

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-11-1610

In the case of

Steven Kalter, M.D.
(Appellant)

(Beneficiaries)

TrailBlazer Health
Enterprises

(Contractor)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(HIC Numbers)

(ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated March 22, 2011, because there is an error of law material to the outcome of the claim. See 42 C.F.R. § 405.1110. The ALJ's decision addressed a sample-based overpayment assessed against the appellant for various physician services provided between January 1, 2005, and October 31, 2007. In that decision, the ALJ invalidated the sample underlying the extrapolated overpayment and remanded the case to the Medicare contractor "to have the statistical sampling and extrapolation re-computated (*sic*) or recalculated to include, if any, the underpayments in the claims during the time period under review." Dec. at 13. The ALJ then found that certain beneficiary-specific claims in the sample had been properly reimbursed by Medicare. Finally, the ALJ found that the appellant was liable for the remaining non-covered costs under section 1879 of the Social Security Act (Act) and that the appellant was not entitled to waiver of recoupment of the remaining overpayment under section 1870 of the Act.

The Council has carefully considered the record that was before the ALJ, as well as the May 19, 2011, memorandum, from the Centers for Medicare & Medicaid Services (CMS) and the appellant's June 13, 2011, memorandum in response. The CMS memorandum is entered into the record in this case as Exhibit

(Exh.) MAC-1. The appellant's memorandum is entered into the record as Exhibit MAC-2. As explained more fully below, the Council reverses the ALJ's decision that the sampling and extrapolation must be recalculated to include all claims (including zero paid claims), and as to coverage for one beneficiary.

BACKGROUND

Case History

On December 12, 2008, TriCenturion, a Program Safeguard Contractor (PSC), notified the appellant of the preliminary results of its post-payment review of claims for various physician services which the appellant provided to beneficiaries between January 1, 2005, and October 31, 2007. See Exh. 1 at 182. The PSC defined the sampled universe as all paid claim lines that included a line item for codes Q0136, Q0137, J0881 and J0885 with dates of service between 1/1/05 and 10/31/07, and paid between those dates. *Id.* at 165, 316. The PSC drew a random sample of 30 claims for 28 beneficiaries from the 6,442 claim universe. The PSC reviewed 128 line items of service, finding that 46 were improperly paid in whole or part. Extrapolating the resulting 36% error rate to the universe, the PSC identified a \$1,831,537.72 overpayment. *Id.* at 186, 243-314 and 318-320. The appellant provided the PSC with additional information which did not alter the PSC's preliminary findings. *Id.* at 182.

Following a January 9, 2009, demand letter from the Medicare contractor (Exhibit 1 at 173), the appellant, through counsel, requested a redetermination. The Medicare contractor issued a partially favorable redetermination finding that the "original overpayment did not take into consideration services that were allowed at a lesser amount for down-coding." Exh. 1 at 137-168.

The appellant requested reconsideration by a Qualified Independent Contractor (QIC), conceding the overpayment pertinent to claims for twelve beneficiaries. The QIC issued a partially favorable reconsideration reducing, to thirteen, the number of beneficiaries with disputed claims. Exh. 1 at 10-39. The QIC also upheld the validity of the statistical methodology underlying the extrapolated overpayment. *Id.* at 25-28.

The appellant requested a hearing before an ALJ. Exh. 1 at 1-9. On February 2, 2011, the ALJ conducted a hearing by telephone.

Represented by counsel, the appellant and associated medical doctors attested to the medical necessity of the disputed beneficiary-specific claims for coverage. The appellant also presented testimony from its statistical expert, Cornelia Dorfshmid, Ph.D. and relied upon a January 24, 2010, report on the PSC's sampling methodology prepared by the appellant's initial statistical expert, Will Yancey, Ph.D. Dr. Yancey passed away after preparing his report and prior to the hearing.¹ Also appearing as a "non-party participant" was Gregg Dobbins, Ph.D. a statistical expert associated with Health Integrity, a Zone Program Integrity Contractor (ZPIC). After the audit, but before the ALJ hearing, ZPICs replaced PSCs in the Medicare audit review process. Dr. Dobbins was accompanied by ZPIC counsel. Dec. at 2 and 11; see also ALJ Hearing CD #1.

