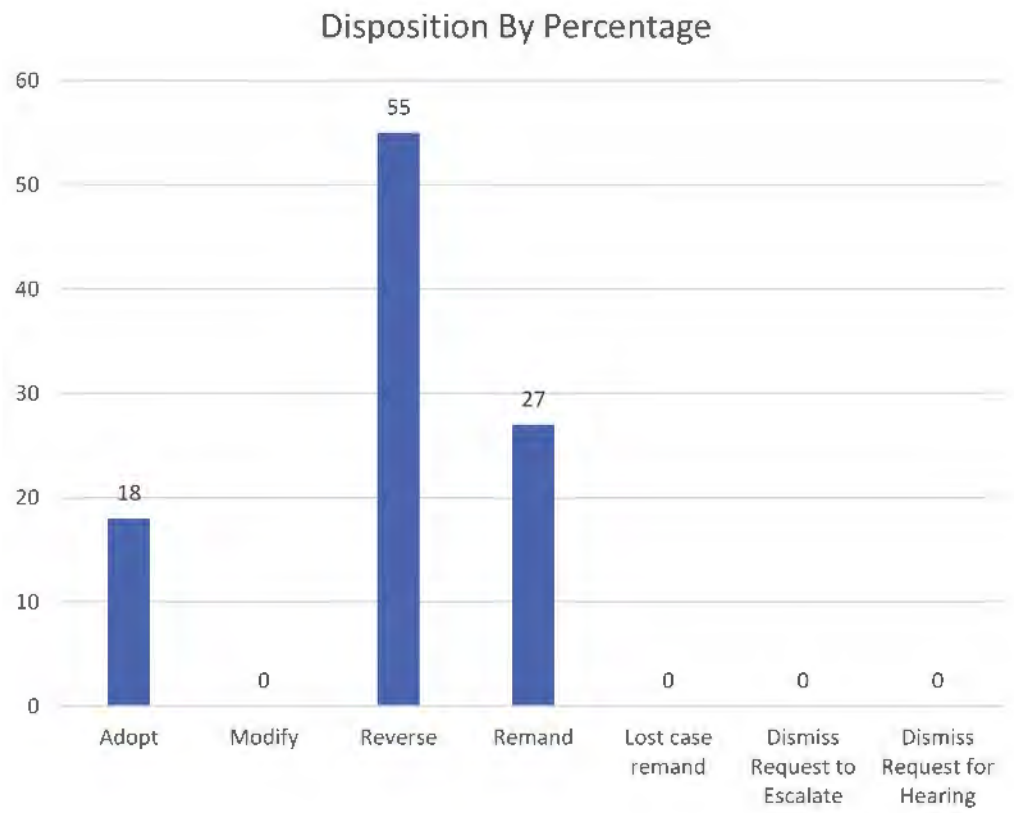


Disposition Statistics: Escalated from OMHA

In FY 2018 the Council closed 11 escalated cases.

All of the cases were Part B

- 8 of 11 or 72% were DME
- 3 of 11 of 27% were Physician Services



Disposition Statistics: Escalations to District Court

In FY 2018, the Council received 3 escalations to district court.

Escalations Analysis

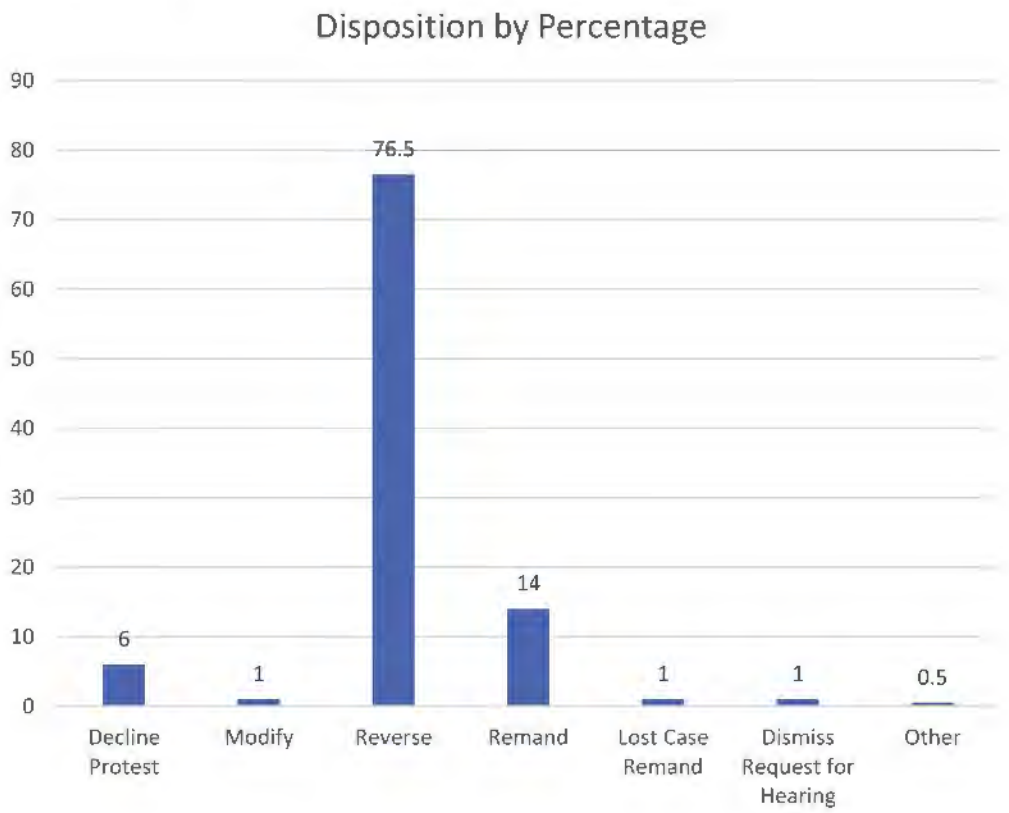
Three escalation requests filed by 3 appellants

Part B: 2 or 67%

MSP: 1 or 33%

Disposition Statistics: Agency Referrals

In FY 2018, the Council received 442 agency referrals.

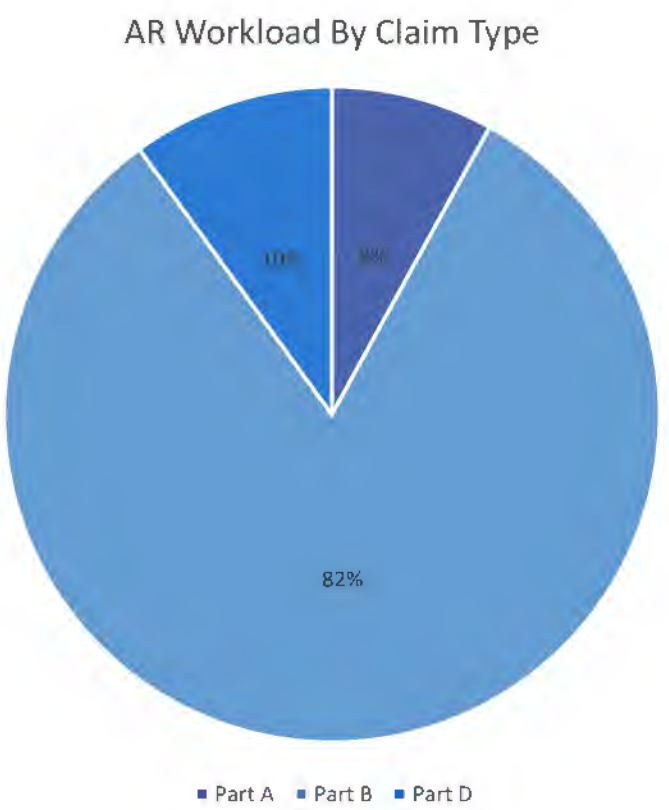


Agency Referrals By Claim Type

Part A – 8%

Part B – 82%

Part D – 10%



Percentage of Agency Referrals In Workload

Percentage of Agency Referrals in Workload By Fiscal Year			
FY	Total Cases	Variance	
		Number	Percentage
2014	288		
2015	395	+107	+37%
2016	336	-59	-15%
2017	344	+8	+2%
2018	442	+98	+29%

Average Appeal Adjudication Timeframes

Fiscal Year	From Date RR Filed to Date of Adjudication (in days)	Variance
2014	327	
2015	495	+168
2016	726	+231
2017	605	-121
2018	472	-133
5-Year Average	525	

Beneficiary Appeals

- The Medicare Operations Division (MOD) prioritizes beneficiary appeals.
- However, MOD does not currently have the staff resources to adjudicate beneficiary appeals within the 90-day timeframe (for most appeals).
- Average adjudication time (from the date of filing to the date of adjudication) for beneficiary appeals over the last five years (FY 2014 – FY 2018) is 366 days.
- Average age of pending for beneficiary appeals during the same period is 677 days.
- Beneficiary appeals account for approximately 9% of the existing backlog.
  - 10 – 15% of MOD's annual receipts.
- Since 2014, approximately 12% of all MOD appeals were filed by beneficiaries.

Council Priorities for FY 2019

Continue to prioritize beneficiary appeals

Pre-service requests

Prior authorization for prescription drugs

Agency Referrals

IT Innovation

Innovation Initiatives

MODACTS enhancements

- DOC Gen Initiative (eliminating MACROS)
- Interoperability with AdQIC, CMS and OMHA
  - In FY 2018, 14% of all claim files were digital
- Increased functionality for E-filing
  - In FY 2018, 63% of appeals were E-filed

Planning and development for MAPS

Case File Scanning Project

MAXIMUS FEDERAL SERVICES

Medical Consultant Review Form

Case Number: 1-2015161179	Project: QIC A East
Review Due Date: Jan 29 00:00 EST 2014	MD ID: (b)(6)

Case Summary:

Review Questions:
Were the documented events of the case more closely described by Medicare's criteria for inpatient level care, or did the case meet criteria for observation level care?

Coverage Rules:
A reviewer should be mindful that QIC determinations are to be made without bias. Decisions are to be based upon a comparison of the events of the case to Medicare policy requirements for inpatient level care.
Whether an admission meets Medicare criteria for inpatient status or conforms to the observation/outpatient level is the central question in a significant number of cases referred to Part A clinical review staff. Each of the levels has a group of defining characteristics.

According to Medicare Benefit Policy Manual 20.6 A and B, observation care is a well-defined set of specific, clinically appropriate services, which include ongoing short term treatment, assessment, and reassessment before a decision can be made regarding whether a patient will require further treatment as a hospital inpatient, or if that patient can be discharged safely and reasonably.

Although in rare instances, observation may extend beyond 48 hours, in the majority of cases, the determination of admission versus discharge can be made within 24 to 48 hours. A patient entering observation can present through an emergency department or, bypassing ED, can be directly referred by a physician. In addition, recipients of many surgeries conventionally done in the outpatient setting are considered to have received observation care when .

.the surgery is not on the inpatient-only list,
. the diagnosis was known prior to the procedure, and the procedure was the reason for the patient's entry into the hospital,
. the procedure is termed "minor" (according to coding designations "000" or "010" in field 16 of the Medicare Fee Schedule Data Base, Pub 100-04, Ch. 12, Sec. 40.) or is a major procedure that is conventionally done in the outpatient setting, and
.the attending physician has not left clear and specific indication prior to the procedure that, for carefully defined reasons, the patient is expected to require more than 24 hours in the hospital.

In contrast, Medicare specifies that an inpatient is a person whose medical condition, safety or health would be significantly and directly threatened if care were provided in a less intensive setting. In determining the medical necessity of inpatient care, the reviewer is asked to give

consideration to the complexity of the medical evaluation, treatment, and medical decision-making documented in the clinical chart. The clinical reviewer is asked as well to apply his/her own judgment regarding which characteristics specific to the patient (referred to in the review as the beneficiary) might make inpatient admission medically necessary. Specifically, the reviewer should consider the following factors:

.the severity of the patient's signs and symptoms at the time of admission,
.the levels of acuity and risk potential involved in the patient's testing, and
.the likelihood that, without a higher level of care, the patient's health and safety could be compromised.

As noted, the patient's condition at the time of arrival at the ED is not the determinant of the appropriate level of care. Rather, the patient's condition at the time of admission is what must warrant inpatient care. Although Medicare does not specify the acuity level that defines inpatient care, reviewers are encouraged to apply both their own expertise and their understanding of accepted standards of care for specific diagnoses to decide on the appropriateness of inpatient admission.

In the clinical setting, the smallest of details can carry the greatest importance. The review process calls for a different perspective. The reviewer examines the events of the case as the attending and consulting teams document them, and compares the sum of those events to two sets of definitions – one for inpatient level care, and the other for observation level care. Look for the better fit. Do not speculate or make assumptions. Base your comparison only upon what is clearly documented. There is no absolute right or wrong as long as conclusions are reached thoughtfully, and arguments are based on substance.

Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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LCD Information

Document Information

LCD ID
L33797

Original ICD-9 LCD ID
L11468
L11446
L27221
L11457

LCD Title
Oxygen and Oxygen Equipment

Proposed LCD in Comment Period
N/A

Source Proposed LCD
N/A

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 08/01/2018

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
N/A

Notice Period End Date
N/A

CMS National Coverage Policy CMS Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1,

Section 240.2, 240.2.1,240.2.2

Coverage Guidance
Coverage Indications, Limitations, and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and necessary" criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the "reasonable and necessary" criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the "reasonable and necessary" criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

Home oxygen is covered only when both the reasonable and necessary criteria discussed below and the statutory criteria discussed in the Policy Article are met. Refer to the Policy Article for additional information on statutory payment policy requirements.

Home oxygen therapy is reasonable and necessary only if all of the following conditions are met:

1. The treating physician has determined that the beneficiary has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, and
2. The beneficiary's blood gas study meets the criteria stated below, and
3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and
4. The qualifying blood gas study was obtained under the following conditions:
    - If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date, or
    - If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the beneficiary is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease, and
5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

In this policy, the term blood gas study refers to either an oximetry test or an arterial blood gas test.

Group I criteria include any of the following:

1. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
2. An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a beneficiary who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or
3. A decrease in arterial PO_2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, for at least 5 minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and [nocturnal restlessness or insomnia]) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia, or

4. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air.

Initial coverage for beneficiaries meeting Group I criteria is limited to 12 months or the physician-specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.)

Group II criteria include the presence of:

A. An arterial PO 2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes, or during exercise (as described under Group I criteria), and
B. Any of the following:
    1. Dependent edema suggesting congestive heart failure, or
    2. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), or
    3. Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for beneficiaries meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.) Group III includes beneficiaries with arterial PO 2 levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these beneficiaries there is a rebuttable presumption of non-coverage.

If all of the coverage conditions specified above are not met, the oxygen therapy will be denied as not reasonable and necessary. Oxygen therapy will also be denied as not reasonable and necessary if any of the following conditions are present:

1. Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood and there are other preferred treatments.
2. Dyspnea without cor pulmonale or evidence of hypoxemia
3. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO 2 will improve the oxygenation of tissues with impaired circulation.
4. Terminal illnesses that do not affect the respiratory system

LONG TERM OXYGEN THERAPY CLINICAL (LTOT) TRIALS

Oxygen and oxygen equipment is covered for beneficiaries who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and who have an arterial PO_2 from 56 to 65 mm Hg or an oxygen saturation at or above 89 percent. The additional Group 2 coverage criteria do not apply to these beneficiaries.

Refer to the APPENDICES section of this policy for additional information about approved clinical trials.

CLUSTER HEADACHES (CH):

Only a stationary gaseous oxygen system (E0424) and related contents (E0441) are covered for the treatment of cluster headaches for beneficiaries enrolled in a clinical trial approved by CMS which are in compliance with the requirements described in the CMS National Coverage Determination Manual (Internet Only Manual 100-03) §240.2.2 for dates of service on or after 01/04/2011. This section states, in part:

Only those beneficiaries diagnosed with the condition of cluster headache are eligible for participation in a clinical study. CMS adopts the diagnostic criteria used by the International Headache Society to form a definitive diagnosis of CH. Therefore, the home use of oxygen to treat CH is covered by Medicare only when furnished to Medicare beneficiaries who have had at least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated. (Intensity of pain: Degree of pain usually expressed in terms of its functional consequence and scored on a verbal 5-point scale: 0=no pain; 1=mild pain, does not interfere with usual activities; 2=moderate pain, inhibits but does not wholly prevent usual activities; 3=severe pain, prevents all activities; 4=very severe pain. It may also be expressed on a visual analogue scale.)

The headaches must be accompanied by at least one of the following findings:

1. Ipsilateral conjunctival injection and/or lacrimation; or
2. Ipsilateral nasal congestion and/or rhinorrhea; or
3. Ipsilateral eyelid edema; or
4. Ipsilateral forehead and facial sweating; or
5. Ipsilateral miosis and/or ptosis; or
6. A sense of restlessness or agitation

Claims for oxygen equipment not meeting the criteria above will be denied as not reasonable and necessary.

Claims for stationary oxygen equipment other than E0424 and all portable oxygen equipment used for cluster headaches will be denied as not reasonable and necessary.

Claims for E0424 and E0441 used to treat cluster headaches follow the same payment rules for all other covered oxygen equipment. Refer to the related Policy Article for information on statutory payment rules and coding guidelines to be used for these claims.

Refer to the APPENDICES section of this policy for additional information about approved clinical trials.

Reference Diagnosis Codes that Support Medical Necessity section for applicable diagnoses.

TESTING SPECIFICATIONS:

General

For purposes of this policy:

- "Blood gas study" shall refer to both arterial blood gas (ABG) studies and pulse oximetry
- "Oximetry" shall refer to routine or "spot" pulse oximetry
- "Overnight oximetry" shall refer to stand-alone pulse oximetry continuously recorded overnight. It does not include oximetry results done as part of other overnight testing such as polysomnography or home sleep testing.

Refer to the Positive Airway Pressure Devises used for the Treatment of Obstructive Sleep Apnea policy for information on sleep tests used for the diagnosis of sleep apnea.

The qualifying blood gas study must be one that complies with the Fiscal Intermediary, Local Carrier, or A/B Medicare Administrative Contractor (MAC) policy on the standards for conducting the test and is covered under Medicare Part A or Part B. This includes a requirement that the test be performed by a provider who is qualified to bill Medicare for the test – i.e., a Part A provider, a laboratory, an Independent Diagnostic Testing Facility (IDTF), or a physician. A supplier is not considered a qualified provider or a qualified laboratory for purposes of this policy. Blood gas studies performed by a supplier are not acceptable. In addition, the qualifying blood gas study may not be paid for by any supplier. These prohibitions do not extend to blood gas studies performed by a hospital certified to do such tests.

