mln MATTERS®
KNOWLEDGE • RESOURCES • TRAINING

January 2021 Update of the Hospital Outpatient Prospective Payment System (OPPS)

MLN Matters Number: MM12120
Related Change Request (CR) Number: 12120
Related CR Release Date: December 31, 2020
Effective Date: January 1, 2021
Related CR Transmittal Number: R10541CP and R10541BP
Implementation Date: January 4, 2021

PROVIDER TYPES AFFECTED

This MLN Matters article is for hospitals billing Medicare Administrative Contractors (MACs) for hospital outpatient services provided to Medicare beneficiaries.

PROVIDER ACTION NEEDED

CR 12120 describes changes to and billing instructions for various payment policies implemented in the January 2021 Outpatient Prospective Payment System (OPPS) update. The January 2021 Integrated Outpatient Code Editor (I/OCE) will reflect the HCPCS, Ambulatory Payment Classification (APC), HCPCS Modifier, and Revenue Code additions, changes, and deletions that CR 12120 discusses. The January 2021 revisions to I/OCE data files, instructions, and specifications are provided in CR 12114. When available, you can review a related article, MM12114, at https://www.cms.gov/files/document/mm12114.pdf.

CR 12120 also makes a change to the Chapter 6 of the Medicare Benefit Policy Manual related to Coverage of Outpatient Therapeutic Services Incident to a Physician's Service Furnished on or after January 1, 2021. The revised portion of the manual is part of CR 12120.

Make sure that your billing staffs are aware of these changes.

BACKGROUND

Here is a summary of the main topics covered by CR 12120:

1. COVID-19 Laboratory Tests and Services Coding Update

Since February 2020, CMS has recognized several COVID-19 laboratory tests and related services. The codes are listed in Table 1 of CR 12120, along with their OPPS status indicators. The codes, along with their short descriptors and status indicators are also listed in the January 2021 OPPS Addendum B. For information on the OPPS status indicator definitions, refer to OPPS Addendum D1 of the CY 2021 OPPS/Ambulatory Surgical Center (ASC) final rule.

CMS CENTERS FOR MEDICARE & MEDICAID SERVICES
Medicare Learning Network®

CMS has established one HCPCS code, U0005, effective January 1, 2021. In addition, the AMA CPT Editorial Panel established five new CPT codes, specifically, CPT codes 87636, 87637, 87811, and 0240U and 0241U effective October 6, 2020. These codes were established too late to include in the October 2020 Update, so they are included in this January 2021 Update with the effective date of October 6, 2020. Also, the AMA CPT Editorial Panel established CPT code 87428 effective November 10, 2020. Since it was established too late to include in the October 2020 Update, it is included in the January 2021 update, with the effective date of November 10, 2020.

2. CPT Proprietary Laboratory Analyses (PLA) Coding Changes Effective October 6, 2020, and January 1, 2021

The AMA CPT Editorial Panel established 13 new PLA codes, specifically, CPT codes 0227U through 0239U, effective January 1, 2021. Also, the AMA CPT Editorial Panel established two new PLA codes, specifically, CPT codes 0240U and 0241U effective October 6, 2020. Because CPT codes 0240U and 0241U were released on October 6, 2020, they were too late to include in the October 2020 OPPS update and are instead being included in the January 2021 update with an effective date of October 6, 2020. Table 2 of CR 12120 lists the long descriptors and status indicators for the codes.

CPT codes 0227U through 0239U have been added to the January 2021 I/OCE with an effective date of January 1, 2021 while CPT codes 0240U and 0241U have been added to the January 2021 I/OCE with an effective date of October 6, 2020. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the January 2021 OPPS Addendum B. For information on the OPPS status indicators, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions.

3. Monoclonal Antibody Therapy Product and Administration Codes

On November 9, 2020, the FDA issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy, bamlanivimab, for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

On November 21, 2020, FDA issued an EUA for two monoclonal antibodies, specifically, casirivimab and imdevimab, that are administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age or older) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for COVID-19. This includes those who are 65 years of age or older or who have certain chronic medical conditions.

To ensure access to these monoclonal antibody treatments during the COVID-19 public health emergency (PHE), Medicare covers and pays for the infusion of monoclonal antibody therapy in accordance with Section 3713 of the Coronavirus Aid, Relief, and Economic Security Act

(CARES Act). That is, as a result of the circumstances of the PHE, Medicare covers and pays for the infusion of monoclonal antibody therapy in the manner in which it will pay for COVID-19 vaccines and other statutory vaccines such as influenza.