In the decision which followed, the ALJ addressed, and rejected, three of the appellant's (per Dr. Yancey's report) four challenges to the statistical sampling. Based upon a finding that the PSC adhered to the CMS sampling guidance in the Medicare Program Integrity Manual (MPIM) (IOM Pub. 100-08), the ALJ determined that - "the PSC followed the proper procedures, for the execution of probability sampling;" the sample's "precision is tenable and should be applied . . . because of the PSC's adherence to the Program Integrity Manual," and "the PSC . . . accurately defined the universe of all claims submitted" for the period at issue. Dec. at 12.

However, the ALJ also found that:

Dr. Yancey's fourth contention that the PSC's definition of the sampling frame is designed to exclude underpayments, thereby making the sample invalid, is persuasive. Dr. Dobbins testified that, notwithstanding the fact that steps two and three in the Program Integrity Manual, establishing a valid statistical sampling, are important for the PSC to follow, he further stated that both overpayments and underpayments should be looked at when performing work for a valid statistical sampling. In addition, . . . Dr. Dobbins, in citing appropriate sections of the Program Integrity Manual, testified that it is

¹ The ALJ identified Dr. Yancey's report as appearing "at Exhibit 1, pages 25-36." See Dec. at 11. Based upon the record before the Council, that range of pages in Exhibit 1 encompasses a segment of the QIC reconsideration including a discussion of Dr. Yancey's report. Dr. Yancey's report, itself, appears at **Exhibit 4, Tab 16, pages 274-285.**

critical for the PSC 'to say exactly what you want to look for' and that disallowing the inclusion of underpayments would not 'skew' the sample. Upon careful consideration, the ALJ agrees with the Provider [appellant] and finds that the issue of statistical sampling and extrapolation should be recomputed and/or recalculated, whereby all of the claims, including overpayments and underpayments, are used in the calculation.

Dec. at 12-13.

The ALJ then turned to the thirteen beneficiary-specific claims which remained in dispute. The ALJ found that accompanying medical documentation supported findings of coverage for the claims for seven beneficiaries (**Beneficiaries 1, 2, 3, 6, 7, 9 and 10**) but did not support coverage, as originally claimed, for the remaining six (**Beneficiaries 4, 5, 8, 11, 12 and 13**). Dec. at 13-19. The ALJ also found the appellant liable for the non-covered services under section 1879 of the Act and determined that the appellant was not entitled to waiver of recoupment of any overpayment under section 1870 of the Act. *Id.* at 20.

The ALJ directed that -

the case is reversed and remanded to have the statistical sampling and extrapolation re-computed (*sic*) or recalculated to include, if any, the underpayments in the claims during the period of time under review; and such recomputation with the resulting extrapolation shall take into account the revised decision of the thirteen beneficiaries' claims

Dec. at 13.

The Position of CMS

The CMS memorandum addresses "only the ALJ's decision to exclude the extrapolated overpayment." Exh. MAC-1 at 8. CMS notes that:

Dr. Yancey did not identify any underpayments; rather, he contended that the PSC erroneously failed to reopen previously denied claims to review whether the denials

were incorrect. Dr. Yancey expressly challenged the PSC's definition of the sampling frame.

The ALJ appeared to construe Dr. Yancey's argument as an assertion the PSC excluded (known) underpayments from its calculations. We infer this based on the ALJ's finding that 'the PSC has accurately defined the universe of all claims submitted from January 1, 2005 to October 31, 2007,' as well as his instructions to the PSC to recalculate the extrapolation 'to include, if any, the underpayments in the claims during the period of time under review.' ALJ decision (*sic*) at 12-13. We believe that the ALJ misconstrued Dr. Yancey's arguments and erroneously invalidated the sample on the basis that it excluded underpayments.

Exh. MAC-1 at 9 (footnote omitted).

CMS argues that the PSC's definition of the universe, sampling unit, and frame are consistent with the MPIM instructions at chapter 3², sections 3.10.3.2.1, 3.10.3.2.2 and 3.10.3.2.3. Specifically, CMS notes that pursuant to MPIM section 3.10.3.2.3:

The frame may be, for example, a list of all beneficiaries receiving items from a selected supplier, *a list of all claims for which fully or partially favorable determinations have been issued*, or a list of all the *line items for specific items or services for which fully or partially favorable determinations have been issued*.