The qualifying blood gas study may be performed while the beneficiary is on oxygen as long as the reported blood gas values meet the Group I or Group II criteria.

When both arterial blood gas (ABG) and oximetry tests have been performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), the ABG result will be used to determine if the coverage criteria were met. If an ABG test done at rest and awake is non-qualifying, but either an exercise or sleep oximetry test on the same day is qualifying, the exercise or oximetry test result will determine coverage.

All oxygen qualification testing must be performed in-person by a physician or other medical professional qualified to conduct oximetry testing. With the exception of overnight oximetry (see below), unsupervised or remotely supervised home testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment.

Exercise testing:

When oxygen is covered based on an oximetry study obtained during exercise, there must be documentation of three (3) oximetry studies in the beneficiary's medical record. (1) Testing at rest without oxygen, (2) testing during exercise without oxygen, and (3) testing during exercise with oxygen applied (to demonstrate the

improvement of the hypoxemia) are required. All 3 tests must be performed within the same testing session. Exercise testing must be performed in-person by a physician or other medical professional qualified to conduct exercise oximetry testing. Unsupervised or remotely supervised home exercise testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment. Only the testing during exercise without oxygen is used for qualification and reported on the CMN. The other two results do not have to be routinely submitted but must be available on request.

Oximetry obtained after exercise while resting, sometimes referred to as "recovery" testing, is not part of the three required test elements and is not valid for determining eligibility for oxygen coverage.

Overnight Oximetry Studies:

Overnight sleep oximetry may be performed in a facility or at home. For home overnight oximetry studies, the oximeter provided to the beneficiary must be tamper-proof and must have the capability to download data that allows documentation of the duration of oxygen desaturation below a specified value.

For all the overnight oximetry criteria described above, the 5 minutes does not have to be continuous. Baseline saturation is defined as the mean saturation level during the duration of the test. For purposes of meeting criterion 3 described in Group I above there must be a minimum of 2 hours test time recorded for sleep oximetry. The result must reach a qualifying test value otherwise the Group III presumption of non-coverage applies.

Home overnight oximetry is limited solely to stand-alone overnight pulse oximetry performed in the beneficiary's home under the conditions specified below. Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered to be eligible under this provision to be used for qualification for reimbursement of home oxygen and oxygen equipment even if the testing was performed in compliance with the requirements of this section.

Beneficiaries may self-administer home based overnight oximetry tests under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility (IDTF). A DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology to a beneficiary's home under the following circumstances:

1. The beneficiary's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed.
2. The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise. The DME supplier may not create this written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test.
3. The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF which is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no case may the DME supplier access or manipulate the test results in any form.

The IDTF must send the test results to the physician. The IDTF may send the test results to the supplier if the supplier is currently providing or has an order to provide oxygen or other respiratory services to the beneficiary or if the beneficiary has signed a release permitting the supplier to receive the report.

Oximetry test results obtained through a similar process as described for home overnight oximetry (see above) while the beneficiary is awake, either at rest or with exercise, may not be used for purposes of qualifying the beneficiary for home oxygen therapy.

Overnight oximetry does not include oximetry obtained during polysomnography or other sleep testing for sleep apnea, regardless of the location the testing was performed. See below for information on sleep testing that may be used to qualify for oxygen coverage.

Obstructive Sleep Apnea (OSA), Polysomnography and Home Sleep Tests:

Some beneficiaries may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Coverage Indications, Limitations and/or Medical Necessity for both the Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. Consequently, in addition to this Oxygen LCD, suppliers should refer to the Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD and related Policy Article for additional coverage, coding and documentation requirements.

Coverage of home oxygen therapy requires that the beneficiary be tested in the "chronic stable state." Chronic stable state is a requirement of the National Coverage Determination (CMS Internet-only Manual, Pub. 100-03, Section 240.2) and is one of the key criteria when determining coverage of home oxygen therapy. The NCD defines chronic stable state as "...not during a period of an acute illness or an exacerbation of their underlying disease." Based on this NCD definition, all co-existing diseases or conditions that can cause hypoxia must be treated and the beneficiary must be in a chronic stable state before oxygen therapy is considered eligible for payment. In addition, the beneficiary must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. In the case of OSA, it is required that the OSA be appropriately and sufficiently treated such that the beneficiary is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy (see PAP LCD for additional information).

For beneficiaries with OSA, this means that the OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy.

For beneficiaries with OSA, a qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split night or stand-alone). The titration PSG is one in which all of the following criteria are met:

1. The titration is conducted over a minimum of two (2) hours; and
2. During titration:
   A. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or
   B. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; and
3. Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; and
4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for 5 minutes total (which need not be continuous)

If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the beneficiary is considered to be in the "chronic stable state." To be eligible for Medicare coverage and payment for home oxygen therapy for concurrent use with PAP therapy, in addition to being in the chronic stable state, the beneficiary must meet all other coverage requirements for oxygen therapy. Beneficiaries that qualify for oxygen therapy based on testing conducted only during the course of a sleep test are eligible only for reimbursement of stationary equipment.

Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered as eligible to be used for qualification for reimbursement of home oxygen and oxygen equipment (see overnight oximetry section above for additional information).

Claims for oxygen equipment and supplies for beneficiaries who do not meet the coverage requirements for home oxygen therapy will be denied as not reasonable and necessary.

CERTIFICATION:

An Initial, Recertification, or Revised CMN must be obtained and submitted in the situations described below. The Initial Date, Recertification Date, and Revised Date specified below refer to the dates reported in Section A of the CMN.

Initial CMN is required:

1. With the first claim for home oxygen, (even if the beneficiary was on oxygen prior to Medicare eligibility or oxygen was initially covered by a Medicare HMO).
2. During the first 36 months of the rental period, when there has been a change in the beneficiary's condition that has caused a break in medical necessity of at least 60 days plus whatever days remain in the rental month during which the need for oxygen ended. Refer to the Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES for additional information.
3. When the equipment is replaced because the reasonable useful lifetime of prior equipment has been reached.
4. When the equipment is replaced because of irreparable damage, theft, or loss of the originally dispensed equipment.

a. Irreparable damage refers to a specific accident or to a natural disaster [e.g., fire, flood]
b. Irreparable damage does not refer to wear and tear over time

Testing and Visit Requirements:

Initial CMN for situations 1 and 2:

- The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.
  - For situation 1, there is an exception to the 30-day test requirement for beneficiaries who were started on oxygen while enrolled in a Medicare HMO and transition to fee-for-service Medicare. For those beneficiaries, the blood gas study does not have to be obtained 30 days prior to the Initial Date, but must be the most recent qualifying test obtained while in the HMO.
- The beneficiary must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification.

Initial CMN for scenarios 3 and 4 (replacement equipment):

- Repeat blood gas testing is not required. Enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

Recertification CMN is required:

5. 12 months after Initial Certification, (i.e., with the thirteenth month's claim) for Group I
6. 3 months after Initial Certification, (i.e., with the fourth month's claim) for Group II

Testing and Visit Requirements:

Recertification following initial certification situations 1 and 2:

- For beneficiaries initially meeting Group I criteria, the most recent qualifying blood gas study prior to the thirteenth month of therapy must be reported on the Recertification CMN.
- For beneficiaries initially meeting Group II criteria, the most recent blood gas study that was performed between the 61st and 90th day following Initial Certification must be reported on the Recertification CMN. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy but the beneficiary continues to use oxygen and a test is obtained at a later date, if that test meets Group I or II criteria, coverage would resume beginning with the date of that test.
- For beneficiaries initially meeting group I or II criteria, the beneficiary must be seen and re-evaluated by the treating physician within 90 days prior to the date of any Recertification. If the physician visit is not obtained within the 90-day window but the beneficiary continues to use oxygen and the visit is obtained at a later date, coverage would resume beginning with the date of that visit.

Recertification following initial situations 3 and 4 (replacement equipment):

- Repeat testing is not required. Enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

Revised CMN is required:

7. When the prescribed maximum flow rate changes from one of the following categories to another:
   a. Less than 1 LPM,
   b. 1-4 LPM,
   c. Greater than 4 LPM

If the change is from category (a) or (b) to category (c), a repeat blood gas study with the beneficiary on 4 LPM must be performed.

8. When the length of need expires – if the physician specified less than lifetime length of need on the most recent CMN
9. When a portable oxygen system is added subsequent to Initial Certification of a stationary system
10. When a stationary system is added subsequent to Initial Certification of a portable system
11. When there is a new treating physician but the oxygen order is the same
12. If there is a new supplier and that supplier does not have the prior CMN

Submission of a Revised CMN does not change the Recertification schedule specified above.

If the indications for a Revised CMN are met at the same time that a Recertification CMN is due, file the CMN as a Recertification CMN.

Testing and Visit Requirements:

None of the Revised Certification situations (7-12) require a physician visit.

Revised Certification situations 7 and 8:

- The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.

Revised Certification situation 9:

- There is no requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the beneficiary is at rest (awake) or during exercise within 30 days prior to the Revised Date.

Revised Certifications situations 10-12:

- No blood gas study is required
- For situations 11 and 12, the revised certification does NOT have to be submitted with the claim.

General:

Beneficiaries do not change group classification going from an initial certification to a recertification based upon changes in blood oxygen testing results. For example: A beneficiary initially qualifies for group II with an 89% oximetry value. At the 3-month retest a result of 87% is obtained. Despite the group I retesting value, the beneficiary remains in group II. There is no reclassification to group I. Further recertification is not required unless:

- A non-qualifying test result is obtained at the time of recertification but the beneficiary later obtains a qualifying test result; or,
- The specified length of need (LON) is reached.

Generally only one recertification is required regardless of group classification unless the LON specified on the recertification CMN is some value other than 99 (indicating lifetime). If other than lifetime is specified the certification will expire when the specified LON time period elapses. A recertification will be required to continue coverage.

Recertification is required to be completed on or prior to the end of the initial certification period. If timely recertification is not completed by the end of the initial certification period, reimbursement ends until the recertification is completed. At such time that the recertification requirements are met, payment will resume at the month in the rental cycle where the rental was stopped due to the expiration of the initial certification. A new, initial rental cycle does not begin when the recertification requirements are met.

A completed and signed Certificate of Medical Necessity (CMN) is required to receive payment for oxygen. Claims submitted without a valid CMN will be denied as not reasonable and necessary.

PORTABLE OXYGEN SYSTEMS:

A portable oxygen system is covered if the beneficiary is mobile within the home and the qualifying blood gas study was performed while at rest (awake) or during exercise. If the only qualifying blood gas study was

performed during sleep, portable oxygen will be denied as not reasonable and necessary.

If coverage criteria are met, a portable oxygen system is usually separately payable in addition to the stationary system. See exception in the related Policy Article Non-Medical Necessity Coverage and Payment Rules, OXYGEN EQUIPMENT, Initial 36-Months section.

If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the beneficiary uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed.

LITER FLOW GREATER THAN 4 LPM:

If basic oxygen coverage criteria have been met, a higher allowance for a stationary system for a flow rate of greater than 4 liters per minute (LPM) will be paid only if a blood gas study performed while the beneficiary is on 4 or more LPM meets Group I or II criteria. If a flow rate greater than 4 LPM is billed and the coverage criterion for the higher allowance is not met, payment will be limited to the standard fee schedule allowance. (Refer to related Policy Article for additional information on payment for greater than 4 LPM oxygen.)

MISCELLANEOUS:

Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment. Oxygen rental is billed using the appropriate code for the provided oxygen equipment. Separately billed options, accessories or supply items will be denied as unbundling.

Emergency or stand-by oxygen systems for beneficiaries who are not regularly using oxygen will be denied as not reasonable and necessary since they are precautionary and not therapeutic in nature.

Topical hyperbaric oxygen chambers (A4575) will be denied as not reasonable and necessary.

Topical oxygen delivery systems (E0446) will be denied as not reasonable and necessary.

REFILLS OF OXYGEN CONTENTS:

For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use.

Oxygen contents are reimbursed with a monthly allowance covering all contents necessary for the month. Supply allowances are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

All other supplies, e.g. tubing, masks or cannulas, etc., are included in the monthly rental payment. Supplies that are not separately payable are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

See the Non-Medical Coverage and Payment Rules section of the related Policy Article for additional information about coverage of oxygen contents.

GENERAL

A Detailed Written Order (DWO) (if applicable) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must also obtain a DWO before submitting a claim for any associated options, accessories, and/or supplies that are separately billed. In this scenario, if the supplier bills for associated options, accessories, and/or supplies without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

A WOPD (if applicable) must be received by the supplier before a DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a completed WOPD, the claim shall be statutorily denied. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence

NA

Analysis of Evidence
(Rationale for Determination)

NA

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A
Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A
CPT/HCPCS Codes
Group 1 Paragraph:
The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY – No physician or other licensed health care provider order for this item or service

GA - Waiver of liability (expected to be denied as not reasonable and necessary, ABN on file)

GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefit

GZ - Item or service not reasonable and necessary (expected to be denied as not reasonable and necessary, no ABN on file)

KX - Requirements specified in the medical policy have been met

Q0 (Q-zero) - Investigational clinical service provided in a clinical research study that is in an approved clinical research study

QA - Prescribed amounts of stationary oxygen for daytime use while at rest and nighttime use differ and the average of the two amounts is less than 1 liter per minute (LPM)

QB - Prescribed amounts of stationary oxygen for daytime use while at rest and nighttime use differ and the average of the two amounts exceeds 4 liters per minute (LPM) and portable oxygen is prescribed

QE - Prescribed amount of stationary oxygen while at rest is less than 1 liter per minute (LPM)

QF - Prescribed amount of stationary oxygen while at rest exceeds 4 liter per minute (LPM) and portable oxygen is prescribed

QG - Prescribed amount of stationary oxygen while at rest is greater than 4 liters per minute (LPM)

QH - Oxygen conserving device is being used with an oxygen delivery system

QR - Prescribed amounts of stationary oxygen for daytime use while at rest and nighttime use differ and the average of the two amounts is greater than 4 liters per minute (LPM)

RA - Replacement of a DME item

HCPCS CODES:

EQUIPMENT:

Group 1 Codes:

E0424	STATIONARY COMPRESSED GASEOUS OXYGEN SYSTEM, RENTAL; INCLUDES CONTAINER, CONTENTS, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING
E0425	STATIONARY COMPRESSED GAS SYSTEM, PURCHASE; INCLUDES REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING
E0430	PORTABLE GASEOUS OXYGEN SYSTEM, PURCHASE; INCLUDES REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK, AND TUBING
E0431	PORTABLE GASEOUS OXYGEN SYSTEM, RENTAL; INCLUDES PORTABLE CONTAINER, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK, AND TUBING
E0433	PORTABLE LIQUID OXYGEN SYSTEM, RENTAL; HOME LIQUEFIER USED TO FILL PORTABLE LIQUID OXYGEN CONTAINERS, INCLUDES PORTABLE CONTAINERS, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK AND TUBING, WITH OR WITHOUT SUPPLY RESERVOIR AND CONTENTS GAUGE
E0434	PORTABLE LIQUID OXYGEN SYSTEM, RENTAL; INCLUDES PORTABLE CONTAINER, SUPPLY RESERVOIR, HUMIDIFIER, FLOWMETER, REFILL ADAPTOR, CONTENTS GAUGE, CANNULA OR MASK, AND TUBING
E0435	PORTABLE LIQUID OXYGEN SYSTEM, PURCHASE; INCLUDES PORTABLE CONTAINER, SUPPLY RESERVOIR, FLOWMETER, HUMIDIFIER, CONTENTS GAUGE, CANNULA OR MASK, TUBING AND REFILL ADAPTOR
E0439	STATIONARY LIQUID OXYGEN SYSTEM, RENTAL; INCLUDES CONTAINER, CONTENTS, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, & TUBING
E0440	STATIONARY LIQUID OXYGEN SYSTEM, PURCHASE; INCLUDES USE OF RESERVOIR, CONTENTS INDICATOR, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING
E0441	STATIONARY OXYGEN CONTENTS, GASEOUS, 1 MONTH'S SUPPLY = 1 UNIT
E0442	STATIONARY OXYGEN CONTENTS, LIQUID, 1 MONTH'S SUPPLY = 1 UNIT
E0443	PORTABLE OXYGEN CONTENTS, GASEOUS, 1 MONTH'S SUPPLY = 1 UNIT
E0444	PORTABLE OXYGEN CONTENTS, LIQUID, 1 MONTH'S SUPPLY = 1 UNIT
E0445	OXIMETER DEVICE FOR MEASURING BLOOD OXYGEN LEVELS NON-INVASIVELY

E0446 TOPICAL OXYGEN DELIVERY SYSTEM, NOT OTHERWISE SPECIFIED, INCLUDES ALL SUPPLIES AND ACCESSORIES
E1390 OXYGEN CONCENTRATOR, SINGLE DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE
E1391 OXYGEN CONCENTRATOR, DUAL DELIVERY PORT, CAPABLE OF DELIVERING 85 PERCENT OR GREATER OXYGEN CONCENTRATION AT THE PRESCRIBED FLOW RATE, EACH
E1392 PORTABLE OXYGEN CONCENTRATOR, RENTAL
E1405 OXYGEN AND WATER VAPOR ENRICHING SYSTEM WITH HEATED DELIVERY
E1406 OXYGEN AND WATER VAPOR ENRICHING SYSTEM WITHOUT HEATED DELIVERY
K0738 PORTABLE GASEOUS OXYGEN SYSTEM, RENTAL; HOME COMPRESSOR USED TO FILL PORTABLE OXYGEN CYLINDERS; INCLUDES PORTABLE CONTAINERS, REGULATOR, FLOWMETER, HUMIDIFIER, CANNULA OR MASK, AND TUBING

Group 2 Paragraph: ACCESSORIES:

Group 2 Codes:
A4575 TOPICAL HYPERBARIC OXYGEN CHAMBER, DISPOSABLE
A4606 OXYGEN PROBE FOR USE WITH OXIMETER DEVICE, REPLACEMENT
A4608 TRANSTRACHEAL OXYGEN CATHETER, EACH
A4615 CANNULA, NASAL
A4616 TUBING (OXYGEN), PER FOOT
A4617 MOUTH PIECE
A4619 FACE TENT
A4620 VARIABLE CONCENTRATION MASK
A7525 TRACHEOSTOMY MASK, EACH
A9900 MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE
E0455 OXYGEN TENT, EXCLUDING CROUP OR PEDIATRIC TENTS
E0555 HUMIDIFIER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC BOTTLE TYPE, FOR USE WITH REGULATOR OR FLOWMETER
E0580 NEBULIZER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC, BOTTLE TYPE, FOR USE WITH REGULATOR OR FLOWMETER
E1352 OXYGEN ACCESSORY, FLOW REGULATOR CAPABLE OF POSITIVE INSPIRATORY PRESSURE
E1353 REGULATOR
E1354 OXYGEN ACCESSORY, WHEELED CART FOR PORTABLE CYLINDER OR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH
E1355 STAND/RACK
E1356 OXYGEN ACCESSORY, BATTERY PACK/CARTRIDGE FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH
E1357 OXYGEN ACCESSORY, BATTERY CHARGER FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH
E1358 OXYGEN ACCESSORY, DC POWER ADAPTER FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH

ICD-10 Codes that Support Medical Necessity
Group 1 Paragraph: The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "Coverage Indications, Limitations and/or Medical Necessity" for other coverage criteria and payment information.