To track and pay appropriately for monoclonal antibodies used to treat COVID-19, CMS established new HCPCS codes M0239 and Q0239 effective November 9, 2020 for bamlanivimab, and new HCPCS codes M0243 and Q0243 effective November 21, 2020 for casirivimab and imdevimab. The codes have been added to the January 2021 I/OCE with their effective dates. Table 3 of CR 12120 lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the January 2021 OPPS Addendum B.

Similar to other vaccines, Medicare will not make a separate payment to the provider for a monoclonal antibody product when that product is given to the provider for free by the government. We anticipate much of the initial volume will be supplied to providers free of charge. Medicare established HCPCS code Q0239 for bamlanivimab and HCPCS code Q0243 for casirivimab and imdevimab (administered together). If HOPDs purchase bamlanivimab or casirivimab and imdevimab, they should report HCPCS codes Q0239 or Q0243, respectively, to receive separate payment for the monoclonal antibody treatments.

Medicare will pay the provider for the administration of monoclonal antibodies regardless of whether the product is given to the provider for free. To receive separate payment for the infusion of bamlanivimab, HOPDs should report HCPCS code M0239. Similarly, to receive separate payment for the infusion of casirivimab and imdevimab, HOPDs should report HCPCS code M0243. For more information on the Medicare Monoclonal Antibody COVID-19 Infusion Program during the Public Health Emergency, refer to the following CMS websites:

- https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion
- https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion#Payment

4. New COVID-19 CPT Vaccines and Administration Codes

On November 10, 2020, the AMA released six new CPT codes associated with the Pfizer and Moderna COVID-19 vaccines. Two of the six CPT codes (91300 and 91301) refer to the specific vaccine products, while the other four CPT codes (0001A, 0002A, 0011A and 0012A) describe the service to administer the vaccines. These codes will be available for use once the applicable coronavirus vaccine product receives EUA or approval from the FDA. The codes have been included in the January 2021 I/OCE. In addition, on December 17, 2020, the AMA released three new CPT codes associated with the AstraZeneca and University of Oxford COVID-19 vaccine. The codes, specifically, CPT codes 91302, 0021A, and 0022A, will be available for use once the vaccine receives EUA or approval from the FDA.

Table 4 of CR 12120 lists the long descriptors for the codes. These codes, along with their short descriptors, status indicators, and payment rates (where applicable) are also listed in the January 2021 OPPS Addendum B. For information on the OPPS status indicators, refer to

OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions. For more information on the payment and effective dates for the COVID-19 vaccines and their administration during the PHE, refer to https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies.

5. a. New Device Pass-Through Categories

Section 1833(t)(6)(B) of the Social Security Act requires that, under the OPPS, categories of devices be eligible for transitional pass-through payments for at least two (2), but not more than three (3) years. Section 1833(t)(6)(B)(ii)(IV) of the Act requires that we create additional categories for transitional pass-through payment of new medical devices not described by existing or previously existing categories of devices.

We are establishing three new device pass-through categories as of January 1, 2021. We are also updating the device offset from payment information for the device category described by HCPCS code C1839 (Iris prosthesis) and HCPCS code C1748 (Endoscope, single, ugi).

Table 5 of CR 12120 provides a listing of new coding and payment information concerning the new device categories for transitional pass-through payment.

b. Device Offset from Payment:

Section 1833(t)(6)(D)(ii) of the Act requires that we deduct from pass-through payments for devices an amount that reflects the device portion of the APC payment amount. This deduction is known as the device offset, or the portion(s) of the APC amount that is associated with the cost of the pass-through device. The device offset from payment represents a deduction from pass-through payments for the applicable pass-through device.

We have determined the device offset amounts for APC 5491 Level 1 Intraocular Procedures and APC 5492 Level 2 Intraocular Procedures associated with the costs of the device category described by HCPCS code C1839 (Iris prosthesis). In the January 2020 Update of the Hospital OPPS (Transmittal 4513, dated February 4, 2020), we stated that the device in the category described by HCPCS C1839 should always be billed with CPT code 66999 (Unlisted procedure, anterior segment of eye). The CPT codes listed below became effective July 1, 2020 and should be billed with C1839 instead of CPT code 66999. The device in the category described by HCPCS code C1839 should always be billed with one of the following CPT codes:

- CPT code 0616T - Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens, which is assigned to APC 5491 for CY 2021.
- CPT code 0617T - Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens, which is assigned to APC 5492 for CY 2021.

- CPT code 0618T - Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange, which is assigned to APC 5492 for CY 2021.