Exh. MAC-1 at 9 (emphasis in original). CMS maintains that the PSC properly "defined its sampling unit as the claim" and the universe as "all claims that included [specific] HCPCS codes . . . for the period between January 1, 2005 and October 31, 2007." *Id.* at 9-10. CMS characterizes as "wholly speculative" Dr. Yancey's position that the PSC "sampling plan prevents the Appellant from obtaining all the payment that is due." CMS contends that there is no basis for Dr. Yancey's contention that "the sampling frame deliberately excluded zero paid claim lines where [the Appellant] may be entitled to more payment." CMS

² Effective June 28, 2011, the sampling instructions previously found at MPIM chapter 3 were moved to a new chapter 8. Citation in this decision, as it was at all prior levels of review, is to the instructions as they appeared at MPIM chapter 3.

notes, however, that neither the appellant, nor Dr. Yancey, identified any underpaid claims or claim lines. *Id.* at 10.

CMS asserts that the appellant's argument that the PSC failed to find "likely underpayments" is an impermissible attempt to shift the burden to the PSC to demonstrate why it did not find underpayments. CMS argues that a party seeking Medicare coverage has the burden of proof to demonstrate medical necessity. CMS notes that an appellant who disagrees with an initial coverage determination has the right to appeal that determination pursuant to 42 C.F.R. § 405.904(b). Further, pursuant to 42 C.F.R. § 405.980(c), a provider or supplier has the right to request that a Medicare contractor reopen an initial determination. CMS maintains that, to the extent it believes an underpayment exists, the appellant has sufficient administrative remedy to challenge a contractor's finding and establish the correct payment due. However, CMS insists that the appellant's "wholly unsupported allegation that the sampling design excluded claims that *might* have been underpaid does not demonstrate the sample is statistically invalid or serve as a basis for voiding the extrapolated overpayment." Exh. MAC-1 at 10 (emphasis in original).

The Appellant's Response

The appellant offers a multi-faceted response, directly responding to the CMS memorandum and then requesting reexamination of certain aspects of the ALJs' decision, in the event the Council were to find merit in the CMS position.

The appellant first asserts that the Council should not review the ALJ's decision because it has met its burden of "rebutting the 'presumption of validity' as to the sample and the overpayment estimate." The appellant asserts that its arguments are not based on "conjecture" as CMS contends, but rather on the evidence of record and the applicable Medicare guidance. The appellant references section 3.10.1.3 of the MPIM, which identifies six "major steps" inherent in the conduct of statistical sampling. Specifically, the appellant highlights Step (5) which identifies "reviewing each of the sampling units and **determining if there was an overpayment or an underpayment**" as the missing element, and fatal flaw, in the PSC review. Exh. MAC-2 at 2-3 (emphasis in original). The appellant contends that CMS erroneously interpreted the ALJ's conclusion as construing Dr. Yancey's report to assert that "the PSC excluded (known) underpayments from its calculation." Rather, the

appellant asserts, the ALJ took issue with the validity of the sampling frame. Exh. MAC-2 at 3-4.

In the event that the Council decided to review the ALJ's decision, the appellant urged the Council to consider three additional arguments relative to the sampling methodology.

The appellant notes that the PSC statistical expert, Dr. Dobbins, testified that the PSC "assumes the payment [of each claim] is either totally right or totally wrong." The appellant indicated that its statistical expert, Dr. Dorfshmid "correctly pointed out that the sampling frame and the sample . . . includes partially paid claims, thereby showing that . . . [the PSC's] sampling methodology is based on an incorrect assumption." The appellant asserts that in response to this testimony, Dr. Dobbins conceded that the "totally right or totally wrong" assumption underlying the sampling methodology was wrong. Exh. MAC-2 at 4.

The appellant points out that Dr. Dobbins agreed with the appellant's position that the sample did not have an acceptable level of precision. Regardless, however, the ALJ found that the sample had a "tenable" level of precision. On the assumption that the ALJ's favorable findings on claims for seven additional beneficiaries are not overturned, the appellant asserts that the sample's level of precision will only worsen upon recalculation. Exh. MAC-2 at 4.