For HCPCS Code E0424 used for cluster headaches:

Group 1 Codes:

ICD-10 Codes	Description
G44.001	Cluster headache syndrome, unspecified, intractable
G44.009	Cluster headache syndrome, unspecified, not intractable
G44.011	Episodic cluster headache, intractable
G44.019	Episodic cluster headache, not intractable
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not intractable

Group 2 Paragraph: Z00.6 (must be used concurrently with one of the above diagnosis codes)

Group 2 Codes:

ICD-10 Codes	Description
Z00.6	Encounter for examination for normal comparison and control in clinical research program

Group 3 Paragraph: For all codes used for long term oxygen therapy - not specified

Group 3 Codes: N/A

ICD-10 Codes that DO NOT Support Medical Necessity
Group 1 Paragraph: For HCPCS code E0424 all other diagnosis not specified above

For all codes used for long term oxygen therapy – not specified

Group 1 Codes: N/A

ICD-10 Additional Information Back to Top

General Information

Associated Information
DOCUMENTATION REQUIREMENTS

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

Refer to the Supplier Manual for additional information on documentation requirements.

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS:

APPENDICES

The term blood gas study in this policy refers to either an arterial blood gas (ABG) test or an oximetry test. An ABG is the direct measurement of the partial pressure of oxygen (PO_2) on a sample of arterial blood. The PO_2 is reported as mm Hg. An oximetry test is the indirect measurement of arterial oxygen saturation using a sensor on the ear or finger. The saturation is reported as a percent.

Oxygen used to treat cluster headaches and for participants in an LTOT Trial is provided under special coverage rules. Reimbursement is only available for beneficiaries who are enrolled in an approved clinical trial. CMS maintains a list of policies that require study participation as a condition of coverage on the CMS web site. For each policy the approved studies are listed and a link provided to the study on the clinicaltrials.gov web site. The clinicaltrials.gov identifier number required on each claim is listed on this site.

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information
CR7235 for cluster headache trial
Bibliography

NA

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		Revision Effective Date: 08/01/2018 HCPCS MODIFIERS: Added: Modifiers GA, GY, GZ, KX	
08/01/2018	R5	*06/07/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.* **Revision Effective Date: 04/01/2018** Coding Information Revised: Modifier QE, QF, QG Added: Modifier QA, QB QR	• Provider Education/Guidance
04/01/2018	R4	*04/19/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.* **Revision Effective Date: 01/01/2017** COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements DOCUMENTATION REQUIREMENTS:	• Provider Education/Guidance
01/01/2017	R3		• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reason(s) for Change
		Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Miscellaneous section Removed: PIM citation from Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs. Revision Effective Date: 10/31/2014	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD POLICY SPECIFIC DOUMENTATION REQUIREMENTS: Revised: Diagnosis code references for Cluster Headaches	• Provider Education/Guidance

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Associated Documents

Attachments CMS-484 Oxygen-Oxygen Equipment CMN (PDF - 163 KB)

Related Local Coverage Documents Article(s) A52514 - Oxygen and Oxygen Equipment - Policy Article A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents N/A

Public Version(s) Updated on 05/31/2018 with effective dates 08/01/2018 - N/A Updated on 04/12/2018 with effective dates 04/01/2018 - 07/31/2018 Updated on 04/12/2017 with effective dates 01/01/2017 - 03/31/2018 Some older versions have been archived. Please visit the MCD Archive Site to retrieve them. Back to Top

Keywords

N/A Read the **LCD Disclaimer** Back to Top

END OF LOCAL COVERAGE DETERMINATION

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

Local Coverage Article:
Oxygen and Oxygen Equipment - Policy Article (A52514)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
CGS Administrators, LLC	DME MAC	17013 - DME MAC J-B	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC J-C	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC J-A	J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC J-D	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Utah Washington Wyoming Northern Mariana Islands

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Article Information

General Information

Article ID
A52514

Original ICD-9 Article ID
A33768
A33750
A33677
A47097

Article Title
Oxygen and Oxygen Equipment - Policy Article

Original Article Effective Date
10/01/2015

Revision Effective Date
08/01/2018

Revision Ending Date
N/A

Retirement Date
N/A

Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Oxygen and oxygen equipment is covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

REASONABLE USEFUL LIFETIME (RUL):

The reasonable useful lifetime for oxygen equipment is 5 years. The RUL is not based on the chronological age of the equipment. It starts on the initial date of service and runs for 5 years from that date.

RUL also does not take into account exchanges of equipment, new suppliers, or changes of modality (concentrator, gaseous, liquid).

Stationary and portable oxygen equipment is often provided at the same time therefore the RUL for both items runs concurrently. When the RUL of a beneficiary's portable oxygen equipment differs from the RUL of the beneficiary's stationary oxygen equipment, the RUL of the stationary oxygen equipment shall govern the application of RUL-based rules and processes for both types, stationary and portable, of oxygen equipment.

Until such time as the end date of the RUL of the stationary oxygen equipment is reached, the supplier must continue to furnish both the portable and stationary oxygen equipment.

1. If the end date of the RUL of the portable oxygen equipment precedes the end date of the RUL of the stationary oxygen equipment, the end date of the RUL of the portable oxygen equipment is adjusted (extended) to coincide with the end date of the RUL of the stationary oxygen equipment.
2. If the end date of the RUL of the portable oxygen equipment follows the end date of the RUL of the stationary oxygen equipment, the end date of the RUL of the portable oxygen equipment is adjusted (shortened) to coincide with the end date of the RUL of the stationary oxygen equipment.

When the end date of the RUL of the stationary oxygen equipment occurs, the beneficiary may elect to obtain replacement of both the stationary and the portable oxygen equipment.

If the beneficiary elects to obtain replacement of the stationary and the portable oxygen equipment, both types of oxygen equipment must be replaced at the same time.

When the stationary and the portable oxygen equipment are replaced, a new 36-month rental period and new RUL is started for both the replacement stationary oxygen equipment and the replacement portable oxygen equipment.

Beginning January 1, 2011, a beneficiary who resides in a DMEPOS competitive bidding area (CBA) may obtain replacement of both the stationary and portable oxygen systems only from a contract supplier having a competitive bidding contract for the CBA in which the beneficiary permanently resides.

A grandfathered supplier for oxygen and other grandfathered equipment as of January 1, 2011, who has continued to furnish such equipment that has not yet reached the 36-month rental cap, does not qualify to furnish replacement equipment once the end date of the RUL of the stationary equipment is reached, if the beneficiary resides in the CBA when the end of the RUL has been reached, unless the status of the grandfathered supplier has changed to a contract supplier for the current round of the competitive bidding program.

OXYGEN EQUIPMENT:

Initial 36 months

Reimbursement for oxygen equipment is limited to 36 monthly rental payments. Payment for accessories (e.g., cannula, tubing, etc.), delivery, back-up equipment, maintenance, and repairs is included in the rental allowance. Payment for oxygen contents (stationary and/or portable) is included in the allowance for stationary equipment (E0424, E0439, E1390, E1391).

Payment for stationary equipment is increased for beneficiaries requiring greater than 4 liters per minute (LPM) of oxygen flow and decreased for beneficiaries requiring less than 1 LPM. If a beneficiary qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, the appropriate modifiers (QB or QF) must be used.

The supplier who provides oxygen equipment for the first month must continue to provide any necessary oxygen equipment and all related items and services through the 36-month rental period, unless one of the following exceptions is met:

- Beneficiary relocates temporarily or permanently outside of the supplier's service area
- Beneficiary elects to obtain oxygen from a different supplier
- Individual case exceptions made by CMS or DME MAC
- Item becomes subject to competitive bidding

Providing different oxygen equipment/modalities (e.g., concentrator [stationary or portable], gaseous, liquid, trans-filling equipment) is not permitted unless one of the following requirements is met:

- Supplier replaces the equipment with the same or equivalent item
- Physician orders different equipment
- Beneficiary chooses to receive an upgrade and signs an Advance Beneficiary Notice of Non-coverage (ABN)
- CMS or the DME MAC determines that a change in equipment is warranted

A new 36-month rental period can begin only in the following situations:

- Specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost
- Break-in-need for at least 60 days plus the days remaining in the month of discontinuation and new medical necessity is established (see "BREAK-IN-SERVICE" below)

A new 36-month rental period does not start in the following situations:

- Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
- Providing different equipment based on a physician order or beneficiary request for an upgrade
- Break-in-need less than 60 days plus the days remaining in the month of discontinuation (see "BREAK-IN-SERVICE" below)
- Break-in-billing (see "BREAK-IN-SERVICE" below)
- Changing suppliers

Months 37-60

There is no further payment for oxygen equipment during the 5-year reasonable useful lifetime (RUL) of the equipment after 36 rental payments have been made. If use of portable equipment (E0431, E0433, E0434, E1392, K0738) begins after the use of stationary equipment begins, payment for the portable equipment can continue after payment for the stationary equipment ends until 36 rental payments have been made for the portable equipment.

For information on payment for contents and maintenance, see separate sections below.

The supplier who provided the equipment during the 36th rental month is required to continue to provide the equipment, accessories, contents (if applicable), maintenance, and repair of the oxygen equipment during the 5 year reasonable useful lifetime of the equipment.

Rules for providing different equipment/modalities are the same in months 37-60 as they are in the initial 36 months (see above).

A new 36-month rental period can begin only in the following situation:

- There is a specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost

A new 36-month rental period does not start in the following situations:

- Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
- Providing different equipment based on a physician order or beneficiary request for an upgrade
- Break-in-need (see "BREAK-IN-SERVICE" below)
- Break-in-billing (see "BREAK-IN-SERVICE" below)
- Changing suppliers

Months 61 and after

At any time after the end of the 5-year reasonable useful lifetime for oxygen equipment, the beneficiary may elect to receive new equipment, thus beginning a new 36-month rental period.

If the beneficiary elects not to receive new equipment after the end of the 5-year reasonable useful lifetime and if the supplier retains title to the equipment, all elements of the payment policy for months 37-60 remain in effect. There is no separate payment for accessories or repairs. If the beneficiary was using gaseous or liquid oxygen equipment during the 36th rental month, payment can continue to be made for oxygen contents.

If the beneficiary elects not to receive new equipment after the end of the 5-year reasonable useful lifetime and if the supplier transfers title of the equipment to the beneficiary, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

If a beneficiary enters Medicare FFS with beneficiary-owned equipment, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

OXYGEN CONTENTS:

Payment for stationary and portable contents is included in the fee schedule allowance for stationary equipment. No payment can be made for oxygen contents in a month in which payment is made for stationary equipment.

If the beneficiary was using stationary gaseous or liquid oxygen equipment during the 36th rental month, payment for stationary contents (E0441 or E0442) begins when the rental period for the stationary equipment ends.

If the beneficiary was using portable gaseous or liquid equipment during the 36th rental month of stationary equipment (gaseous, liquid, or concentrator), payment for portable contents (E0443 or E0444) begins when the rental period for the stationary equipment ends. If the beneficiary began using portable gaseous or liquid equipment after starting on stationary equipment, payment for the portable equipment would continue until the end of the 36-month rental period for that equipment even though payment was also being made for the portable contents.

If the beneficiary was using both stationary and portable gaseous or portable equipment during the 36th rental month of stationary equipment, payment for both stationary contents (E0441 or E0442) and portable contents (E0443 or E0444) begins when the rental for the stationary equipment ends.

If the beneficiary is using only portable gaseous or liquid equipment and not stationary equipment during months 1 through 36 of the portable equipment rental, payment for portable contents begins when the rental period for the portable equipment begins. If stationary equipment is subsequently added, separate payment for portable contents ends because payment for contents is included in the payment for stationary equipment.

If the beneficiary was not using gaseous or liquid equipment (stationary or portable) in the 36th month, but was subsequently switched to gaseous or liquid oxygen based on a physician order, contents may be paid.

If the beneficiary has a stationary concentrator, portable liquid equipment, and a stationary liquid tank to fill the portable cylinders, when payment for contents begins, payment will only be made for portable liquid contents.

Suppliers must provide whatever quantity of oxygen contents are needed for a beneficiary's activities both inside and outside the home.

A maximum of 3 months of oxygen contents may be delivered at any one time. (Refer to Billing Information section [below] for additional information concerning billing oxygen contents.)

There is no difference in payment for oxygen contents for beneficiaries receiving more than 4 LPM or less than 1 LPM.

No more than 1 unit of service (UOS) for stationary contents and/or 1 UOS for portable contents per month are billable.

Refer to the Coverage Indications, Limitations and/or Medical Necessity section of the LCD for additional information about refills of oxygen contents.

MAINTENANCE OF EQUIPMENT:

Initial 36 months

There is no separate payment for maintenance and servicing (M&S).

Months 37 through 60

If a beneficiary was using a stationary concentrator, portable concentrator, or trans-filling equipment during the 36th rental month, Medicare will pay for an M&S visit no more often than every 6 months, beginning no sooner than 6 months following the end of the rental period. If the equipment is covered under a warranty that covers labor related to routine/general maintenance and servicing (e.g., inspection, changing filters, cleaning, and calibration), payment for the first M&S visit can be no sooner than 6 months following the end of that warranty.

A supplier must actually make a visit to bill the service. If multiple M&S visits are made during a 6 month period, only one will be paid.

There is no M&S payment for gaseous or liquid equipment.

Month 61 and after

If the beneficiary elects not to replace a concentrator or trans-filling equipment and if the supplier retains title to the equipment, coverage for M&S is the same as in months 37-60.

If the beneficiary elects not to replace a concentrator or trans-filling equipment and if the supplier transfers title to the beneficiary, M&S is statutorily non-covered.

OXYGEN ACCESSORIES:

Accessories, including but not limited to, trans-tracheal catheters (A4608), cannulas (A4615), tubing (A4616), mouthpieces (A4617), face tent (A4619), masks (A4620, A7525), oxygen conserving devices (A9900), oxygen tent (E0455), humidifiers (E0555), nebulizer for humidification (E0580), regulators (E1353), and stand/rack (E1355) are included in the allowance for rented oxygen equipment. The supplier must provide any accessory ordered by the physician. Accessories used with beneficiary-owned oxygen equipment will be denied as non-covered.

RELOCATION and TRAVEL:

Months 1 through 36

If the beneficiary relocates outside the supplier's service area (either short-term travel, extended temporary relocation, or permanent relocation), then for the remainder of the rental month for which it billed, the home supplier is required to provide the equipment and related items/service itself or make arrangements with a different supplier to provide the equipment, items, and services. For subsequent rental months that the beneficiary is outside the service area, the home supplier is encouraged to either provide the equipment and related items/services itself or assist the beneficiary in finding another supplier in the new location. The home supplier may not bill for or be reimbursed by Medicare if it is not providing oxygen equipment or has not made arrangements with a different supplier to provide the equipment on the anniversary billing date. Medicare will pay only one supplier to provide oxygen during any one-rental month.

Months 37 through 60

If the beneficiary relocates outside the supplier's service area (either short-term travel, extended temporary relocation, or permanent relocation), the home supplier is required to either provide the equipment and related

items/services itself or make arrangements with a different supplier to provide the equipment and related items/services.

Miscellaneous

Oxygen services furnished by an airline to a beneficiary are non-covered. Payment for oxygen furnished by an airline is the responsibility of the beneficiary and not the responsibility of the supplier.

Medicare does not cover items or services provided/used outside the United States and its territories. The supplier is not required to provide or arrange for oxygen use in those situations.

BREAK-IN-SERVICE:

- Break-in-billing/Part B payment without break-in-medical necessity
  - If beneficiary enters hospital or SNF or joins Medicare HMO and continues to need/use oxygen, when beneficiary returns home or rejoins Medicare FFS, payment resumes where it left off
- Break-in-medical necessity (break-in-need)
  - If need/use of oxygen ends for less than 60 days plus the remainder of the rental month of discontinuation and then resumes, payment resumes where it left off
  - During the 36-month rental period, if need/use of oxygen ends for more than 60 days plus the remainder of the rental month of discontinuation and new medical necessity is established, a new 36 month rental period would begin
  - During months 37-60, if need/use of oxygen ends for more than 60 days plus the remainder of the rental month of discontinuation and new medical necessity is established, a new rental period does not begin. The supplier who provided the oxygen equipment during the 36th rental month must provide all necessary items and services for the duration of the reasonable useful lifetime.

MISCELLANEOUS:

Only rented oxygen equipment is eligible for coverage. Purchased oxygen equipment is statutorily non-covered.

Oximeters (E0445) and replacement probes (A4606) will be denied as non-covered because they are monitoring devices that provide information to physicians to assist in managing the beneficiary's treatment.

Respiratory therapist services are non-covered under the DME benefit.

REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PERSUANT TO 42 CFR 410.38(g)

42 CFR 410.38(g) requires a face-to-face evaluation and a specific written order prior to delivery for specified HCPCS codes. CMS provides a list of the specified codes, which is periodically updated, located here.

Claims for the specified items subject to 42 CFR 410.38(g) that do not meet the requirements specified in the LCD-related Standard Documentation Requirements Article will be denied as statutorily noncovered – failed to meet statutory requirements.

If the supplier delivers the item prior to receipt of a written order, it will be denied as statutorily noncovered. If the written order is not obtained prior to delivery, payment will not be made for that item even if a written order is subsequently obtained. If a similar item is subsequently provided by an unrelated supplier who has obtained a written order prior to delivery, it will be eligible for coverage.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

NCD 240.2

Documentation for initial coverage requires information in the medical record showing:

- Evidence of qualifying test results done within 30 days before the initial date of service
- Evidence of an in-person visit with a treating physician done within 30 days before the initial date of service

As required by the NCD Home Use of Oxygen (240.2), coverage of home oxygen therapy requires that the beneficiary be tested in the "chronic stable state" and that all co-existing diseases or conditions that can cause hypoxia must be treated sufficiently. Moreover, the beneficiary must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy.