We have determined the device offset amount for APC 5465 (Level 5 Neurostimulator and Related Procedures) associated with the cost of the device category described by HCPCS code C1825 (Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)). The device in the category described by HCPCS code C1825 should always be billed with one of the following CPT code:

- CPT code 0266T - (Implt/rpl crtd sns dev total), which is assigned to APC 5465 for CY 2021.

We have determined the device offset amounts for APC 5302 (Level 2 Upper GI Procedures) and APC 5312 (Level 2 Lower GI Procedures) associated with the cost of the device category described by HCPCS code C1052 (Hemostatic agent, gastrointestinal, topical). The device in the category described by HCPCS code C1052 should always be billed with one of the following CPT codes:

- CPT code 43227 (Esophagoscopy control bleed), which is assigned to APC 5302 for CY 2021.
- CPT code 43255 (Egd control bleeding any), which is assigned to APC 5302 for CY 2021.
- CPT code 44366 (Small bowel endoscopy), which is assigned to APC 5302 for CY 2021.
- CPT code 44378 (Small bowel endoscopy), which is assigned to APC 5302 for CY 2021.
- CPT code 44391 (Colonoscopy for bleeding), which is assigned to APC 5312 for CY 2021.
- CPT code 45334 (Sigmoidoscopy for bleeding), which is assigned to APC 5312 for CY 2021.
- CPT code 45382 (Colonoscopy w/control bleed), which is assigned to APC 5312 for CY 2021.

We have determined the device offset amount for APC 5114 (Level 4 Musculoskeletal Procedures) associated with the cost of the device category described by HCPCS code C1062 (Intravertebral body fracture augmentation with implant (e.g., metal, polymer). The device in the category described by HCPCS code C1062 should always be billed with one of the following CPT codes:

- CPT code 22513 (Perq vertebral augmentation), which is assigned to APC 5114 for CY 2021.
- CPT code 22514 (Perq vertebral augmentation), which is assigned to APC 5114 for CY 2021.

On July 1, 2020, we determined that an offset would apply to C1748 (Endoscope, single-use,

(i.e. disposable), Upper GI, imaging/illumination device (insertable)) because APC 5303 (Level 3 Upper GI Procedures) and APC 5331 (Complex GI Procedures) already contain costs associated with the device described by C1748. C1748 should always be billed with the CPT codes listed below. The device offset is a deduction from pass-through payments for C1748. After further review, we have determined that the costs associated with C1748 aren't already reflected in APCs 5303 or 5331. Therefore, we aren't applying a device offset to C1748. This determination to not apply the device offset from payment will be retroactive to July 1, 2020. See 68 FR 63438-9 for further discussion about the device offset policy.

- CPT code 43260 (Ercp w/specimen collection), which is assigned to APC 5303 for CY 2021.
- CPT code 43261 (Endo cholangiopancreatograph), which is assigned to APC 5303 for CY 2021.
- CPT code 43262 (Endo cholangiopancreatograph), which is assigned to APC 5303 for CY 2021.
- CPT code 43263 (Ercp sphincter pressure meas), which is assigned to APC 5303 for CY 2021.
- CPT code 43264 (Ercp remove duct calculi), which is assigned to APC 5303 for CY 2021.
- CPT code 43265 (Ercp lithotripsy calculi), which is assigned to APC 5331 for CY 2021.
- CPT code 43274 (Ercp duct stent placement), which is assigned to APC 5331 for CY 2021.
- CPT code 43275 (Ercp remove forgn body duct), which is assigned to APC 5303 for CY 2021.
- CPT code 43276 (Ercp stent exchange w/dilate), which is assigned to APC 5331 for CY 2021.
- CPT code 43277 (Ercp ea duct/ampulla dilate), which is assigned to APC 5303 for CY 2021.
- CPT code 43278 (Ercp lesion ablate w/dilate), which is assigned to APC 5303 for CY 2021.

Also, refer to https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html for the most current device pass-through information.

c. Transitional Pass-Through Payments for Designated Devices

Certain designated new devices are assigned to APCs and identified by the I/OCE as eligible for payment based on the reasonable cost of the new device reduced by the amount included in the APC for the procedure that reflects the packaged payment for device(s) used in the procedure. The I/OCE will determine the proper payment amount for these APCs as well as the coinsurance and any applicable deductible. All related payment calculations will be returned on the same APC line and identified as a designated new device. We refer readers to Addendum P of the CY 2021 final rule with comment period for the most current OPPS HCPCS Offset file. Addendum P is available on the CMS website.

d. Alternative Pathway for Devices That Have a Food and Drug Administration (FDA) Breakthrough Designation

For devices that have received FDA marketing authorization and a Breakthrough Device designation from the FDA, we provided an alternative pathway to qualify for device pass-through payment status, under which devices would not be evaluated in terms of the current substantial clinical improvement criterion for the purposes of determining device pass-through payment status. The devices would still need to meet the other criteria for pass-through status. This applies to devices that receive pass-through payment status effective on or after January 1, 2020.