The appellant notes that the PSC used the lower-bound of a one-sided 90 percent confidence interval to determine the overpayment which was approximately \$865,000. The appellant argues that although Dr. Dobbins testified that this model gave the appellant "the benefit of the doubt," Dr. Dorfshmid testified that the lower-bound of a two-sided 90 percent confidence interval would result in an overpayment of approximately \$693,000. The appellant argues that in light of the fact that the appellant's model results in "an overpayment estimate more than \$200,000 less,"³ Dr. Dobbins' "benefit of the doubt" argument "falls apart." The appellant does not dispute that HCFA Ruling 86-1 places the burden on an appellant "to rebut the presumption of validity as to the amount of an overpayment." The appellant argues that as CMS was "silent" regarding this argument, the appellant has met that burden, demonstrating that the overpayment estimate is too high. Exh. MAC-2 at 4-5.

³ The difference in the appellant's projections is actually \$172,000.

Finally, in the event the Council finds the underlying sampling methodology valid, the appellant also urges the Council to reexamine the ALJ's six unfavorable beneficiary-specific claim determinations. See Exh. MAC-2 at 5-10.

APPLICABLE LEGAL AUTHORITIES

CMS (formerly HCFA) Ruling 86-1 describes the agency's policy on the use of statistical sampling to project overpayments made to Medicare providers and suppliers. The Ruling also outlines the history and authority, both statutory and precedential, for the use of statistical sampling and extrapolation in calculating overpayments. The Ruling provides, in part:

Sampling does not deprive a provider of its rights to challenge the sample, nor of its rights to procedural due process. Sampling only creates a presumption of validity as to the amount of an overpayment which may be used as the basis for recoupment. The burden then shifts to the provider to take the next step. The provider could attack the statistical validity of the sample, or it could challenge the correctness of the determination in specific cases identified by the sample (including waiver of liability where medical necessity or custodial care is at issue). In either case, the provider is given a full opportunity to demonstrate that the overpayment determination is wrong. If certain individual cases within the sample are determined to be decided erroneously, the amount of overpayment projected to the universe of claims can be modified. If the statistical basis upon which the projection was based is successfully challenged, the overpayment determination can be corrected.

CMS Ruling 86-1-9, 86-1-10.

The sampling guidelines in chapter 3 of the MPIM reflect that the time and expense of drawing and reviewing claims from large sample sizes, and finding point estimates which accurately reflect the estimated overpayment with relative precision, may not be administratively or economically feasible for contractors. Instead, the guidelines allow for smaller sample sizes and less precise point estimates, but offset such lack of precision with direction to the carriers to assess the overpayment at the lower level of a confidence interval - generally, the lower level of a ninety percent one-sided

confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed, thus giving the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. As a result of the above policy decision, the question becomes whether sample size and design are sufficiently adequate to provide a meaningful measure of the overpayment, and whether the provider/supplier is treated fairly despite any imprecision in the estimation.

The MPIM provides guidance to contractors in conducting statistical samples for use in estimating overpayment amounts. The instructions are intended to ensure that a statistically valid sample is drawn and that statistically valid methods are used to project overpayments where claim review indicates that overpayments have been made. The MPIM describes the purpose of its guidance as follows:

These instructions are provided so that a sufficient process is followed when conducting statistical sampling to project overpayments. ***Failure by the PSC or the BI unit or the contractor MR unit to follow one or more of the requirements contained herein does not necessarily affect the validity of the statistical sampling that was conducted or the projection of the overpayment. An appeal challenging the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted. Failure by the PSC BI units or the contractor MR units to follow one or more requirements may result in review by CMS of their performance, but should not be construed as necessarily affecting the validity of the statistical sampling and/or the projection of the overpayment.***

MPIM, ch. 3, § 3.10.1.1 (emphasis supplied).

The MPIM further provides that a contractor may employ any sampling methodology that results in a "probability sample," as follows:

[The contractor] shall follow a procedure that results 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 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 as is discussed below.

MPIM, ch. 3, § 3.10.2 (emphasis supplied). The MPIM recognizes that a number of sampling designs are acceptable, including: simple random sampling, systematic sampling, stratified sampling, and cluster sampling, or a combination of these. *Id.* at § 3.10.4.1.