In order to provide coverage for these beneficiaries, there must be evidence in the medical record documenting:

A. A severe underlying lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy; and
B. The beneficiary is not experiencing an exacerbation of their underlying lung disease described in (A) or other acute condition(s) impacting the beneficiary's oxygen saturation;
C. For beneficiaries with concurrent PAP therapy, the qualifying oxygen saturation test is performed following optimal treatment of the OSA as described in the Coverage Indications, Limitations and/or Medical Necessity.

LONG TERM OXYGEN THERAPY TRIALS (LTOT):

For LTOT Trial claims, the "clinicaltrials.gov" identifier number of the CMS approved clinical trial must be included in the narrative field on each claim.

Claims for LTOT Trial participants that meet the approved clinical trial and testing requirements described in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD must be submitted with the Q0 (Q-zero) modifier. Claims for oxygen that do not meet these criteria must not use this modifier.

CLUSTER HEADACHES:

A CMN is not required for claims for cluster headaches.

The diagnosis code(s) for the qualifying cluster headache condition must be included on the claim (reference Group 1 Diagnosis Codes that Support Medical Necessity in the related LCD).

The diagnosis code for EXAMINATION OF PARTICIPANT IN CLINICAL TRIAL (reference Group 2 Diagnosis Codes that Support Medical Necessity in the related LCD) must also be included on the claim for cluster headache if the beneficiary is enrolled in an approved study.

For cluster headache claims there must be information in the medical record justifying:

- Participation in an approved study
- The qualifying diagnosis code(s)

For cluster headache claims, the "clinicaltrials.gov" identifier number of the CMS approved clinical trial must be included in the narrative field on each claim.

Claims for oxygen used for the treatment of cluster headaches that meet the approved clinical trial and diagnosis requirements described in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD must be submitted with the Q0 (Q-zero) modifier. Claims for oxygen used for cluster headaches that do not meet these criteria must not use this modifier.

REPAIRS:

The supplier must maintain detailed records describing the need for and nature of all repairs including a detailed explanation of the justification for any component or part replaced as well as the labor time to restore the item to its functionality.

REPLACEMENT EQUIPMENT:

For situations 3 and 4 described in the CERTIFICATION section of the "Coverage Indications, Limitations and/or Medical Necessity" of the LCD, the following special instructions apply:

Initial Date should be the date that the replacement equipment is initially needed. This is generally understood to be the date of delivery of the oxygen equipment.

The Recertification Date should be 12 months following the Initial Date when the value on the Initial CMN (for the replacement equipment) meets Group I criteria or 3 months following the Initial Date when the qualifying blood gas value on the Initial CMN meets the Group II criteria. (Note: The Initial Date [for the replacement equipment] should also be entered on the Recertification CMN.)

Claims for the initial rental month (and only the initial rental month) must have the RA modifier (Replacement of DME item) added to the HCPCS code for the equipment when there is replacement due to reasonable useful lifetime or replacement due to damage, theft, or loss.

Claims for the initial rental month must include a narrative explanation of the reason why the equipment was replaced and supporting documentation must be maintained in the supplier's files.

A physician's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

CERTIFICATE OF MEDICAL NECESSITY (CMN)

A Certificate of Medical Necessity (CMN), which has been completed, signed, and dated by the treating physician, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for home oxygen is CMS Form 484 (DME form 484.03). In addition to the order information that the physician enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the oxygen order or the physician can enter the other details directly–e.g., the means of oxygen delivery (cannula, mask, etc.) and the specifics of varying oxygen flow rates and/or non-continuous use of oxygen.

For beneficiaries who qualify for oxygen coverage based only on an overnight oximetry study, the oxygen saturation value reported in question 1b of the Oxygen CMN must be the lowest value (not related to artifact) during the 5 minute qualifying period reported on the sleep oximetry study. A report of the home overnight study documenting the qualifying desaturation must be available upon request.

If both an arterial blood gas and oximetry test have been performed on the same day under the condition reported on the CMN (i.e., at rest/awake, during exercise, or during sleep), the ABG PO 2 must be reported on the CMN.

In the following situations, a new order must be obtained and kept on file by the supplier, but neither a new CMN nor a repeat blood gas study are required:

- Prescribed maximum flow rate changes but remains within one of the following categories: (a) less than 1 LPM, (b) 1-4 LPM, (c) greater than 4 LPM
- Change from one type of stationary system to another (i.e., concentrator, liquid, gaseous)
- Change from one type of portable system to another (i.e., gaseous or liquid tanks, portable concentrator, trans-filling system)

A new CMN is not required just because a beneficiary changes from Medicare secondary to Medicare primary.

A new CMN is not required just because the supplier changes assignment status on the submitted claim.

Suppliers are reminded that in an audit they may be asked to provide a copy of the actual test report and/or information from the medical record to verify that coverage criteria have been met.

MODIFIERS

KX, GA, GY, and GZ MODIFIERS:

Suppliers must add a KX modifier only if all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity" section of the related LCD have been met.

If all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity section have not been met, the GA, GY or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN), a GZ modifier if they have not obtained a valid ABN, or a GY modifier if the item or service is statutorily excluded.

Claim lines billed without a KX, GA, GY or GZ modifier will be rejected as missing information.

QA, QB, QE, QF, QG and QR MODIFIERS:

42 CFR Section 414.226(e) stipulates:

1. If prescribed flow rate is different for stationary versus portable, the flow rate for stationary is used.
2. If prescribed flow rate is different for the patient at rest versus the patient with exercise, the flow rate at rest is used.
3. If prescribed flow rate is different for nighttime versus daytime use, the flow rates are averaged.

QA: For scenarios where the beneficiary has different daytime and nighttime oxygen flow requirements. Used if the average documented flow requirement from a daytime "at rest" qualifying test and flow rate for nocturnal oxygen requirement (standard arithmetic rounding rules apply) is <1 LPM.

QB: For scenarios where the beneficiary has different daytime and nighttime oxygen flow requirements. Used if the average documented flow requirement from a daytime "at rest" qualifying test and flow rate for nocturnal oxygen requirement (standard arithmetic rounding rules apply) is >4 LPM, and portable oxygen is prescribed.

QE: Used if the documented flow requirement on an "at rest" qualifying test is <1 LPM.

QF: Used if the documented flow requirement on an "at rest" qualifying test is >4 LPM, and portable oxygen is prescribed. DO NOT use a flow requirement from a "with exercise" qualifying test.

QG: Used if the documented flow requirement on an "at rest" qualifying test is >4 LPM. DO NOT use a flow requirement from a "with exercise" qualifying test.

QR: For scenarios where the beneficiary has different daytime and nighttime oxygen flow requirements. Used if the average documented flow requirement from a daytime "at rest" qualifying test and flow rate for nocturnal oxygen requirement (standard arithmetic rounding rules apply) is >4 LPM.

CODING GUIDELINES

The appropriate modifier must be used if the prescribed flow rate is less than 1 LPM (QA or QE) or greater than 4 LPM (QG or QR).

For claims with dates of service on or after 04/01/2018 the modifier "QB or QF" should be used in conjunction with claims submitted for stationary oxygen (codes E0424, E0439, E1390, or E1391) and portable oxygen (codes E0431, E0433, E0434, E1392, or K0738) when the prescribed amount of oxygen is greater than 4 liters per minute (LPM).

Code E1391 (Oxygen concentrator, dual delivery port) is used in situations in which two beneficiaries are both using the same concentrator. In this situation, this code should only be billed for one of the beneficiaries.

Codes E1405 and E1406 (oxygen and water vapor enriching systems) may only be used for products for which a written coding verification has been received from the PDAC. The modifiers QB, QF, QG or QR, which are appended to claim lines to indicate oxygen flow rates greater than 4 liters/minute, must not be used with codes E1405 and E1406.

Code E1392 describes an oxygen concentrator which is designed to be portable, is capable of delivering 85% or greater oxygen concentration, and is capable of operating on either AC or DC (e.g., auto accessory outlet) power. Code E1392 includes the device itself, an integrated battery or beneficiary-replaceable batteries that are capable of providing at least 2 hours of remote portability at a minimum of 2 LPM equivalency, a battery charger, an AC power adapter, a DC power adapter, and a carry bag and/or cart. The combined weight of the concentrator and

the battery/batteries capable of 2 hours of portability must be 20 pounds or less. If a concentrator meets all of these criteria and is also capable of functioning as a stationary concentrator, operating 24 hours per day, 7 days per week, the stationary concentrator code (E1390) is billed in addition to code E1392.

Code K0738 describes a feature of an oxygen concentrator that allows the beneficiary to fill portable gaseous oxygen cylinders from a stationary concentrator. This feature may be integrated into the stationary concentrator or be a separate component. When code K0738 is billed, code E0431 (portable gaseous oxygen system, rental) must not be used.

Code E0433 describes a feature of an oxygen concentrator that allows the beneficiary to fill portable liquid oxygen cylinders from a stationary concentrator. This feature may be integrated into the stationary concentrator or be a separate component. When code E0433 is billed, code E0434 (portable liquid oxygen system, rental) must not be used.

When oxygen is supplied as part of a CMS approved clinical trial for cluster headaches, equipment must be coded E0424 (STATIONARY COMPRESSED GASEOUS OXYGEN SYSTEM, RENTAL; INCLUDES CONTAINER, CONTENTS, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING).

Refill contents used with equipment to treat cluster headaches must be coded using E0441 (STATIONARY OXYGEN CONTENTS, GASEOUS, 1 MONTH'S SUPPLY = 1 UNIT).

E1352 (OXYGEN ACCESSORY, FLOW REGULATOR CAPABLE OF POSITIVE INSPIRATORY PRESSURE) provides positive pressure inspiratory support for patients using oxygen. This product consists of multiple components - control unit, flow regulator, connecting hose and nasal interface (pillows). E1352 is an all-inclusive code for this product that includes all components.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC) contractor for guidance on the correct coding of these items.

BILLING INFORMATION

When billing oxygen contents (refer to the Policy Article, Non-Medical Necessity Coverage and Payment Rules section), suppliers should use a date of service (DOS) that is the anniversary date of the equipment whose rental period has ended. The billed DOS will usually not be the actual delivery date. The supplier must have a delivery slip for the actual delivery date.

A supplier does not have to deliver contents every month in order to bill every month. In order to bill for contents, the supplier must have previously delivered quantities of oxygen that are expected to be sufficient to last for one month following the DOS on the claim. Suppliers should monitor usage of contents. Billing may continue on a monthly basis as long as sufficient supplies remain to last for one month as previously described. If there are insufficient contents to be able to last for a month additional contents should be provided.

Suppliers may bill a flat rate for contents each month. The submitted charges do not have to vary with the quantity of tanks delivered.

Claims for oxygen contents and/or oxygen accessories should not be submitted in situations in which they are not separately payable.

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Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A
ICD-10 Codes that are Covered N/A
ICD-10 Codes that are Not Covered N/A
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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation
08/01/2018	R6	**Revision History Effective Date: 08/01/2018** CERTIFICATE OF MEDICAL NECESSITY (CMN): Removed: Flow rate instructions when answering CMN question 5 MODIFIERS: Added: GA, GY, GZ, and KX modifier requirement instructions Added: "Q" modifier instructions *06/07/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.*
04/01/2018	R5	**Revision History Effective Date: 04/01/2018** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES Oxygen Equipment: Initial 36 months Added: "the appropriate modifiers (QB or QF) must be used." in paragraph regarding flow rate greater than 4 LPM and also meets requirements for portable oxygen Added: 42 CFR 410.38(g) language, previously in POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section CERTIFICATE OF MEDICAL NECESSITY Added: Flow rate guidelines for beneficiaries who require differing day and night rates CODING GUIDELINES Revised: Flow rate modifiers for beneficiaries who require differing day and night rates Revised: Coding guidelines for E1405 and E1406 to indicate that high flow rate modifiers (QB, QF, QG or QR) must not be used with these two HCPCS codes. *04/19/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.*
01/01/2018	R4	**Revision History Effective Date: 01/01/2018** NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES Oxygen Equipment: Initial 36 months Added: "the appropriate modifiers (QB or QF) must be used." in paragraph regarding flow rate greater than 4 LPM and also meets requirements for portable oxygen Added: 42 CFR 410.38(g) language, previously in POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section CERTIFICATE OF MEDICAL NECESSITY Added: Flow rate guidelines for beneficiaries who require differing day and night rates

Revision History Date	Revision History Number	Revision History Explanation
		CODING GUIDELINES Revised: Flow rate modifiers for beneficiaries who require differing day and night rates Revised: Coding guidelines for E1405 and E1406 to indicate that high flow rate modifiers (QB, QF, QG or QR) must not be used with these two HCPCS codes.
01/01/2017	R3	*04/19/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.* Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: NCD 240.2, Long Term Oxygen Therapy Trails, Cluster Headaches, 42 CFR 410.38(g), Repair, Replacement and CMN requirements CODING GUIDELINES: Effective 04/01/2017, modifier QF may be used with portable systems or oxygen. RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC Articles is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the Articles.
10/01/2015	R1	Revision Effective Date: 10/31/2014 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: "When required by state law" from ACA new prescription requirements Revised: Face-to-Face Requirements for treating practitioner

Back to Top **Related Local Coverage Document(s)** Article(s) A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs LCD(s) L33797 - Oxygen and Oxygen Equipment

Related National Coverage Document(s) N/A

Statutory Requirements URL(s) N/A

Rules and Regulations URL(s) N/A

CMS Manual Explanations URL(s) N/A

Other URL(s) N/A

Public Version(s) Updated on 05/31/2018 with effective dates 08/01/2018 - N/A Updated on 04/13/2018 with effective dates 04/01/2018 - N/A Updated on 04/12/2018 with effective dates 01/01/2018 - N/A Updated on 04/12/2017 with effective dates 01/01/2017 - N/A Some older versions have been archived. Please visit MCD Archive Site to retrieve them. Back to Top

Keywords

N/A Read the **Article Disclaimer** Back to Top

CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Part D 2019 Opioid Policies

November 13, 2018

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Topics

- 2019 Part C and D Regulation – CARA Drug Management Programs
- 2019 Call Letter Updates – Part D Opioid Overutilization Guidance
- Impact of Part D Policy

Drug Management Programs – Part C and D Regulation

Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program

https://www.gpo.gov/fdsys/pkg/FR-2018-04-16/pdf/2018-07179.pdf

As required by the Comprehensive Addiction and Recovery Act (CARA), in this final rule, CMS finalized the framework under which Part D plan sponsors may voluntarily adopt drug management programs for beneficiaries who are at risk of misusing or abusing frequently abused drugs.

Drug Management Programs – General Structure

- Integrated with the existing Medicare Part D Overutilization Monitoring System (OMS)
- Clinical Guidelines/OMS Criteria to Identify Program Size of Potential At-Risk Beneficiaries (PARBs)
- Frequently Abused Drugs (FADs) for purposes of Drug Management Programs
- Exempted Beneficiaries

Drug Management Programs – General Structure (continued)

- Written Policies and Procedures
- Case Management/Clinical Contact/Prescriber Verification/ Reporting to CMS
- Overutilization Tools for At-Risk Beneficiaries (ARBs), if Needed:
  - Limitation on Access to Coverage for FADs through Limiting to Selected Pharmacy(ies)/Prescriber(s)
    - Beneficiary Preferences/Exceptions; Reasonable Access
  - Beneficiary-Specific Point-of-Sale (POS) Claim Edits for FADs
- Beneficiary Notices
- Beneficiary Appeals
- Termination/Extension of Prescriber/Pharmacy Limitations and POS Edits

Drug Management Programs – 2019 Clinical Guidelines/Program Size

- ***Minimum Criteria*** *(Sponsors must review PARBs)*
  - ≥ 90 morphine milligram equivalent (MME) AND either
  - 3+ opioid prescribers AND 3+ opioid dispensing pharmacies OR
  - 5+ opioid prescribers AND 1+ opioid dispensing pharmacies
  - Currently estimate 44,332 PARBs will be identified
- ***Supplemental Criteria*** *(Sponsors may review as many PARBs as manageable)*
  - Any Level MME AND
  - 7+ opioid prescribers OR 7+ opioid dispensing pharmacies
  - Currently estimate 22,841 PARBs will be identified

Drug Management Programs – Frequently Abused Drugs (FADs)

- ***FADs = Opioids and Benzodiazepines***
  - Except for buprenorphine for medication-assisted treatment (MAT) and injectables
- ***Note about OMS criteria and FADs***
  - PARBs are identified by opioid use, but coverage limitations can apply to all FADs
  - Final regulatory definitions of clinical guidelines and FADs contain standards which the OMS criteria and FADs must meet; this structure allows CMS to update the OMS criteria and drugs that constitute FADs through the annual Parts C&D Call Letter process, as long as these standards are met

Drug Management Programs – Exempted Beneficiaries

- An **exempted beneficiary**
  - Has elected to receive hospice care or is receiving palliative or end-of-life care, or
  - Is a resident of a long-term care facility, of a facility described in section 1905(d) of the Act, or of another facility for which FADs are dispensed for residents through a contract with a single pharmacy, or
  - Is being treated for active cancer-related pain

Drug Management Programs – Case Management, Clinical Contact, Prescriber Verification

- The final rule requires Part D plan sponsors' clinical staff to perform case management for each PARB for the purpose of engaging in clinical contact with the prescribers of FADs and verifying whether a PARB is an ARB
- Based on information obtained during case management, plan sponsor makes the determination whether a PARB is an ARB

Drug Management Programs – Requirements for Limiting Access to Coverage of FADs

- Case management
- Prescriber agreement (except when not required), and
- Beneficiary notice required before limiting ARB's access to coverage of FADs

Coverage Limitation	Prescriber Verification of At-Risk Status	Prescriber Agreement for Coverage Limitation (Initial 12 Months)	Prescriber Agreement for Coverage Limitation (Extend Additional 12 Months)
POS Edit	Yes**	Yes**	Yes**
Pharmacy Limitation	Yes**	No*	No*
Prescriber Limitation	Yes***	Yes***	Yes***

*If prescriber rejects pharmacy limitation, the plan should take this into consideration
**If prescriber does not respond to case management, the plan may proceed with limitation
***If prescriber does not respond to case management, the plan cannot proceed with prescriber limitation

Drug Management Programs – At-Risk Determinations

- An at-risk determination is a decision made under a plan sponsor's drug management program that involves:
  - Identification as an ARB for prescription drug abuse
  - A limitation, or the continuation of a limitation, on access to coverage for FADS
  - Information sharing for subsequent plan enrollments
- Once an enrollee is identified as at-risk, the enrollee will receive a second written notice that explains the limitations and appeal rights
- If a limitation is continued beyond the initial 12-month period, the enrollee will receive an additional second notice