6. New HCPCS Code Describing the Administration of Subretinal Therapies Requiring Vitrectomy

CMS is establishing a new HCPCS code, C9770, to describe a vitrectomy, mechanical, pars plana approach, with subretinal injection of a pharmacologic or biologic agent. Table 6 of CR 12120 lists the official long descriptor, status indicator, and APC assignment for HCPCS code C9770. For information on OPPS status indicators, please refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definitions. This code, along with its short descriptor, status indicator, and payment rate, is also listed in the January 2021 OPPS Addendum B.

7. New HCPCS Code Describing Nasal Endoscopy with Cryoablation of Nasal Tissue(s) and/or Nerve(s)

CMS is establishing HCPCS code C9771 to describe the technology associated with nasal endoscopy with cryoablation of nasal tissues and/or nerves. Table 7 of CR 12120 lists the long descriptor, status indicator, and APC assignment for HCPCS code C9771. For more information on OPPS status indicator “J1”, refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definition. This code, along with the short descriptor, status indicator, and payment rate is also listed in the January 2021 Update of the OPPS Addendum B.

8. New HCPCS Codes Describing Peripheral Intravascular Lithotripsy (IVL) Procedures

For the January 2021 update, CMS is establishing four additional new HCPCS codes to describe the technology describing the IVL procedure, which has integrated lithotripsy emitters and is designed to enhance percutaneous transluminal angioplasty by enabling delivery of the calcium disrupting capability of lithotripsy prior to full balloon dilatation at low pressures. The application of lithotripsy mechanical pulse waves alters the structure of an occlusive vascular deposit (stenosis) prior to low-pressure balloon dilation of the stenosis and facilitates the passage of blood and is used for the treatment of peripheral artery disease (PAD).

Specifically, CMS is establishing HCPCS codes C9772, C9773, C9774, and C9775 to describe procedures utilizing IVL.

Note: For the July 2020 Update, we also established HCPCS codes C9764 through C9767 to describe the IVL procedures.

Table 8 of CR 12120 lists the long descriptors, status indicators, and APC assignments for the HCPCS codes. For more information on OPPS status indicator "J1", refer to OPPS Addendum D1 of the CY 2021 OPPS/ASC final rule for the latest definition. We note these codes, along with their short descriptors, status indicator, and payment rates are also listed in the January 1, 2021 OPPS Addendum B.

9. Comprehensive APCs (C-APCs)

a. Two New C-APCs Effective January 1, 2021

C-APCs provide a single payment for a primary service, and payment for all adjunctive services reported on the same claim is packaged into payment for the primary service. With a few exceptions, all other services reported on a hospital outpatient claim in combination with the primary service are related to the delivery of the primary service and packaged into the single payment for the primary service.

Each year, in accordance with Section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As stated in the CY 2021 OPPS/ASC final rule with comment period, as a result of our annual review of the services and the APC assignments under the OPPS, we finalized the addition of two new C-APCs under the existing C-APC payment policy effective January 1, 2021. The new C-APCs that are effective January 1, 2021, include:

- C-APC 5378 (Level 8 Urology and Related Services); and
- C-APC 5465 (Level 5 Neurostimulator and Related Procedures)

Table 9 of CR 12120 lists these new C-APCs, which increases the total number of C-APCs to 69 for CY 2021. We note that Addendum J to the CY 2021 OPPS/ASC final rule with comment period contains all of the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2021. In addition, we note that HCPCS codes assigned to comprehensive APCs are designated with status indicator "J1" in the latest OPPS Addendum B.

b. C-APC Exclusion for COVID-19 Treatments

In the interim final with request for comments (IFC) entitled, ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency", published on November 6, 2020, we stated that effective for services furnished on or after the effective date of the IFC and until the end of the PHE for COVID-19, there's an exception to the OPPS C-APC policy to ensure separate payment for new COVID–19 treatments that meet certain criteria (85 FR 71158 through 71160). Under this exception, any new COVID-19 treatment that meets the two following criteria will, for the remainder of the PHE for COVID-19, will always be separately paid and won't be packaged into a C-APC when it's provided on the same claim as the primary C-APC service.

1. The treatment must be a drug or biological product (which could include a blood product) authorized to treat COVID-19, as indicated in Section I, "Criteria for Issuance of Authorization," of the letter of authorization for the drug or biological product, or the drug or biological product must be approved by the FDA for treating COVID-19.
2. Second, the EUA for the drug or biological product (which could include a blood product) must authorize the use of the product in the outpatient setting or not limit its use to the inpatient setting, or the product must be approved by the FDA to treat COVID-19 disease and not limit its use to the inpatient setting.