The MPIM provides the following guidance with respect to sample size:

The size of the sample (i.e., the number of sampling units) will have a direct bearing on the precision of the estimated overpayment, but it is not the only factor that influences precision. The standard error of the estimator also depends on (1) the underlying variation in the target population, (2) the particular sampling method that is employed (such as simple random, stratified, or cluster sampling), and (3) the particular form of the estimator that is used (e.g., simple expansion of the sample total by dividing by the selection rate, or more complicated methods such as ratio estimation). It is neither possible nor desirable to specify a minimum sample size that applies to all situations. A determination of sample size may take into account many things, including the method of sample selection, the estimator of overpayment, and prior knowledge (based on experience) of the variability of the possible overpayments that may be contained in the total population of sampling units.

In addition to the above considerations, real-world economic constraints shall be taken into account. As stated earlier, sampling is used when it is not administratively feasible to review every sampling unit in the target population. In determining the sample size to be used, the PSC BI unit or the contractor MR unit shall also consider their available resources. That does not mean, however, that the resulting estimate of overpayment is not valid, so long as proper procedures for the execution of probability sampling have been followed. A challenge to the validity of the sample that is sometimes made

is that the particular sample size is too small to yield meaningful results. Such a challenge is without merit as it fails to take into account all of the other factors that are involved in the sample design.

MPIM, ch. 3, § 3.10.4.3 (emphasis supplied).

The MPIM further provides that:

If the decision on appeal upholds the sampling methodology but reverses one or more of the revised initial claim determinations, the estimate of overpayment shall be recomputed *and a revised projection of overpayment issued.*

MPIM, ch. 3, § 3.10.9.2 (emphasis supplied).

With respect to component parts of a statistical sample, a statistical sample "universe and sampling frame will usually cover all relevant claims or line items for the period under review," and CMS assumes, for purposes of discussion, "that *the sampling unit is the claim.*" MPIM, ch. 3, § 3.10.3.2 (emphasis supplied). In its discussion of the universe of Part B claims, CMS states that "[t]he universe shall consist of all **fully and partially paid claims**" *Id.* at § 3.10.3.2.1 (emphasis supplied). The sampling frame is a list of all "possible sampling units from which the sample is selected." MPIM, ch. 3, § 3.10.3.2.3. As example, the frame can be "all the line items for specific items or services for which **fully or partially favorable determinations have been issued.**" *Id.* (emphasis supplied). CMS states that an "ideal frame is a list that covers the target universe completely" although, in some cases, duplicate sampling units must be eliminated before selecting the sample. MPIM, ch. 3, § 3.10.3.3.

A contractor must keep sufficient documentation of the sampling methodology "so that the sampling frame can be re-created, should the methodology be challenged." MPIM, ch. 3 § 3.10.4.4.1. Documentation should include worksheets which reflect both overpayments **and underpayments** discovered during the review. *Id.* at §§ 3.10.4.4.3. and 3.10.4.4.4. The "total overpayment 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." *Id.* at

§ 3.10.5.1 (emphasis supplied).⁴ "In this estimation procedure, which is unbiased, the amount of overpayment dollars in the sample is expanded to yield an overpayment figure for the universe." *Id.*⁵ CMS explains that this process results in the "point estimate of the overpayment," which is "the difference between what was paid and what should have been paid." *Id.* In stratified sampling, estimates are obtained for each stratum and "the weighted stratum estimates are added together to produce an overall point estimate." *Id.*

CMS directs that "[i]n most situations, the lower limit of a one-sided 90 percent confidence interval shall be used as the amount of overpayment to be demanded for recovery" MPIM, ch. 3, § 3.10.5.1. The lower limit calculation involves subtracting a multiple of the estimated standard error from the point estimate, thereby "yielding a lower figure." *Id.* "This procedure, which, through confidence interval estimation, incorporates the uncertainty inherent in the sample design, is a conservative method that works to the financial advantage of the provider or supplier." MPIM, ch. 3, § 3.10.5.1. CMS states that this procedure results not only in an amount "that is very likely less than the true amount of the overpayment," but it "allows a reasonable recovery **without requiring the tight precision that might be needed to support a demand for the point estimate.**" *Id.* A Medicare contractor is "not precluded from demanding the point estimate [of the overpayment] where high precision has been achieved." *Id.* In discussing ratio and regression estimation methods, CMS states that they "can result in smaller margins of error than the simple expansion method." *Id.* CMS notes that, in those cases, when "actual correlation between the original paid amount is high enough, greater precision in estimation will be attained, i.e., the lower limit of the one-sided 90 percent confidence interval will be closer to the point estimate." *Id.*

⁴ The MPIM provides that "[s]ampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall be used in calculating the estimated overpayment." MPIM, ch. 3, § 3.10.5.2.