Drug Management Programs – Beneficiary Notices and Timeframes (1 of 4)

Initial Notice includes:

- Notice to beneficiary that plan sponsor has identified them as a PARB and the proposed coverage limitation on their access to FADs
- 30 days for the PARB to submit relevant information and preferences for selected pharmacy/prescriber, in the case of a proposed limitation
- Timeframe for plan sponsor's decision
- Information on any limitation on the availability of the LIS SEP, if applicable

Drug Management Programs – Beneficiary Notices and Timeframes (2 of 4)

Second Notice includes:

- Notice that plan sponsor has identified them as an ARB
- Coverage limitation on access to FADs with effective and end dates
- Selected pharmacy(ies)/prescriber(s), or both, if applicable, from which the beneficiary must obtain FADs for coverage by plan
- Explanation that beneficiary may still submit preferences for selected pharmacy/prescriber, in the case of such limitation
  - Note: Plan sponsor must send additional written notice with new pharmacy(ies)/prescriber(s) within 14 days after receipt of submission
- Information on any limitation on the availability of the LIS SEP, if applicable
- Explanation of the beneficiary's right to a redetermination

Drug Management Programs – Beneficiary Notices and Timeframes (3 of 4)

Alternate Second Notice informs the beneficiary that:

- Plan sponsor has not identified them as an ARB
- Plan sponsor will not implement a coverage limitation
- SEP limitation no longer in effect, if applicable

Drug Management Programs – Beneficiary Notices and Timeframes (4 of 4)

The plan sponsor must provide a Second Notice or Alternate Second Notice to the beneficiary

- No less than 30 days and
- Not more than the earlier of:
  - The date that the sponsor makes the relevant determination, or
  - 60 days after the date of the Initial Notice

Exception: No Initial Notice required for an ARB who switched plans if the POS edit or, in the case of prescriber or pharmacy limitation, the selected pharmacy or prescriber, is the same

Drug Management Programs – LIS SEP Limitation (1 of 3)

- Starting 1/1/2019, duals/LIS SEP only used once per calendar quarter
  - Only allowed in quarters 1, 2, and 3
  - Annual Enrollment Period (AEP) can be used in quarter 4
- Individuals notified they are a PARB or an ARB under a drug management program can't use the duals/LIS SEP to change plans
- Other election periods still available – AEP, other SEPs, which the individual meets the criteria to use

Drug Management Programs – LIS SEP Limitation (2 of 3)

- Notification – Once identified as a PARB, sponsor provides an Initial Notice with SEP limitation

- Effective as of the date on the Initial Notice

Drug Management Programs – LIS SEP Limitation (3 of 3)

- Duration: If sponsor takes no additional action within 60 days to identify an individual as an ARB, the SEP limitation ends
- Limitation lasts:
  - As long as individual is enrolled in that plan, or
  - Until the at-risk determination is successfully appealed, or
  - When the status expires or is terminated by the plan –
    - Initial 12-month period
    - Plan's option to extend for a maximum of 24 months in total upon reassessment of the at-risk status

Drug Management Programs – Beneficiary Preferences (Exceptions) and Reasonable Access (1 of 2)

- In the case of prescriber/pharmacy limitation, plan sponsor must accept beneficiary's pharmacy/prescriber preferences (as long as in-network), unless an exception applies
- Exception to beneficiary preferences if:
  - Plan sponsor determines that selection would contribute to drug abuse or diversion; and
  - There is strong evidence of inappropriate action by the prescriber, pharmacy, or beneficiary
- Plan sponsor must provide beneficiary with 30 days advance written notice and a rationale if the sponsor changes the selections

Drug Management Programs – Beneficiary Preferences (Exceptions) and Reasonable Access (2 of 2)

- When plan sponsor selects the pharmacy/prescriber, sponsor must ensure beneficiary has reasonable access to FADs taking into account all relevant factors
- Reasonable access may necessitate selection of more than one pharmacy/prescriber or an out-of-network pharmacy or prescriber

Drug Management Programs – Termination/Extension of At-Risk Status (1 of 2)

Identification as an ARB terminates as of the earlier of:

- Date beneficiary demonstrates they are no longer an ARB without the coverage limitation for FADs
- End of a one-year period unless the limitation was extended for an additional year
- End of a two-year period, if the limitation was extended

Drug Management Programs – Termination/Extension of At-Risk Status (2 of 2)

To extend a limitation, plan sponsor must:

- Determine that there is a clinical basis for the extension
- Obtain the agreement of a prescriber of FADs for extension
  - Note: Not required for pharmacy limitation; not required for a beneficiary-specific POS edit if no prescriber is responsive
- Provide a Second Notice to the beneficiary

Drug Management Programs - Appeals

- At-risk determinations are subject to the existing Part D benefit appeals process
- If an enrollee disagrees with an at-risk determination made under a plan's drug management program, the enrollee has the right to request a redetermination
- The enrollee has 60 days from the date of the second notice to request an appeal, unless there is good cause for late filing
- All disputes raised in an appeal request must be adjudicated as a single case

Part D Benefit Appeals Process

- Appeals of at-risk determinations are subject to the standard and expedited appeals processes
- Standard Timeframes
  - Redetermination – 7 days
  - Reconsideration – 7 days
- Expedited Timeframes
  - Redetermination – 72 hours
  - Reconsideration – 72 hours
- In all cases, the enrollee must be notified of the decision as expeditiously as the enrollee's health condition requires

Changes to At-Risk Determinations

An at-risk determination made under a drug management program can be changed by:

- The appeals process – An enrollee, an enrollee's representative, or their prescriber may dispute an at-risk determination and a change is made on appeal
- A new at-risk determination made by a plan sponsor – As a result of ongoing case management, a plan sponsor may make a new at-risk determination that changes a previous limitation

Coverage Determinations

- In addition to the right to appeal an at-risk determination, an enrollee always has the right to request a coverage determination, including an exception, for a drug he or she believes may be covered.

Plan Sponsor Redeterminations

- In notifying an enrollee of a redetermination of an at-risk determination, a plan sponsor may use CMS' model Redetermination Notice or develop their own notice
- An adverse redetermination decision must clearly and specifically explain the reason for the denial and include an explanation of the enrollee's right to appeal to the IRE
- Favorable decisions must clearly explain the conditions of approval
- Changes made by a redetermination (or higher level of appeal) must be effectuated using the existing effectuation requirements for Part D benefit requests

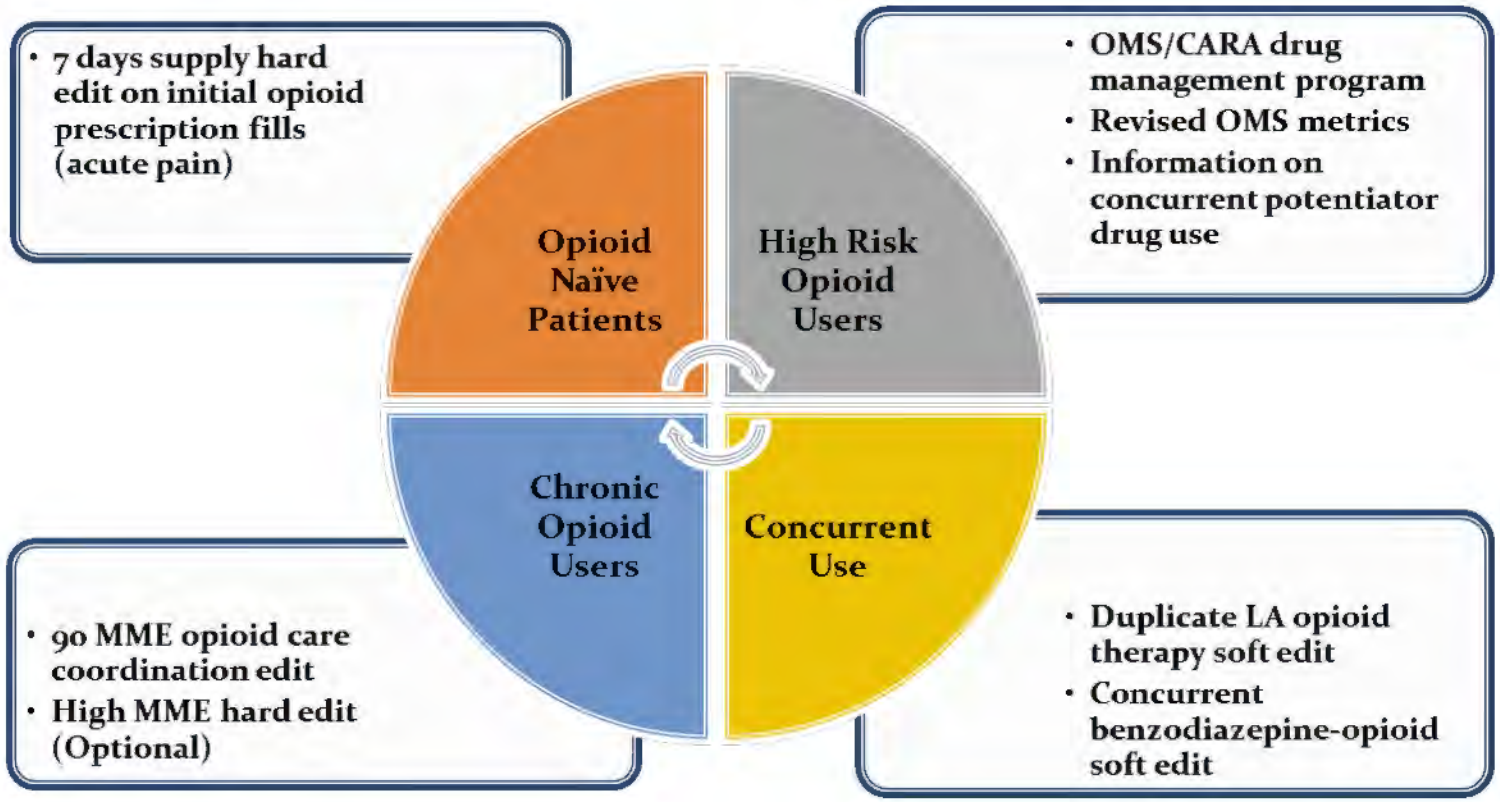
Other Opioid Policy Changes for 2019

- **2019 Medicare Parts C&D Call Letter**

  https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html

- Effective January 1, 2019, CMS announced new strategies to further help Medicare Part D plan sponsors prevent and combat opioid overuse.

2019 Opioid Overutilization Guidance



Beneficiary Protections

- Beneficiaries who are residents of a long-term care facility, in hospice care or receiving palliative or end-of-life care, or being treated for active cancer-related pain should be excluded
- Beneficiaries' access to medication-assisted treatment (MAT), such as buprenorphine, should not be not impacted
- For claims not resolved at point of sale, beneficiaries must receive written copy of standardized CMS pharmacy notice explaining their right to request a coverage determination

Safety Edit Pilot

- Summer/Fall 2018, CMS conducted an informal pilot to test the opioid naïve and care coordination edit specifications
- Goals of the pilot:
  - Test coding/specifications
  - Measure impact/outcomes of those edits on beneficiaries, pharmacies and prescribers
  - Assess information on provider education
  - Test pharmacy preparedness
  - Identify any need for additional technical guidance to Part D plan sponsors and other stakeholders

Safety Edit Pilot - Highlights

- Participant activities included:
  - Live testing the new edits
  - Developing educational and/or training materials for beneficiaries, prescribers, network pharmacies and plan/PBM staff
  - Providing data about volume and impacts on beneficiaries, as well as feedback from stakeholders
- Early lessons learned:
  - Coordination internally among plan sponsor and PBM or other downstream entities is crucial to successful implementation of these edits
  - Education and training of health care providers, pharmacists, beneficiaries and plan staff is vitally important

Quality Measures

Driving performance improvement through quality metrics

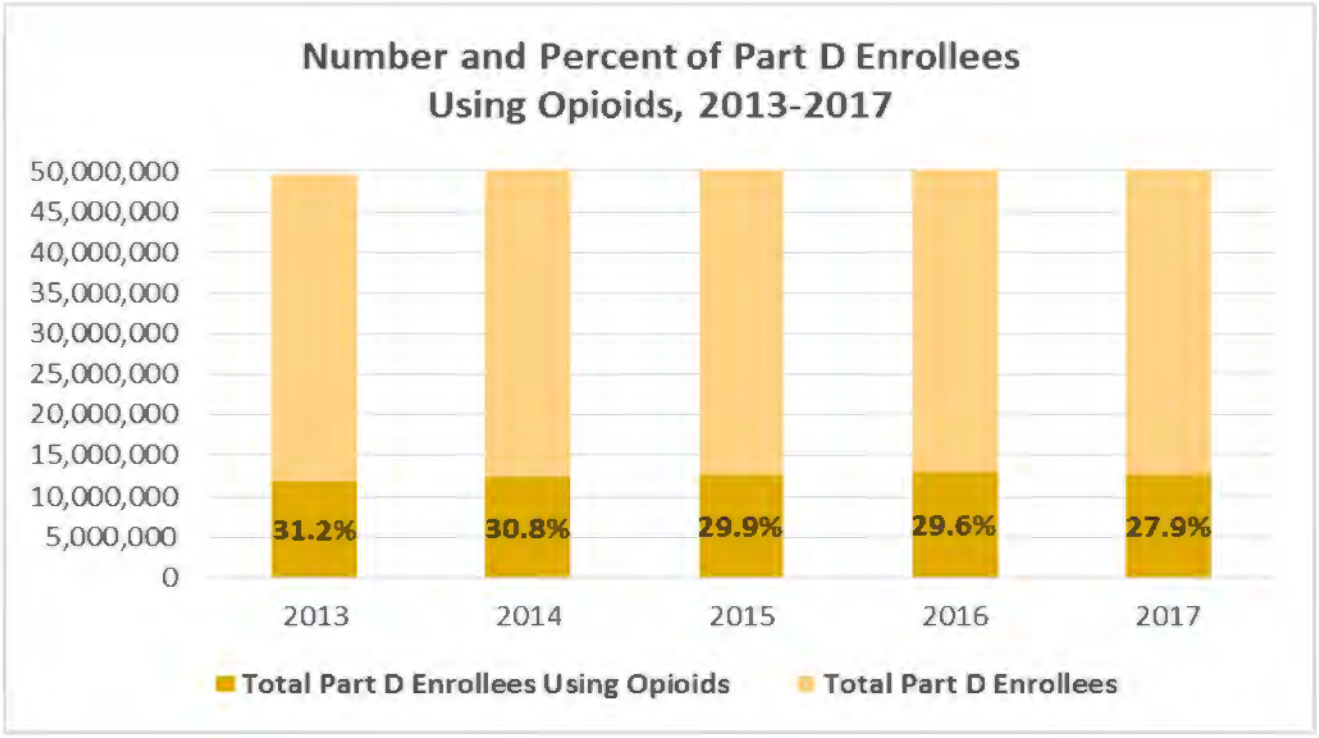
PQA Use of Opioids at High Dosage / Multiple Providers

- Continue to report three measures through Patient Safety Reports
- Implement technical revisions
- Add one measure to 2019 Display Page (using 2017 data)

PQA Concurrent Use of Opioids and Benzodiazepines

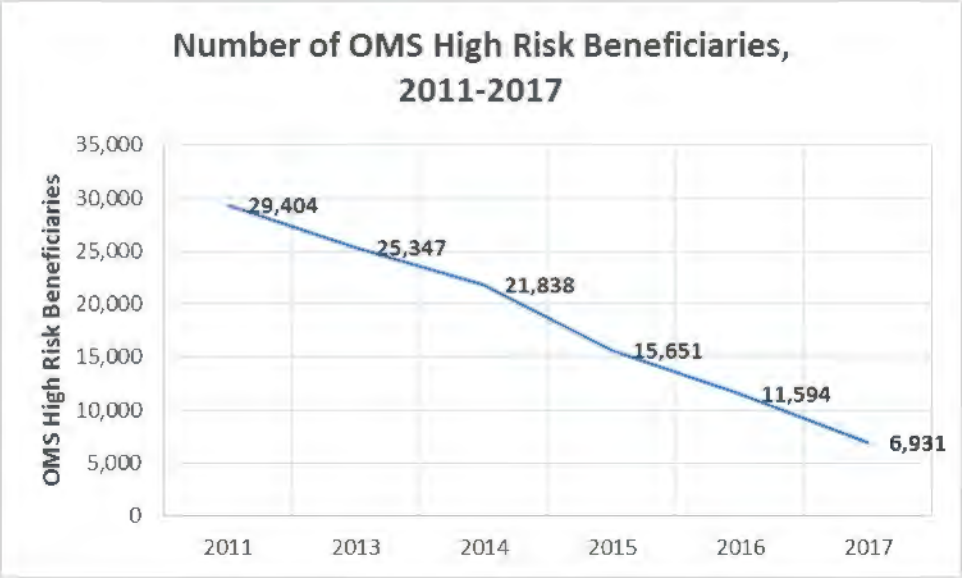
- Begin to report through Patient Safety Reports (2018 Reports launched in April 2018)
- Plan to add to Display Page: 2021 (2019 data) & 2022 (2020 data); Consider for future Star Ratings (pending rulemaking)

Reduction in Share of Part D Enrollees Using Opioids



Source: Table 27 in 2019 Call Letter; Hospice and cancer patients excluded from opioid utilizer counts