For further information regarding the exception to the C-APC policy for COVID–19 treatments, please refer to the IFC (85 FR 71158 through 71160) at https://www.federalregister.gov/documents/2020/11/06/2020-24332/additional-policy-and-regulatory-revisions-in-response-to-the-covid-19-public-health-emergency.

10. Changes to the Inpatient-Only List (IPO) for CY 2021

The Medicare IPO list includes procedures that are typically only provided in the inpatient setting and therefore aren't paid under the OPPS. We are eliminating the IPO list over the course of a 3-year period beginning in CY 2021. For CY 2021, CMS is removing 298 services from the IPO list. These changes are included in Table 10 of CR 12120.

11. Removal of Selected National Coverage Determinations (NCDs) Effective January 1, 2021

As stated in the CY 2021 Physician Fee Schedule (PFS) final rule with comment period, effective January 1, 2021, CMS removed certain NCDs. See Table 11 of CR 12120 for the NCD name and manual citation.

As a result of this change, the coverage determinations for the procedures, services, and items associated with the NCDs listed above will be made by the local MAC. Also, we revised the status indicators for the codes listed in Table 12 of CR 12120 from OPPS status indicator "E1" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to the status indicators and/or APCs listed in Table 12.

12. Changes to some Opioid Treatment Program (OTP) – Related Codes

The existing OTP-related HCPCS codes G2067-G2080 were established by CMS on January 1, 2020 and weren't previously paid on the institutional claims. They were only paid on professional claims. For CY 2021, we are allowing these OTP codes to be billed on institutional claims only by certified OTP providers who are enrolled with Medicare as an OTP. Therefore, we're changing status indicators for G2068-G2080 from SI "E1" (Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI "A" (Not paid under OPPS. Paid by MACs under a fee schedule or payment system other than OPPS) so the payment can be made on the OTP fee schedule effective January 1, 2020.

HCPCS codes G2215-G2216 were established by CMS effective January 1, 2021 and are assigned to SI "A", similar to the existing HCPCS codes, G2067-G2080. Table 13, "Long

Descriptors and Effective Dates for the OTP — related HCPCS codes," attached to this CR, lists the long descriptors and the effective dates for these codes. These codes, along with their short descriptors and status indicators, are also listed in the January 2021 OPPS Addendum B.

13. Change to the Status Indicator for HCPCS code P9099

Effective January 1, 2021, the status indicator for HCPCS code P9099 has changed from SI = "E2" (Items, codes and services for which pricing information and claims data aren't available. Not paid by Medicare when submitted on outpatient claims (any outpatient bill type)) to SI = "R" (Blood and blood products that are paid under OPPS; separate APC payment) as described in Table 14 of CR 12120.

14. Drugs, Biologicals, and Radiopharmaceuticals

a. New CY 2021 HCPCS Codes and Dosage Descriptors for Certain Drugs, Biologicals, and Radiopharmaceuticals Receiving Pass-Through Status

Nine (9) new HCPCS codes have been created for reporting drugs and biologicals in the hospital outpatient setting, where there have not previously been specific codes available starting on January 1, 2021. These drugs and biologicals will receive drug pass-through status starting January 1, 2021. These HCPCS codes are listed in Table 15 of CR 12120.

b. Existing HCPCS Codes

There are two existing HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will start to receive pass-through status beginning on January 1, 2021. These HCPCS codes are listed in Table 16 of CR 12120.

c. Existing HCPCS Codes for Certain Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Status Ending on December 31, 2020

There are eight HCPCS codes for certain drugs, biologicals, and radiopharmaceuticals in the outpatient setting that will have their pass-through status end on December 31, 2020. These codes are listed in Table 17 of CR 12120.

d. Drugs and Biologicals that Will Retroactively Change from Non-Payable Status to Separately Payable Status from October 1, 2020 to December 31, 2020

The status indicator for HCPCS code J1437 (Injection, ferric derisomaltose, 10 mg) for the period of October 1, 2020, through December 31, 2020, will be changed retroactively from status indicator = "E2" to status indicator = "K" (Nonpass-through drugs and nonimplantable biologicals, including therapeutic radiopharmaceuticals that are paid under OPPS; separate APC payment). This drug/biological is reported in Table 18 of CR 12120.

e. Newly Established HCPCS Codes for Drugs, Biologicals, and Radiopharmaceuticals as of January 1, 2021

Eighteen new drug, biological, and radiopharmaceutical HCPCS codes will be established on January 1, 2021. These HCPCS codes are listed in Table 19 of CR 12120.

f. Drugs and Biologicals with Payments Based on Average Sales Price (ASP)

For CY 2021, payment for the majority of nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were not acquired through the 340B Program is made at a single rate of ASP + 6 percent (or ASP + 6 percent of the reference product for biosimilars). Payment for nonpass-through drugs, biologicals, and therapeutic radiopharmaceuticals that were acquired under the 340B program is made at the single rate of ASP – 22.5 percent (or ASP – 22.5 percent of the biosimilar's ASP if a biosimilar is acquired under the 340B Program), which provides payment for both the acquisition cost and pharmacy overhead costs associated with the drug, biological, or therapeutic radiopharmaceutical.

In CY 2021, a single payment of ASP + 6 percent for pass-through drugs, biologicals, and radiopharmaceuticals is made to provide payment for both the acquisition cost and pharmacy overhead costs of these pass-through items (or ASP + 6 percent of the reference product for biosimilars). Payments for drugs and biologicals based on ASP will be updated on a quarterly basis as later quarter ASP submissions become available.

Effective January 1, 2021, payment rates for many drugs and biologicals have changed from the values published in the CY 2021 OPPS/ASC final rule with comment period as a result of the new ASP calculations based on sales price submissions from second quarter of CY 2020. In cases where adjustments to payment rates are necessary, changes to the payment rates will be incorporated in the January 2021 Fiscal Intermediary Standard System (FISS) release.

CMS isn't publishing the updated payment rates in this CR implementing the January 2021 update of the OPPS. However, the updated payment rates effective January 1, 2021, can be found in the January 2021 update of the OPPS Addendum A and Addendum B at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS.

g. Drugs and Biologicals Based on ASP Methodology with Restated Payment Rates

Based on ASP methodology, some drugs and biologicals will have payment rates that are corrected retroactively. These retroactive corrections typically occur on a quarterly basis. The list of drugs and biologicals with corrected payments rates will be accessible on the CMS website on the first date of the quarter at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/OPPS-Restated-Payment-Rates.html.

Providers may resubmit claims that were impacted by adjustments to previous quarter's payment files

h. Restatement of the payment rate for HCPCS code A9600 (Strontium Sr-89 chloride, therapeutic, per millicurie) for the period October 1, 2020, through December 31, 2020

The payment rate of HCPCS code A9600 (Strontium sr-89 chloride, therapeutic, per millicurie) for the period of October 1, 2020, through December 31, 2020, needs to be restated. This

drug/biological with the new payment rate is reported in Table 20 of CR 12120.

15.Skin Substitutes

The payment for skin substitute products that do not qualify for pass-through status will be packaged into the payment for the associated skin substitute application procedure. The skin substitute products are divided into two groups:

1. High-cost skin substitute products
2. Low-cost skin substitute products for packaging purposes

Note: The final rule skin substitute table incorrectly assigned Q4222 (Progenamatrix, per sq cm) to the low-cost group when it should have been assigned to the high-cost group for January. This correction is currently reflected in all relevant January OPPS payment files and tables.

Table 21 of CR 12120 lists the skin substitute products and their assignment as either a high cost or a low cost skin substitute product, when applicable.

16. Reporting for Certain Outpatient Department Services (that are Similar to Therapy Services) ("Non-Therapy Outpatient Department Services") and are Adjunctive to Comprehensive APC Procedures

This language was originally published in the October 2016 Update of the OPPS (Transmittal 3602). We are updating this language based on the removal of regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) related to functional reporting for therapy services.

Non-therapy outpatient department services are services such as physical therapy (PT), occupational therapy (OT), and speech-language pathology (SLP) rendered during the perioperative period (of a Comprehensive APC (C-APC) procedure) without a certified therapy plan of care. These aren't therapy services as described in Section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other non-therapist health care workers.

Therapy services are those provided by therapists under a plan of care in accordance with sections 1835(a)(2)(C) and 1835(a)(2)(D) of the Act and are paid for under Section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800), until they were repealed by Bipartisan Budget Act of 2018, effective January 1, 2018. Because these services are outpatient department services and not therapy services, the requirement for functional reporting under the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) doesn't apply. The functional reporting requirements were applicable until January 1, 2019, at which time the regulations at 42 CFR 410.59(a)(4) and 42 CFR 410.60(a)(4) were removed (83 FR 41786 and 83 FR 59452).