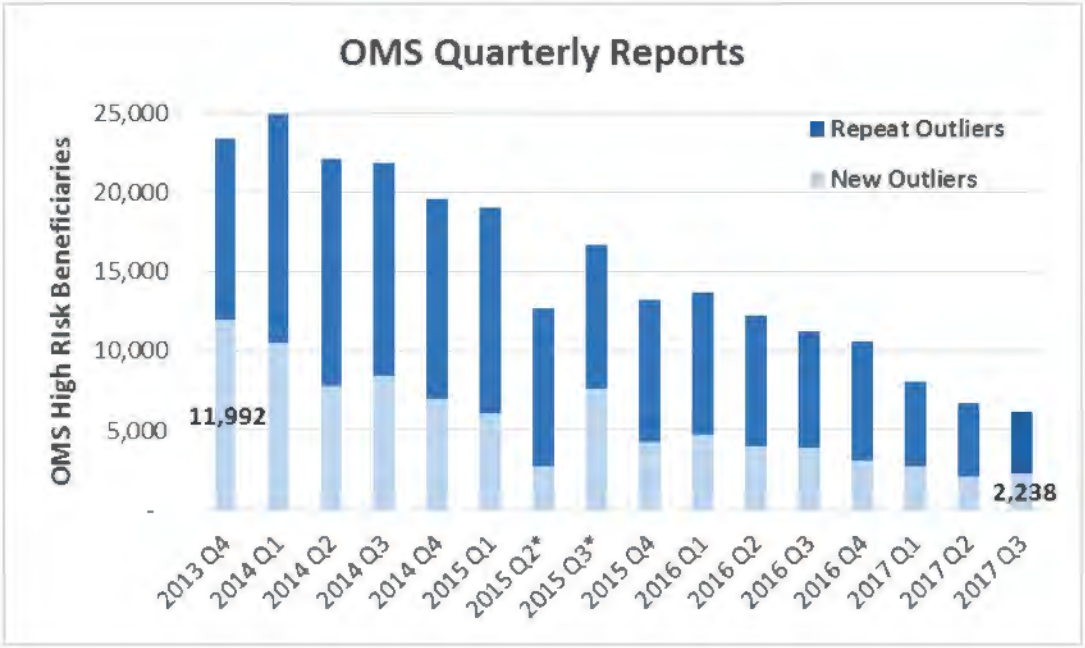
Impact of Policy, OMS



Number of potential high-risk opioid overutilizers decreased by 76%

Source: Table 27 in 2019 Call Letter; 2011 = pre-policy/pilots; 2013 – 2017 OMS criteria: During previous 12 months, > 120 MME for at least 90 consecutive days with more than 3 opioid prescribers and more than 3 opioid dispensing pharmacies contributing to their opioid claims, excluding beneficiaries with cancer and in hospice

Impact of Policy, OMS, "First Time" Overutilizers

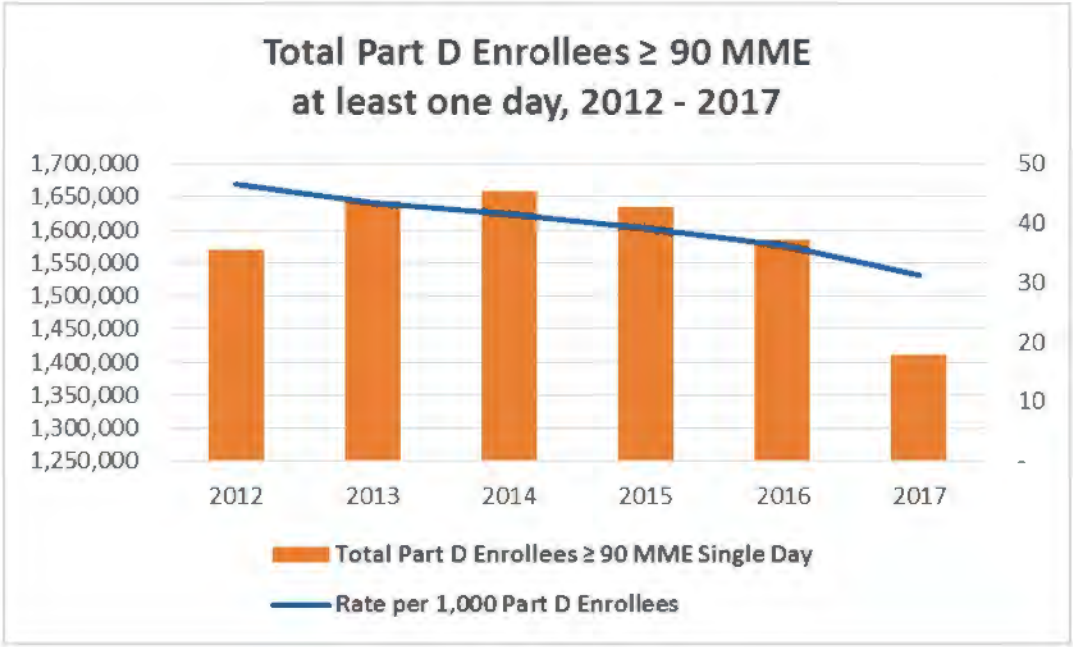


Number of "first-time" potential high-risk overutilizers decreased by 81%

Source: CMS OMS Quarterly Reports; *PDE data load lag issue Q2 2015-Q3 2015

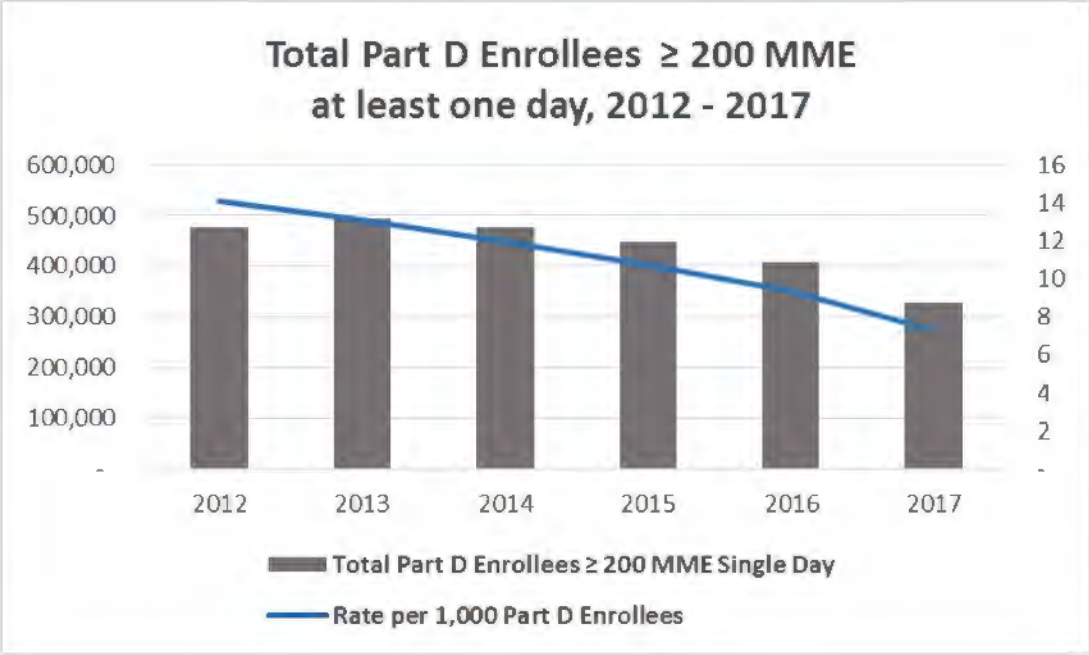
Impact of Policy, 90 MME Levels

33% decrease in rate of Part D enrollees meeting or exceeding 90 MME for at least one day from 2012 to 2017



Source: 2012 – 2016 SAF; 2017 PDE data as of 3/26/2018; Excluding beneficiaries with cancer, in hospice, or with overlapping dispensing dates for timely continued fills for the same opioid

Impact of Policy, 200 MME Levels



49% decrease in rate of Part D enrollees meeting or exceeding 200 MME for at least one day from 2012 to 2017

Source: 2012 – 2016 SAF; 2017 PDE data as of 3/26/2018; Excluding beneficiaries with cancer, in hospice care, or with overlapping dispensing dates for timely continued fills for the same opioid

Additional Information

- Part D Opioid Overutilization Policy Guidance: (https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/RxUtilization.html)
- Part D Appeals Guidance: Chapter 18 of the Prescription Drug Benefit Manual: (https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip)

Additional Information (continued)

- Eligibility & Enrollment Guidance – Medicare Prescription Drug Benefit Manual:

  Chapter 2 – MAPD
  https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/Downloads/CY_2018_MA_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf

  Chapter 3 – Part D
  https://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicarePresDrugEligEnrol/Downloads/CY_2018_PDP_Enrollment_and_Disenrollment_Guidance_6-15-17.pdf

MASH UNIT

PLEASE COMBINE THE FOLLOWING SIXTEEN (16) ALJ NUMBERS USING THE HIGHLIGHTED FIRST APPEAL NUMBER AS THE NUMBER FOR THE COMBINED CASE. THANK YOU.

OMHA Appeal Number	Appellant	Beneficiary	Medicare #	Claim Number
1-9000000001	MASH UNIT	AB	****0001A	9999999001
1-9000000002	MASH UNIT	AC	****0002A	9999999002
1-9000000003	MASH UNIT	AD	****0003	9999999003
1-9000000004	MASH UNIT	AE	****0004	9999999004
1-9000000005	MASH UNIT	AF	****0005	9999999005
1-9000000006	MASH UNIT	AG	****0006	9999999006
1-9000000007	MASH UNIT	AH	****0007	9999999007
1-9000000008	MASH UNIT	AI	****0008	9999999008
1-9000000009	MASH UNIT	AJ	****0009	9999999009
1-9000000010	MASH UNIT	AK	****0010	9999999010
1-9000000011	MASH UNIT	AL	****0011	9999999011
1-9000000012	MASH UNIT	AM	****0012	9999999012
1-9000000013	MASH UNIT	AN	****0013	9999999013
1-9000000014	MASH UNIT	AO	****0014	9999999014
1-9000000015	MASH UNIT	AP	****0015	9999999015
1-9000000016	MASH UNIT	AQ	****0016	9999999016

Master Appeal Number 1-9000000001

Federal Administrative Law Judges
Office of Medicare Hearing and Appeals

Judicial Educational Symposium – II

The Honorable William P. Farley

The Honorable Leslie B. Holt

Best Practices

Their Methods for Combining Medicare Cases

October 16, 2018

PRESENATION

- Combining a Part B case (Judge Farley)
- How to combine a Part A case (Judge Holt)

DISCLAIMER

- PEPD wants it clear that the documents we use are not templates and are not OMHA-recognized standards for adjudicators to follow.
- Feedback for improvement is highly encouraged.
- Nothing said today conflicts with the OCPM – any ambiguity would be settled by the OCPM.
- The OCPM is right.

Four Basic Parts of This Presentation

A. Beginning
B. Middle
C. End
D. Practicum Review

Beginning

A. Identify Appropriate Cases
- Same appellant
- Same item or service at issue
- Same or similar DRG Codes

Beginning (Con't)

B. Rule

- The controlling Rule/Law/Regulation is the same
- There is a common LCD
- There is more than one LCD, but they have the same requirements

Beginning (Con't)

Legal Assistants

- Discuss exhibiting
- Review Notice requirements
- Ensure the representative is still the same
- Identify if there may be PII issues
- Plan hearing schedule
- MAS/Settlement Check

Middle

- Develop/Acquire templates for writing decisions
- Train attorneys for writing decision
- Review current docket to ensure all appropriate cases will be combined
- Hold prehearing conference
- Hold consolidated hearing
  - Ensure that beneficiary PII is protected during the hearing in case a copy of the record is requested

End

- Remove cases that were dismissed at the hearing
- Send request for combination to (b)(6)
- Issue Combination Order (will change with eCAPE) and send encrypted to Central Operations
- Review decision plan with attorney
- Finalize decision

End (Continued)

- Go over PII with Legal Assistant for mailing decision
- Ensure decisions are combined in MAS and closed
- Thank staff for hard work

Practicum Review

- Two documents required for combining.
  - Combination Appeals Request
  - Combination Order
  - A Service Request is included, but not necessary

- Part B documents
  - Hearing Introduction and Form
  - Part B Decision
  - Contractor documents – LCD and Oxygen Check

REVIEW -- STEPS

- Identifying Appropriate Cases
- Reviewing
- Analyzing
- Tentatively select
- Determine need for pre-hearing conference
- Scheduling
- Hearing
- Deciding
- Closing

Judge Holt

- Part A Cases
- Part A Handouts Identification
- Overview of Part A Combination Determination
- Practical issues and concerns
- MAC Concerns
- Provider Concerns
- Results


Questions?

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Arlington, Virginia

Appeal of:	**MASH UNIT**	OMHA Appeal No.:	**1-9000000001**
Beneficiary:	**Multiple (16)**	**Medicare Part B**	
Medicare No.:	**Multiple (16)**	Before:	**William P. Farley** **Administrative Law Judge**

ORDER

In order to provide for administrative efficiency, the following OMHA Appeal Numbers are combined into the Appeal Number noted above and bolded on the following table.

OMHA Appeal Number	Appellant	Beneficiary	Medicare #	Claim Number	DOS From	DOS To
1-9000000001	MASH UNIT	1	****0001A	9999999001	10/3/2015	1/3/2016
1-9000000002	MASH UNIT	2	****0002A	9999999002	1/12/2016	3/12/2016
1-9000000003	MASH UNIT	3	****0003	9999999003	9/9/2016	12/9/2016
1-9000000004	MASH UNIT	4	****0004	9999999004	9/12/2016	12/12/2016
1-9000000005	MASH UNIT	5	****0005	9999999005	9/14/2016	12/14/2016
1-9000000006	MASH UNIT	6	****0006	9999999006	11/10/2016	11/10/2016
1-9000000007	MASH UNIT	7	****0007	9999999007	4/4/2016	4/4/2016
1-9000000008	MASH UNIT	8	****0008	9999999008	9/12/2016	12/12/2016
1-9000000009	MASH UNIT	9	****0009	9999999009	1/6/2016	2/6/2016
1-9000000010	MASH UNIT	10	****0010	9999999010	4/10/2016	5/10/2016
1-9000000011	MASH UNIT	11	****0011	9999999011	9/23/2016	12/23/2016
1-9000000012	MASH UNIT	12	****0012	9999999012	10/12/2015	1/12/2016
1-9000000013	MASH UNIT	13	****0013	9999999013	10/11/2015	12/11/2015
1-9000000014	MASH UNIT	14	****0014	9999999014	10/11/2015	1/11/2016
1-9000000015	MASH UNIT	15	****0015	9999999015	10/1/2015	1/11/2016
1-9000000016	MASH UNIT	16	****0016	9999999016	10/12/2016	10/12/2016

SO ORDERED.

Dated: _____

_____
William P. Farley
Administrative Law Judge

Judicial Education Symposium
QAP Recommendations OTR and Part A
November 14, 2019

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    b. On-the-Record
        i. Appropriate citation
        ii. Notice to appropriate parties pursuant to 42 C.F.R. § 405.1038(b)
    c. Admission and Exclusion of New Evidence
        i. Submitting evidence – 42 C.F.R. § 405.1018
        ii. Review of evidence submitted by the parties – 42 C.F.R. § 405.1028
    d. Hearings – Best Practices
    e. Notice of Decision
IV. Conclusion

Social Security Act Section 1879(a) Where—

(1) a determination is made that, by reason of section **1862(a)(1) or (9)** or by reason of a coverage denial described in subsection **(g)**, payment may not be made under part A or part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(iii), and

(2) both such individual and such provider of services or such other person, as the case may be, **did not know, and could not reasonably have heen expected to know**, that payment would not be made for such items or services under such part A or part B,

then to the extent permitted by this title, **payment shall**, notwithstanding such determination, **be made** for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this title), as though section 1862(a)(1) and section 1862(a)(9) did not apply and as though the coverage denial described in subsection (g) had not occurred.

Basis for Denial	Example/Explanation
Act § 1862(a)(1)*	Act § 1861(a)(1)(A) - Items and services found to be **not reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member AND See Table Below
Act § 1862(a)(9)	No payment may be made under part A or part B for any expenses incurred for **custodial care** (except, in the case of hospice care, pursnant to Act § 1861(a) (1)(C)).
Act § 1879(g)(1)	With respect to the provision of home health services to an individual, a failure to meet the requirements of Act §§ 1814(a)(2)(c) or 1835(a)(2)(A) in that the individual— (A) was **not confined to his home**, or (B) did not need skilled nursing care on an intermittent basis;
Act § 1879(g) (2)	With respect to the provision of hospice care to an individnal, a determination that the individual is **not terminally ill**. *See* Act § 1861(dd)(3)

When Medicare payment is made under the limitation on liability provisions, the payment determination includes claims for any **dependent services** that are denied as an indirect result of the original denial. Thus, where a particular qualifying service is denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act, any dependent services are also denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act.

If the limitation on liability provisions apply to the denial of the qualifying service, it will also apply to the dependent service, and Medicare will make payment for both services, provided all other conditions for coverage and payment are met. Also, the limitation on liability provisions may apply if a reduction in payment occurs because the furnished items or services are at a **higher level of care** and provide more extensive items or services than was reasonable and necessary to meet the needs of the beneficiary, i.e. ambulance transportation service down-coding, DRG down-coding, RUG down-coding, hospice service down-coding, and over-utilization.

Coverage Denial

1862(a)(1)(A)	Items and services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.
1862(a)(1)(B)	Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness. *See* Act § 1861(s)(10).
1862(a)(1)(C)	In the case of hospice care, items and services that are not reasonable and necessary for the palliation or management of terminal illness.
1862(a)(1)(D)	In the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6) of the Act.
1862(a)(1)(E)	Items and services that, in the case of research conducted pursuant to section1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures).
1862(a)(1)(F)	Screening mammography that is performed more frequently than is covered under section 1834(c)(2) of the Act or that is not conducted by a facility described in section 1834(c)(1)(B) of the Act and screening pap smears and screening pelvic exams performed more frequently than is provided for under section1861(nn) of the Act. Screening for glaucoma, which is performed more frequently than is provided under section 1861(uu) of the Act.
1862(a)(1)(G)	Prostate cancer screening tests (as defined section §1861(oo) of the Act), which are performed more frequently than is covered nnder snch section.
1862(a)(1)(H)	Colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d) of the Act.
1862(a)(1)(I)	The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation.
1862(a)(1)(J)	Drugs or biologicals specified in section 1847A(c)(6)(C) of the Act, for which payment is made under part B, furnished in a competitive area under section 1847B of the Act, but not furnished by an entity under a contract under section 1847(B) of the Act.
1862(a)(1)(K)	An initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under Medicare Part B.
1862(a)(1)(L)	Cardiovascular screening blood tests (as defined in section 1861(xx)(1) of the Act), which are performed more frequently than is covered under section 1861(xx)(2).
1862(a)(1)(M)	A diabetes screening test (as defined in section 1861(yy)(1) of the Act), which is performed more frequently than is covered under section 1861(yy)(3) of the Act.
1862(a)(1)(N)	An ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section1861(s)(2)(AA) of the Act
1862(a)(1)(O)	Kidney disease education services (as defined in section 1861(ggg)(1) of the Act) which are furnished in excess of the number of sessions covered under section 1861(ggg)(4) of the Act. Personalized prevention plan services (as defined in section 1861 (hhh)(1) of the Act), which are performed more frequently than is covered under such section.

Social Security Act Section 1870.

(a) Any payment under this title to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

(b) Where

(1) **more than the correct amount is paid** under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, **within such period** as he may specify, the excess over the correct amount **cannot be recouped from** such provider of services or other person, or (B) that such **provider of services or other person was without fault** with respect to the payment of such excess over the correct amount, . . .