The comprehensive APC payment policy packages payment for adjunctive items, services, and procedures into the costliest primary procedures under the OPPS at the claim level. When non-therapy outpatient department services are included on the same claim as a C-APC procedure (status indicator (SI) = J1) (see 80 FR 70326) or the specific combination of services assigned

to the Observation Comprehensive APC 8011 (SI = J2), these services are considered adjunctive to the primary procedure. Payment for non-therapy outpatient department services is included as a packaged part of the payment for the C-APC procedure.

Effective for claims received on or after October 1, 2016, with dates of service on or after January 1, 2015, providers may report non-therapy outpatient department services (that are similar to therapy services) that are adjunctive to a C-APC procedure (SI = J1) or the specific combination of services assigned to the Observation Comprehensive APC 8011 (SI = J2), in one of two ways:

1. Without using the therapy CPT codes and instead reporting these non-therapy services with Revenue Code 0940 (Other Therapeutic Services); or
2. Reporting non-therapy outpatient department services that are adjunctive to J1 or J2 services with the appropriate occurrence codes, CPT codes, modifiers, and revenue codes.

17. Payment Adjustment for Certain Cancer Hospitals Beginning CY 2021

For certain cancer hospitals that receive interim monthly payments associated with the cancer hospital adjustment at 42 CFR 419.43(i), Section 16002(b) of the 21st Century Cures Act requires that, for CY 2018 and subsequent CYs, the target Payment-to-Cost Ratio (PCR) that should be used in the calculation of the interim monthly payments and at final cost report settlement is reduced by 0.01. For CY 2021, the target PCR, after including the reduction required by Section 16002(b), is 0.89.

18. Method to Control for Unnecessary Increases in Utilization of Outpatient Services/G0463 with Modifier PO

In CY 2020, CMS finalized a policy to use our authority under Section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus Provider-Based Department (PBD) (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from Section 1833(t)(21) of the Act (departments that bill the modifier “PO” on claim lines). We completed the phase-in of the policy in CY 2020.

The PFS-equivalent amount paid to nonexcepted off-campus PBDs is 40 percent of OPPS payment (60 percent less than the OPPS rate) for CY 2021. Specifically, the total 60-percent payment reduction will apply in CY 2021. Thus, these departments will be paid 40 percent of the OPPS rate for the clinic visit services in CY 2021.

19. Changes to OPPS Pricer Logic

- Rural Sole Community Hospitals (SCH) and Essential Access Community Hospitals (EACHs) will continue to receive a 7.1 percent payment increase for most services in CY 2021. The rural SCH and EACH payment adjustment excludes drugs, biologicals, items and services paid at charges reduced to cost, and items paid under the pass-through payment policy in accordance with section 1833(t)(13)(B) of the Act, as added by section

411 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA).

- New OPPS payment rates and copayment amounts will be effective January 1, 2021. All copayment amounts will be limited to a maximum of 40 percent of the APC payment rate. Copayment amounts for each service can't exceed the CY 2021 inpatient deductible of $1,484. For most OPPS services, copayments are set at 20 percent of the APC payment rate.
- For hospital outlier payments under OPPS, there will be no change in the multiple thresholds of 1.75 for 2021. This threshold of 1.75 is multiplied by the total line-item APC payment to determine eligibility for outlier payments. This factor also is used to determine the outlier payment, which is 50 percent of estimated cost less 1.75 times the APC payment amount. The payment formula is (cost-(APC paymentx1.75))/2.
- The fixed-dollar threshold for OPPS outlier payments increases in CY 2021 relative to CY 2020. The estimated cost of a service must be greater than the APC payment amount plus $5,300 to qualify for outlier payments
- For outliers for Community Mental Health Centers (bill type 76x), there will be no change in the multiple thresholds of 3.4 for 2021. This threshold of 3.4 is multiplied by the total line-item APC payment for APC 5853 to determine eligibility for outlier payments. This multiple amount is also used to determine the outlier payment, which is 50 percent of estimated costs less 3.4 times the APC payment amount. The payment formula is (cost-(APC 5853 paymentx3.4))/2.
- Continuing our established policy for CY 2021, the OPPS Pricer will apply a reduced update ratio of 0.9805 to the payment and copayment for hospitals that fail to meet their hospital outpatient quality data reporting requirements or that fail to meet CMS validation edits. The reduced payment amount will be used to calculate outlier payments.
- Effective January 1, 2021, CMS is adopting the Fiscal Year (FY) 2021 Inpatient Prospective Payment System (IPPS) post-reclassification wage index values with application of the CY 2021 out-commuting adjustment authorized by Section 505 of the MMA to non- IPPS (non-Inpatient Prospective Payment System) hospitals as implemented through the Pricer logic.
- Effective January 1, 2021, for claims with APCs, which require implantable devices and have significant device offsets (greater than 30%), a device offset cap will be applied based on the credit amount listed in the "FD" (Credit Received from the Manufacturer for a Replaced Medical Device) value code. The credit amount in value code "FD" which reduces the APC payment for the applicable procedure, will be capped by the device offset amount for that APC. The offset amounts for the above referenced APCs are available on the CMS website.

20. Update the Outpatient Provider Specific File (OPSF)

For January 1, 2021, contractors will maintain the accuracy of the provider records in the Outpatient Provider Specific File (OPSF) as changes occur in data element values.

A. Updating the OPSF for Expiration of Transitional Outpatient Payments (TOPs)

Cancer and children's hospitals are held harmless under Section 1833(t)(7)(D)(ii) of the Act and continue to receive hold harmless TOPs permanently. For CY 2021, cancer hospitals will continue to receive an additional payment adjustment.

B. Updating the OPSF for Cost to Charge Ratios (CCR)

As stated in Chapter 4, Section 50.1 of the Medicare Claims Processing Manual at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c04.pdf, MACs must maintain the accuracy of data and update the OPSF as changes occur in data element values, including changes to provider cost–to-charge ratios and, when applicable, device department cost-to-charge ratios. The file of OPPS hospital upper limit CCRs and the file of Statewide CCRs are located at www.cms.gov/HospitalOutpatientPPS/ under "*Annual Policy Files*."

21. Wage Index Policies in the CY 2021 OPPS

In the FY 2021 IPPS and CY 2021 IPPS we made the following changes to the wage index: increased the wage index values for hospitals with a wage index value below the 25th percentile wage index value of 0.8469 across all hospitals and applied a 5-percent cap for CY 2021 on any wage index values that decreased relative to CY 2020 (implemented through the Supplemental Wage Index in the OPSF).

22. Coverage Determinations

Reminder: The fact that a drug, device, procedure or service is assigned an HCPCS code and a payment rate under the OPPS doesn't imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. MACs determine whether a drug, device, procedure, or other service meets all program requirements for coverage. For example, MACs determine that it's reasonable and necessary to treat the beneficiary's condition and whether it's excluded from payment.

23. General Supervision of Outpatient Hospital Therapeutic Services Currently Assigned to the Non-Surgical Extended Duration Therapeutic Services (NSEDTS) Level of Supervision

NSEDTS describe services that have a significant monitoring component that can extend for a lengthy period of time, that aren't surgical, and that typically have a low risk of complications after the assessment at the beginning of the service. Currently, these services have a minimum default level of supervision of NSEDTS. The NSEDTS level of supervision requires direct supervision during the initiation of the service, which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. The NSEDTS level of supervision is described at 42 Code of Federal Regulations (CFR) 410.27(a)(1)(iv)(E).

The generally applicable minimum required level of supervision for NSEDTS will change on January 1, 2021, from the current NSEDTS level of supervision to general supervision for

NSEDTS furnished by all hospitals and CAHs. Also, the NSEDTS level of supervision will be eliminated, as 42 CFR 410.27(a)(1)(iv)(E) will be deleted as of January 1, 2021.

General supervision is defined in regulations at 42 CFR 410.32(b)(3)(i) to mean that the procedure is rendered under the physician's overall direction and control, but that the physician's presence isn't required during the performance of the procedure. All of the policy safeguards that have been in place to ensure the safety, health, and quality standards of the outpatient therapeutic services that beneficiaries receive will continue to be in place under our new policy.

These safeguards include:

- Allowing providers and physicians the discretion to require a higher level of supervision to ensure an NSEDTS is performed without risking beneficiary safety or quality of care.
- The presences of outpatient hospitals and CAH Conditions of Participation (CoPs), and other state and Federal laws and regulations.

The list of services starting January 1, 2020 and ending December 31, 2020 that are defined as non-surgical extended duration therapeutic services where the initiation of the service must be performed under direct supervision is available at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html. Starting January 1, 2021, the minimum level of supervision for non-surgical extended duration therapeutic services will be general supervision for the entire service including for the initiation of the service.

ADDITIONAL INFORMATION

The official instruction, CR 12120, issued to your MAC regarding this change consists of two transmittals. The first transmittal involves the Medicare Claims Processing manual and it is at https://www.cms.gov/files/document/r10541cp.pdf. The second updaters the Medicare Benefit Policy Manual and it is at https://www.cms.gov/files/document/r10541bp.pdf.

If you have questions, your MACs may have more information. Find their website at http://go.cms.gov/MAC-website-list.

DOCUMENT HISTORY

Date of Change	Description
January 5, 2021	Initial article released.