For purposes of clause (B) of paragraph (1), **such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination** that more than such correct amount was paid **was made subsequent to the fifth year following the year in which notice was sent** to such individual **that such amount had been paid;** except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

(c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to **an individual who is without fault** or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) **would defeat the purposes of title II or title XVIII or would be against equity and good conscience.** Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1862(a) and (B) if the Secretary's determination that such payment was **incorrect was made subsequent to the fifth year following the year in which notice of such payment** was sent to such individual; except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

Categorical Denials are items and services specifically excluded by statute. The limitation on liability provision does not apply because the Medicare payment denial is based on a statutory provision not referenced in section 1879 of the Act.

1862(a)(2)	Services for which there is no legal obligation to pay.
1862(a)(3)	Services paid for by a governmental entity that is not Medicare.
1862(a)(4)	Health care received outside of the U.S. not covered by Medicare.
1862(a)(5)	Services required as a result of war.
1862(a)(6)	**Personal comfort items.**
1862(a)(7)	**Routine physicals and most screening tests** of the Act.
1862(a)(7)	**Most immunizations (vaccinations); Routine eye care, most eyeglasses and examinations; Hearing aids and hearing aid examinations**
1862(a)(8)	**Orthopedic shoes and foot supports (orthotics).**
1862(a)(10)	**Cosmetic surgery.**
1862(a)(11)	Services by immediate relatives.
1862(a)(12)	**Dental care and dentures (in most cases).**
1862(a)(13)	Routine foot care and flat foot care.
1862(a)(14)	Physicians' services performed by a physician assistant, midwife, psychologist, or nurse anesthetist, when **furnished to an inpatient,** unless they are furnished under arrangement with the hospital.
1862(a)(15)	Services of an assistant at surgery without prior approval from the peer review organization.
1862(a)(16)	Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997.
1862(a)(17)	Items or services furnished in a competitive acquisition area by any entity that does not have a contract with the Department of Health and Human Services (except in a case of urgent need).
1862(a)(18)	Items and services furnished **to an individual who is a resident of a skilled nursing facility** or of a part of a facility that includes a skilled nursing facility, unless they are furnished under arrangements by the skilled nursing facility.

1862(a)(19)	Services under a physician's private contract.
1862(a)(20)	Outpatient occupational and physical therapy services furnished incident to a physician's services.
1862(a)(21)	Home health services furnished under a plan of care, if **the agency does not submit the claim**.
1862(a)(22)	Claims submitted other than in an electronic form specified by the Secretary, subject to the exceptions set forth in section 1862(h) of the Act.
1862(a)(23)	The technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) of the Act for which payment is made under the fee schedule established under section 1848(b) of the Act and that are furnished by an accredited supplier. *See* Act §§ 1861(d) and 1834(e)(2)(B).
1862(a)(24)	Renal dialysis services (as defined in 1881(b)(14)(B) of the Act) for which payment is made under such section, unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.
1862(a)(25)	Not later than January 1, 2014, for which the payment is other than by electronic funds transfer or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Technical Denial - When the **definition** for a particular item or service is not met, it is not a Medicare benefit; therefore, Medicare denies payment.

1861(s)(2)	Part B Drugs that are usually self-administered.
1861(s)(5)	Payment for a dressing is denied because it does not meet the definition for "surgical dressings"
1861(s)(6)	Payment is denied for item because it does not meet the definition of "Durable Medical Equipment"
1861(s)(7)	Ambulance services denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR 410.40, such as those relating to destination or nearest appropriate facility, are not met.
1861(s)(12)	Exception for orthopedic shoes (Act § 1862(a)(8)).
1861(i)	Payment for SNF stays not preceded by the required 3-day hospital stay or Payment for SNF stay because the beneficiary did not meet the requirement for transfer to a SNF and for receiving covered services within 30 days after discharge from the hospital and because the special requirements for extension of the 30 days were not met.
1861(v)(2)	Payment for the additional cost of a private room in a hospital or SNF is denied when the private accommodations are not required for medical reasons.

Technical Denial - Payment is also barred for failure to meet a **condition of payment** required by regulations. A condition that the provider/supplier must satisfy, even if the coverage criteria are met, to receive Medicare reimbursement.

Part A – Condition of Payment

42 C.F.R. § 412.622	Missing/Invalid or Untimely **IRF** Patient Assessment Instrument
42 C.F.R. §§ 424.5 and 424.20	Missing/Invalid Certification or recertification of POC for **SNF** Services
42 C.F.R. §§ 424.5 and 424.22	Missing/Invalid Certification or recertification of POC for **HH** Services
42 C.F.R. § 418.22	Missing/Invalid Certification or recertification of terminal illness for **Hospice** Services

42 C.F.R. § 489.21(b)(2) provides that, as part of Part A provider agreements, providers agree not to charge beneficiaries for services that beneficiaries would have been entitled payment, if the required certification and recertification were on file, or if information required by the CMS contractor was furnished to determine the amount due. *See* Act § 1866(a)(1)(A).

Part B – Condition of Payment

42 C.F.R. § 424.24	Missing/Invalid Certification or recertification of POC for **Outpatient Therapy** Services
42 C.F.R. § 410.38(c)	Missing/Invalid Written Order Prior to Delivery, including face-to-face requirement, for **Power Mobility Device** – 42 C.F.R. § 410.38(c)(2)(i) Missing/Invalid Seven-Element Order for **Power Mobility Device** • Order completed within 45 days following the face-to-face exam • Order must be signed and dated by same physician who conducted the face-to-face exam – 42 C.F.R. § 410.38(c)(2)(ii)
42 C.F.R. § 410.38(g)	Missing/Invalid Written Order Prior to Delivery, including face-to-face examination in the preceding six months: (1) Items that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A **list of these items is updated annually** in the Federal Register and include items described by HCPCS code for the following types of DME: • Transcutaneous Electrical Nerve Stimulation unit • Rollabout chair • Oxygen and respiratory equipment • Hospital beds and accessories and • Cervical traction https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html (March 26, 2015), (2) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling or greater than $1,000, and (3) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

Other

I. **Therapy Cap** - Limit on the amount of outpatient therapy that Medicare will cover for a beneficiary each calendar year from 2006 – 2017. There is no therapy cap for services after January 1, 2018.

Dates of Service	Denial basis	Result
Denials January 1, 2006 – December 31, 2012	Act § 1833(g)	Act § 1879 does not apply
Denials Post-January 1, 2013 – December 31, 2017	Act § 1833(g)(5)(D)	Act § 1879 applies
Denials Post - January 1, 2018	N/A	N/A

II. **Special Payment Rules for Particular Items and Services and Refund Requirement Provisions**

a. **Non-Participating Supplier**

i. Act § 1834(j)(1) – **No payment** may be made for items furnished by a supplier of medical equipment and supplies **unless** such supplier obtains a **supplier nnmber.**

ii. Act § 1834(j)(4) – Non-participating **suppliers are responsible for the costs** of DMEPOS furnished without a valid supplier number.

iii. Act § 1834(a)(18) – Non-participating suppliers are responsible for the costs **nnless:** 1) Supplier shows it did not know or could not reasonably have been expected to know that payment may not be made; or 2) Before the item was furnished, the patient was informed that payment may not be made and the **patient agreed to pay** for that item.

iv. Act § 1879(h) – If a supplier of medical equipment and supplies furnishes an item or service to a beneficiary for which no payment may be made by reason of section 1834(j)(1) of the Act.

b. **Non-Participating Physician**

i. Act §1842(l)(1)(A)(i) – nonparticipating physician furnishes services to beneficiary.

ii. Act § 1841(l)(1)(A)(iv) – if the physician has collected any amounts for such services, the physician shall refund on a timely basis to the individual any amounts so collected.

iii. Act § 1842(l)(1)(C) – non-participating physician are responsible **unless**: the non-participating physician establishes that (1) the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1862(a)(1) of the Act; or (2) the physician establishes that before the service were rendered the physician informed the patient that payment may not be made for the specific service and the **patient agreed to pay** for that service.

III. NCCI Edits - CPT codes representing services denied based on NCCI edits may not be billed to Medicare beneficiaries. Because these denials are based on incorrect coding rather than medical necessity, the provider cannot utilize an "Advanced Beneficiary Notice" form or a "Notice of Exclusions from Medicare Benefits" form to seek payment from a Medicare beneficiary. *See* CMS, *National Correct Coding Initiative Policy Manual, Introduction.*

a. Column One/Column Two Correct Code Edits – NCCI code pair edits are automated prepayment edits that prevent improper payment when certain codes are submitted together for Part B-covered services. If two codes of a code pair edit are billed by the same provider for the same beneficiary for the same date of service without an appropriate modifier, the column 1 HCPCS/CPT code is paid. There are two types of code pair edits:

   i. One type contains a column 2 HCPCS/ CPT code which is an **integral part** of the column 1 HCPCS/CPT code.

   ii. The other type contains code pairs that should not be reported together where one HCPCS/CPT code is assigned as the column 1 code and the other HCPCS/CPT code is assigned as the column 2 code.

b. Medically Unlikely Edits (MUE) – An MUE is a unit of service edit for a HCPCS)/ CPT code for services rendered by a single provider/supplier to a single beneficiary on the same date of service.

   i. The ideal MUE is the **maximum unit of service that would be reported** for a HCPCS/CPT code on the **vast majority of appropriately reported claims**. The MUE program provides a method to report medically reasonable and necessary units of service in excess of an MUE for MUEs that are adjudicated as claim line edits.

   ii. The MUE file included edits where two procedures could not be performed at the same patient encounter because the two procedures were **mutually exclusive** based on anatomic, temporal, or gender considerations.

c. Modifiers may be appended to HCPCS/CPT codes only if the clinical circumstances justify the use of the modifier. A modifier should not be appended to a HCPCS/CPT code solely to bypass an NCCI edit if the clinical circumstances do not justify its use.

IV. Capped Rental Items

a. Act § 1834(a)(7) – Ownership after Rental. If an item is purchased, then on the first day that begins after the **13th continuous** month during which payment is made for the rental of a "capped rental item," the supplier of the item shall transfer title to the item to the individual.

b. 42 C.F.R. § 414.229 – Other Durable Medical Equipment – capped rental items (wheel chairs, parenteral/enteral pump, oxygen supplies, hospital beds, mattress overlays, alternating pressure pads, suction pumps, continuous airway pressure devices, patient lifts, trapeze bars, etc.)

c. CMS, *Medicare Claims Processing Manual (Internet-only Manual Publ'n 100-04)* ch. 20, § 30.5.

   i. Medicare Part B does not cover purchase of capped rental item without renting first.

   ii. The option to purchase is given at the tenth month. Except in the case of electric wheelchairs only, the beneficiary must be given a purchase option at the time the equipment is first provided.

   iii. If the purchase option is not exercised, Medicare will continue to pay rental fees until the 15-month cap is reached and ownership of the equipment remains with the supplier. The supplier must continue to provide the item without any charge, other than for the maintenance and servicing fees until medical necessity ends.

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Social Security Act Section 1879(a) Where—

(1) a determination is made that, by reason of section **1862(a)(1) or (9)** or by reason of a coverage denial described in subsection **(g)**, payment may not be made under part A or part B of this title for any expenses incurred for items or services furnished an individual by a provider of services or by another person pursuant to an assignment under section 1842(b)(3)(B)(iii), and

(2) both such individual and such provider of services or such other person, as the case may be, **did not know, and could not reasonably have heen expected to know**, that payment would not be made for such items or services under such part A or part B,

then to the extent permitted by this title, **payment shall**, notwithstanding such determination, **be made** for such items or services (and for such period of time as the Secretary finds will carry out the objectives of this title), as though section 1862(a)(1) and section 1862(a)(9) did not apply and as though the coverage denial described in subsection (g) had not occurred.

Basis for Denial	Example/Explanation
Act § 1862(a)(1)*	Act § 1862(a)(1)(A) - Items and services found to be **not reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member AND See Table Below
Act § 1862(a)(9)	No payment may be made under part A or part B for any expenses incurred for **custodial care** (except, in the case of hospice care, pursnant to Act § 1862(a)(1)(C)).
Act § 1879(g)(1)	With respect to the provision of home health services to an individual, a failure to meet the requirements of Act §§ 1814(a)(2)(c) or 1835(a)(2)(A) in that the individual— (A) was **not confined to his home**, or (B) did not need skilled nursing care on an intermittent basis;
Act § 1879(g)(2)	With respect to the provision of hospice care to an individnal, a determination that the individual is **not terminally ill**. *See* Act § 1861(dd)(3)

When Medicare payment is made under the limitation on liability provisions, the payment determination includes claims for any **dependent services** that are denied as an indirect result of the original denial. Thus, where a particular qualifying service is denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act, any dependent services are also denied as not reasonable and necessary under section 1862(a)(1)(A) of the Act.

If the limitation on liability provisions apply to the denial of the qualifying service, it will also apply to the dependent service, and Medicare will make payment for both services, provided all other conditions for coverage and payment are met. Also, the limitation on liability provisions may apply if a reduction in payment occurs because the furnished items or services are at a **higher level of care** and provide more extensive items or services than was reasonable and necessary to meet the needs of the beneficiary, i.e. ambulance transportation service down-coding, DRG down-coding, RUG down-coding, hospice service down-coding, and over-utilization.

Coverage Denial

1862(a)(1)(A)	Items and services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.
1862(a)(1)(B)	Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness. *See* Act § 1861(s)(10).
1862(a)(1)(C)	In the case of hospice care, items and services that are not reasonable and necessary for the palliation or management of terminal illness.
1862(a)(1)(D)	In the case of clinical care items and services provided with the concurrence of the Secretary and with respect to research and experimentation conducted by, or under contract with, the Medicare Payment Advisory Commission or the Secretary, which are not reasonable and necessary to carry out the purposes of section 1886(e)(6) of the Act.
1862(a)(1)(E)	Items and services that, in the case of research conducted pursuant to section1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures).
1862(a)(1)(F)	Screening mammography that is performed more frequently than is covered under section 1834(c)(2) of the Act or that is not conducted by a facility described in section 1834(c)(1)(B) of the Act and screening pap smears and screening pelvic exams performed more frequently than is provided for under section1861(nn) of the Act. Screening for glaucoma, which is performed more frequently than is provided under section 1861(uu) of the Act.
1862(a)(1)(G)	Prostate cancer screening tests (as defined section §1861(oo) of the Act), which are performed more frequently than is covered nnder snch section.
1862(a)(1)(H)	Colorectal cancer screening tests, which are performed more frequently than is covered under section 1834(d) of the Act.
1862(a)(1)(I)	The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation.
1862(a)(1)(J)	Drugs or biologicals specified in section 1847A(c)(6)(C) of the Act, for which payment is made under part B, furnished in a competitive area under section 1847B of the Act, but not furnished by an entity under a contract under section 1847(B) of the Act.
1862(a)(1)(K)	An initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under Medicare Part B.
1862(a)(1)(L)	Cardiovascular screening blood tests (as defined in section 1861(xx)(1) of the Act), which are performed more frequently than is covered under section 1861(xx)(2).
1862(a)(1)(M)	A diabetes screening test (as defined in section 1861(yy)(1) of the Act), which is performed more frequently than is covered under section 1861(yy)(3) of the Act.
1862(a)(1)(N)	An ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section1861(s)(2)(AA) of the Act
1862(a)(1)(O)	Kidney disease education services (as defined in section 1861(ggg)(1) of the Act) which are furnished in excess of the number of sessions covered under section 1861(ggg)(4) of the Act. Personalized prevention plan services (as defined in section 1861 (hhh)(1) of the Act), which are performed more frequently than is covered under such section.

Social Security Act Section 1870.

(a) Any payment under this title to any provider of services or other person with respect to any items or services furnished any individual shall be regarded as a payment to such individual.

(b) Where

(1) **more than the correct amount is paid** under this title to a provider of services or other person for items or services furnished an individual and the Secretary determines (A) that, **within such period** as he may specify, the excess over the correct amount **cannot be recouped from** such provider of services or other person, or (B) that such **provider of services or other person was without fault** with respect to the payment of such excess over the correct amount, . . .

For purposes of clause (B) of paragraph (1), **such provider of services or such other person shall, in the absence of evidence to the contrary, be deemed to be without fault if the Secretary's determination** that more than such correct amount was paid **was made subsequent to the fifth year following the year in which notice was sent** to such individual **that such amount had been paid;** except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

(c) There shall be no adjustment as provided in subsection (b) (nor shall there be recovery) in any case where the incorrect payment has been made (including payments under section 1814(e)) with respect to **an individual who is without fault** or where the adjustment (or recovery) would be made by decreasing payments to which another person who is without fault is entitled as provided in subsection (b)(4), if such adjustment (or recovery) **would defeat the purposes of title II or title XVIII or would be against equity and good conscience.** Adjustment or recovery of an incorrect payment (or only such part of an incorrect payment as the Secretary determines to be inconsistent with the purposes of this title) against an individual who is without fault shall be deemed to be against equity and good conscience if (A) the incorrect payment was made for expenses incurred for items or services for which payment may not be made under this title by reason of the provisions of paragraph (1) or (9) of section 1862(a) and (B) if the Secretary's determination that such payment was **incorrect was made subsequent to the fifth year following the year in which notice of such payment** was sent to such individual; except that the Secretary may reduce such five-year period to not less than one year if he finds such reduction is consistent with the objectives of this title.

Categorical Denials are items and services specifically excluded by statute. The limitation on liability provision does not apply because the Medicare payment denial is based on a statutory provision not referenced in section 1879 of the Act.

1862(a)(2)	Services for which there is no legal obligation to pay.
1862(a)(3)	Services paid for by a governmental entity that is not Medicare.
1862(a)(4)	Health care received outside of the U.S. not covered by Medicare.
1862(a)(5)	Services required as a result of war.
1862(a)(6)	**Personal comfort items.**
1862(a)(7)	**Routine physicals and most screening tests** of the Act.
1862(a)(7)	**Most immunizations (vaccinations); Routine eye care, most eyeglasses and examinations; Hearing aids and hearing aid examinations**
1862(a)(8)	**Orthopedic shoes and foot supports (orthotics).**
1862(a)(10)	**Cosmetic surgery.**
1862(a)(11)	Services by immediate relatives.
1862(a)(12)	**Dental care and dentures (in most cases).**
1862(a)(13)	Routine foot care and flat foot care.
1862(a)(14)	Physicians' services performed by a physician assistant, midwife, psychologist, or nurse anesthetist, when **furnished to an inpatient,** unless they are furnished under arrangement with the hospital.
1862(a)(15)	Services of an assistant at surgery without prior approval from the peer review organization.
1862(a)(16)	Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997.
1862(a)(17)	Items or services furnished in a competitive acquisition area by any entity that does not have a contract with the Department of Health and Human Services (except in a case of urgent need).
1862(a)(18)	Items and services furnished **to an individual who is a resident of a skilled nursing facility** or of a part of a facility that includes a skilled nursing facility, unless they are furnished under arrangements by the skilled nursing facility.

1862(a)(19)	Services under a physician's private contract.
1862(a)(20)	Outpatient occupational and physical therapy services furnished incident to a physician's services.
1862(a)(21)	Home health services furnished under a plan of care, if **the agency does not submit the claim**.
1862(a)(22)	Claims submitted other than in an electronic form specified by the Secretary, subject to the exceptions set forth in section 1862(h) of the Act.
1862(a)(23)	The technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) of the Act for which payment is made under the fee schedule established under section 1848(b) of the Act and that are furnished by an accredited supplier. *See* Act §§ 1861(d) and 1834(e)(2)(B).
1862(a)(24)	Renal dialysis services (as defined in 1881(b)(14)(B) of the Act) for which payment is made under such section, unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.
1862(a)(25)	Not later than January 1, 2014, for which the payment is other than by electronic funds transfer or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

Technical Denial - When the **definition** for a particular item or service is not met, it is not a Medicare benefit; therefore, Medicare denies payment.

1861(s)(2)	Part B Drugs that are usually self-administered.
1861(s)(5)	Payment for a dressing is denied because it does not meet the definition of "surgical dressings"
1861(s)(6)	Payment is denied for item because it does not meet the definition of "Durable Medical Equipment"
1861(s)(7)	Ambulance services denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR § 410.40, such as those relating to destination or nearest appropriate facility, are not met.
1861(s)(12)	Exception for orthopedic shoes (Act § 1862(a)(8)).
1861(i)	Payment for SNF stays not preceded by the required 3-day hospital stay or Payment for SNF stay because the beneficiary did not meet the requirement for transfer to a SNF and for receiving covered services within 30 days after discharge from the hospital and because the special requirements for extension of the 30 days were not met.
1861(v)(2)	Payment for the additional cost of a private room in a hospital or SNF is denied when the private accommodations are not required for medical reasons.

Technical Denial - Payment is also barred for failure to meet a **condition of payment** required by regulations. A condition that the provider/supplier must satisfy, even if the coverage criteria are met, to receive Medicare reimbursement.

Part A – Condition of Payment

42 C.F.R. § 412.622	Missing/Invalid or Untimely **IRF** Patient Assessment Instrument
42 C.F.R. §§ 424.5 and 424.20	Missing/Invalid Certification or recertification of POC for **SNF** Services
42 C.F.R. §§ 424.5 and 424.22	Missing/Invalid Certification or recertification of POC for **HH** Services
42 C.F.R. § 418.22	Missing/Invalid Certification or recertification of terminal illness for **Hospice** Services

42 C.F.R. § 489.21(b)(2) provides that, as part of Part A provider agreements, providers agree not to charge beneficiaries for services that beneficiaries would have been entitled payment, if the required certification and recertification were on file, or if information required by the CMS contractor was furnished to determine the amount due. *See* Act § 1866(a)(1)(A).

Part B – Condition of Payment

42 C.F.R. § 424.24	Missing/Invalid Certification or recertification of POC for **Outpatient Therapy** Services
42 C.F.R. § 410.38(c)	Missing/Invalid Written Order Prior to Delivery, including face-to-face requirement, for **Power Mobility Device** – 42 C.F.R. § 410.38(c)(2)(i) Missing/Invalid Seven-Element Order for **Power Mobility Device** • Order completed within 45 days following the face-to-face exam • Order must be signed and dated by same physician who conducted the face-to-face exam – 42 C.F.R. § 410.38(c)(2)(ii)
42 C.F.R. § 410.38(g)	Missing/Invalid Written Order Prior to Delivery, including face-to-face examination in the preceding six months: (1) Items that CMS has specified in accordance with section 1834(a)(11)(B)(i) of the Act. A **list of these items is updated annually** in the Federal Register and include items described by HCPCS code for the following types of DME: • Transcutaneous Electrical Nerve Stimulation unit • Rollabout chair • Oxygen and respiratory equipment • Hospital beds and accessories and • Cervical traction https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html (March 26, 2015), (2) Any item of durable medical equipment that appears on the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies Fee Schedule with a price ceiling or greater than $1,000, and (3) Any other item of durable medical equipment that CMS adds to the list of Specified Covered Items through the notice and comment rulemaking process in order to reduce the risk of fraud, waste, and abuse.

Other

I. **Therapy Cap** - Limit on the amount of outpatient therapy that Medicare will cover for a beneficiary each calendar year from 2006 – 2017. There is no therapy cap for services after January 1, 2018.

Dates of Service	Denial basis	Result
Denials January 1, 2006 – December 31, 2012	Act § 1833(g)	Act § 1879 does not apply
Denials Post-January 1, 2013 – December 31, 2017	Act § 1833(g)(5)(D)	Act § 1879 applies
Denials Post - January 1, 2018	N/A	N/A

II. **Special Payment Rules for Particular Items and Services and Refund Requirement Provisions**

a. **Non-Participating Supplier**

i. Act § 1834(j)(1) – **No payment** may be made for items furnished by a supplier of medical equipment and supplies **unless** such supplier obtains a **supplier nnmber.**

ii. Act § 1834(j)(4) – Non-participating **suppliers are responsible for the costs** of DMEPOS furnished without a valid supplier number.

iii. Act § 1834(a)(18) – Non-participating suppliers are responsible for the costs **nnless:** 1) Supplier shows it did not know or could not reasonably have been expected to know that payment may not be made; or 2) Before the item was furnished, the patient was informed that payment may not be made and the **patient agreed to pay** for that item.

iv. Act § 1879(h) – If a supplier of medical equipment and supplies furnishes an item or service to a beneficiary for which no payment may be made by reason of section 1834(j)(1) of the Act.

b. **Non-Participating Physician**

i. Act §1842(l)(1)(A)(i) – nonparticipating physician furnishes services to beneficiary.

ii. Act § 1841(l)(1)(A)(iv) – if the physician has collected any amounts for such services, the physician shall refund on a timely basis to the individual any amounts so collected.

iii. Act § 1842(l)(1)(C) – non-participating physician are responsible **unless**: the non-participating physician establishes that (1) the physician did not know and could not reasonably have been expected to know that payment may not be made for the service by reason of section 1862(a)(1) of the Act; or (2) the physician establishes that before the service were rendered the physician informed the patient that payment may not be made for the specific service and the **patient agreed to pay** for that service.

III. NCCI Edits - CPT codes representing services denied based on NCCI edits may not be billed to Medicare beneficiaries. Because these denials are based on incorrect coding rather than medical necessity, the provider cannot utilize an "Advanced Beneficiary Notice" form or a "Notice of Exclusions from Medicare Benefits" form to seek payment from a Medicare beneficiary. *See* CMS, *National Correct Coding Initiative Policy Manual, Introduction.*

a. Column One/Column Two Correct Code Edits – NCCI code pair edits are automated prepayment edits that prevent improper payment when certain codes are submitted together for Part B-covered services. If two codes of a code pair edit are billed by the same provider for the same beneficiary for the same date of service without an appropriate modifier, the column 1 HCPCS/CPT code is paid. There are two types of code pair edits:

   i. One type contains a column 2 HCPCS/ CPT code which is an **integral part** of the column 1 HCPCS/CPT code.

   ii. The other type contains code pairs that should not be reported together where one HCPCS/CPT code is assigned as the column 1 code and the other HCPCS/CPT code is assigned as the column 2 code.

b. Medically Unlikely Edits (MUE) – An MUE is a unit of service edit for a HCPCS)/ CPT code for services rendered by a single provider/supplier to a single beneficiary on the same date of service.

   i. The ideal MUE is the **maximum unit of service that would be reported** for a HCPCS/CPT code on the **vast majority of appropriately reported claims**. The MUE program provides a method to report medically reasonable and necessary units of service in excess of an MUE for MUEs that are adjudicated as claim line edits.

   ii. The MUE file included edits where two procedures could not be performed at the same patient encounter because the two procedures were **mutually exclusive** based on anatomic, temporal, or gender considerations.

c. Modifiers may be appended to HCPCS/CPT codes only if the clinical circumstances justify the use of the modifier. A modifier should not be appended to a HCPCS/CPT code solely to bypass an NCCI edit if the clinical circumstances do not justify its use.

IV. Capped Rental Items

a. Act § 1834(a)(7) – Ownership after Rental. If an item is purchased, then on the first day that begins after the **13th continuous** month during which payment is made for the rental of a "capped rental item," the supplier of the item shall transfer title to the item to the individual.

b. 42 C.F.R. § 414.229 – Other Durable Medical Equipment – capped rental items (wheel chairs, parenteral/enteral pump, oxygen supplies, hospital beds, mattress overlays, alternating pressure pads, suction pumps, continuous airway pressure devices, patient lifts, trapeze bars, etc.)

c. CMS, *Medicare Claims Processing Manual (Internet-only Manual Publ'n 100-04)* ch. 20, § 30.5.

   i. Medicare Part B does not cover purchase of capped rental item without renting first.

   ii. The option to purchase is given at the tenth month. Except in the case of electric wheelchairs only, the beneficiary must be given a purchase option at the time the equipment is first provided.

   iii. If the purchase option is not exercised, Medicare will continue to pay rental fees until the 15-month cap is reached and ownership of the equipment remains with the supplier. The supplier must continue to provide the item without any charge, other than for the maintenance and servicing fees until medical necessity ends.

OCPM Chapter 15: Practical Applications

Or

Why can't I just keep doing hearings the way I have done them for the last 14 years?

Brian J. Haring

Deputy Chief Administrative Law Judge

OCPM Ch. 15 – Background and Basis

- Why?

  - APA standards
  - Uniformity and Fairness
  - Public Service

OCPM Ch. 15 – Background and Basis

Statutes

- APA, Pub. L. 79–404, 60 Stat. 237 (June 11, 1946)
- Medicare Prescription Drug, Improvement and Modernization Act of 2003

Case Law

- J. W. Hampton, Jr. & Co. v. United States, 276 U.S. 394, 407 (1928)
- Chevron v. Natural Resources Defense Council, 467 U.S. 837 (1984)
- Jefferson University v. Shalala, 512 U.S. 504 (1994);
- Maximum Comfort Inc. v. Secretary of Health and Human Services, 512 F.3d 1081 (9th Cir. 2007)
- Goldberg v Kelly, 397 U.S. 254 (1970)

OCPM Ch. 15 – Background and Basis

- **SALJ Position Description**
- **CALJ Delegation of Authority (Secretary)**

Quality Assurance Program (QAP) Results

- Example – "Right to Counsel"
  - 5 U.S.C. § 555(b)
  - 42 C.F.R. § 405.902
  - 42 C.F.R. §405.910

Section 15.1: Prehearing and posthearing conferences

Is there a right to a prehearing or posthearing conference?

- No. A party may request a conference, but the ALJ determines whether one will be conducted.
- An ALJ may also decide, on his or her own motion, to conduct a conference.

Who may conduct a prehearing or posthearing conference?

- An ALJ, or an OMHA attorney designated by the ALJ, may conduct a conference.
- An attorney adjudicator may not conduct a conference for an appeal assigned to him or her.

Section 15.1: Prehearing and posthearing conferences

Can testimony and evidence be taken at a conference?

- No. Testimony and other evidence may not be taken at a conference.

Are parties and non-party participants sworn in at a conference?

- No. Parties and non-party participants are not sworn in at a conference because testimony is not taken at a conference.

Are conferences recorded?

- Yes. An audio recording is made of the conference and included in the administrative record.

- What is required when an ALJ covers a hearing for another ALJ that is unexpectedly unavailable?

  - **OCPM 15.2.5**
    - **Verify if there are any objections**

- When do I address late submitted evidence?

  - **42 U.S.C. §§ 405.1018 and 405.1028**
  - **OCPM 15.2.7**
    - **No later than the start of the hearing.**

Best Practices for identifying hearing attendees:

- The ALJ should ask for the correct spelling of each hearing attendee's first and last name, as well as role or job title, if not already known from the administrative record.
- If there are any objections to the presence of an observer or OMHA staff, the ALJ should rule on the objection pursuant to 42 C.F.R. sections 405.1030(a) and 423.2030(a), which state that a hearing is open to the parties and other persons the ALJ considers necessary and proper.
- If a CMS contractor is present, the ALJ should confirm whether the CMS contractor is appearing as a party or as a non-party participant.

Swearing in witnesses:

- All witnesses must be sworn in, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation.
- The concept of a "witness" is construed broadly at OMHA hearings. The individuals providing testimony frequently have no first-hand account of the items or services furnished, but are often presenting statements and arguments based on their own review of the evidentiary documentation.
- Attorneys and other representatives, who are present only to provide legal arguments and question witnesses, do not need to be sworn in.
- Observers do not need to be sworn in.

Best Practices for notifying the parties of the right to representation:

- If there are unrepresented parties present at the hearing, the ALJ should explain the right to representation and confirm whether they wish to waive their right to representation.
- If an unrepresented party requests a continuance in order to obtain an attorney or other representative, the ALJ should remind the party to submit a valid appointment of representative or other documentation so that the notice of continued hearing can be sent to the representative.
- "Right to representation" is the correct language for an OMHA proceeding, not "right to counsel."

Best Practices for the admission of exhibits:

- At the hearing, the ALJ should determine whether the record is complete, and whether any party objects to the admission of the exhibits identified in the index of the administrative record.
- ALJ should identify the evidence that is *excluded* from consideration (for example, duplicative evidence or no good cause found for new evidence).
- The ALJ's script may vary with a paper case file versus an ECAPE case file.

Best Practices for ending a hearing:

- The ALJ should ask if the parties have anything further to add.
- The ALJ should explain that a written decision will be issued.
- Unless the record is kept open for submission of posthearing documentation, the ALJ should explain that the administrative record is closed.

What is a consolidated hearing?

- A consolidated hearing occurs when an ALJ conducts a single hearing on multiple appeals that are before the same ALJ. Send a Notice of Consolidated Hearing (OMHA-1024DT).
- If the ALJ holds a consolidated hearing, the ALJ may either:
  - Issue a separate decision and maintain a separate administrative record for each appeal; or
  - Issue a consolidated decision and record.
- If the ALJ chooses to consolidate the decision and record, the appeals are *combined* in the case processing system into one OMHA appeal number (see OCPM 9.9.3.1).

Best Practices for conducting a consolidated hearing:

- When multiple beneficiaries are involved, the ALJ should avoid using individual beneficiary names or their Medicare numbers. Instead, the ALJ should identify cases by the OMHA appeal number (if there are separate ones) or by the beneficiary's first and last initials.
- Doing so reduces the risk that another beneficiary's PII will be inadvertently disclosed if a copy of the hearing recording is later requested by a beneficiary.

Best Practices for conducting a consolidated hearing:

- For consolidated hearings where the administrative record and decision will be consolidated, the ALJ should take note of the *time* at which the substantive portion of the hearing begins for each beneficiary, as these times will be used when labeling the audio recording of the hearing.
- The ALJ should also ensure that hearing attendees are present for only those portions of the hearing for which their attendance is necessary and proper.

U.S. Department of Health & Human Services
Office of Medicare Hearings and Appeals

OCPM Chapter 15: Conducting Conferences and Hearings, Posthearing Development

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Section 15.1: Prehearing and posthearing conferences

Reasons for a <u>prehearing</u> conference:

- To clarify or narrow the issues or claims on appeal;
- To establish how the hearing will proceed; or
- To discuss what information the ALJ may find most useful in preparation for the hearing or for presentation at the hearing.

Reasons for a <u>posthearing</u> conference:

- To obtain a status update on the submission of posthearing documentation;
- To grant or deny a party's request for extending the deadline for documentation submission; or
- To confirm that posthearing documentation has been sent to the other parties and to establish deadline for party's response.

Section 15.1: Prehearing and posthearing conferences

Is there a right to a prehearing or posthearing conference?

- No. A party may request a conference, but the ALJ determines whether one will be conducted.
- An ALJ may also decide, on his or her own motion, to conduct a conference.

Who may conduct a prehearing or posthearing conference?

- An ALJ, or an OMHA attorney designated by the ALJ, may conduct a conference.
- An attorney adjudicator may not conduct a conference for an appeal assigned to him or her.

What matters may be discussed at the conference?

- The **matters stated in the notice** of the prehearing or posthearing conference may be discussed.
- **Additional matters** may only be considered if:
  - The **ALJ** is conducting the conference; and
  - The **parties consent** to consideration of the additional matters in writing.

Section 15.1: Prehearing and posthearing conferences

- **Attendance at a prehearing or posthearing conference is voluntary.**
  - An ALJ may request, but may not require CMS, a CMS contractor, or a Part D plan sponsor to participate in a conference. An ALJ may not draw any adverse inferences if they do not participate in a conference.
  - An ALJ may not require a party, a non-party participant, or a witness to participate in a conference.

Section 15.1: Prehearing and posthearing conferences

- **Can testimony and evidence be taken at a conference?**
  - No. Testimony and other evidence may not be taken at a conference.
- **Are parties and non-party participants sworn in at a conference?**
  - No. Parties and non-party participants are not sworn in at a conference because testimony is not taken at a conference.
- **Are conferences recorded?**
  - Yes. An audio recording is made of the conference and included in the administrative record.

Prehearing/Posthearing Conference Order (OMHA-154T):

- The order documents the agreements and actions resulting from the conference.
- Only the ALJ may issue the order, even if the conference was conducted by an OMHA attorney.
- The Prehearing/Posthearing Conference Order (OMHA-154T) with a Generic Notice (OMHA-120T) is sent to all parties and non-party participants who attended the conference.

Prehearing/Posthearing Conference Order (OMHA-154T) (*continued*):

- If the parties do **not** object to the order within 10 calendar days of receiving the order (or 1 calendar day for expedited Part D appeals), plus any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are **binding** on all parties.
- If a party objects to the order, the order is **not** binding, but must **remain** in the administrative record.

Section 15.2: Matters to consider before the hearing

Who may hold a hearing?

- Only an ALJ may hold a hearing. An attorney adjudicator may not hold a hearing.

Where may a hearing be held?

- With the exception of in-person hearings that are held at an offsite location, hearings must be conducted on OMHA premises, or other location authorized in advance by the Chief ALJ or designee.
- An ALJ may not conduct a hearing while teleworking from ADS.