⁵ CMS explains that the term "bias" in statistical sampling is used in a technical sense and does not reflect unfair treatment of a provider or supplier. MPIM, ch. 3, § 3.10.5.1. "A biased estimator is often used rather than an unbiased estimate because the advantage of its greater precision outweighs the tendency of the point estimate to be a bit high or low." *Id.*

ANALYSIS

Generally, in deciding whether to accept own motion review, the Council "will limit its consideration of the ALJ's action to those exceptions raised by CMS." 42 C.F.R. § 405.1110(c)(2). The ALJ's decision was partially favorable to the appellant both as to the validity of the sample and specific claims coverage determinations for seven of the thirteen beneficiaries in issue before the ALJ. The effect of the ALJ's decision was a significant, and presumably acceptable to the appellant, reduction in the amount of the overpayment. Under those circumstances, there was no apparent practical reason for the appellant to request review of those aspects of the ALJ's decision unfavorable to it. However, because the Council's determination below on the sampling issues significantly redefines the financial scope of the overpayment, the Council will address the appellant's exceptions with respect to the sampling methodology and the six unfavorable beneficiary-specific claims. This action is taken in recognition of the impact of the Council's review of the issues raised in the CMS memorandum of referral and with the knowledge that the appellant did not otherwise request review in a timely manner. See 42 C.F.R. § 405.1102(a)(1).

The Statistical Validity of the Sample

Underpayments

The Council need not find that CMS or its contractor undertook statistical sampling and extrapolation based on the most precise methodology that might be devised in order to uphold an overpayment extrapolation based on that methodology. Rather, as the above-quoted authorities make clear, the test is whether the methodology is statistically valid. CMS argues that applicable guidance, including CMS Ruling 86-1 and the MPIM, establishes that the reasons cited by the ALJ in support of his decision to invalidate the sampling methodology in this case do not, in fact, demonstrate that the methodology was invalid. CMS further argues that the ALJ erred in placing the burden on the PSC to demonstrate that the sampling methodology was appropriate, and not the appellant to demonstrate that the methodology was invalid. Exh. MAC-1 at 2.

These arguments have considerable force. As stated in CMS Ruling 86-1, the use of statistical sampling "creates a presumption of validity as to the amount of an overpayment which

may be used as the basis for recoupment." The Ruling goes on to state that "the burden then shifts to the provider to take the next step." Thus, the provisions of CMS Ruling 86-1 establish that the burden is on the appellant to prove that the statistical sampling methodology was invalid, and not on the contractor to establish that it chose the most precise methodology. Therefore, the ALJ erred to the extent that he concluded that the sample was invalid because "the PSC definition of the sampling frame is designed to exclude underpayments." See Dec. at 12. The ALJ's finding is unsupported by both CMS authority and the facts of the case as there is no documentary evidence in the record that the sample was designed to exclude underpayments.

The PSC's definition of the sampling unit, here a "paid claim line," is consistent with CMS authority on statistical sampling methodology. For example, CMS assumes, for purposes of discussing statistical sampling, that the sampling unit is a provider or supplier's "claim." MPIM, ch. 3, § 3.10.3.2. CMS also states that the universe of Part B claims "shall consist of all fully and partially paid claims submitted by the supplier for the period selected for review and for the sampling units to be reviewed." *Id.* at § 3.10.3.2.1.B. The sample frame may list claims or line items "for which fully or partially favorable determinations have been issued" *Id.* at § 3.10.3.2.3.

The purpose of the statistical sample is to determine potential overpayments. It is unsurprising that the PSC would select payments to the appellant as a basis for reviewing whether the appellant had been overpaid. The Council thus finds no basis for invalidating the statistical sample because the sampling unit is defined as positive amounts of monies previously paid to the appellant.

As the MPIM emphasizes, a challenge to "the validity of the sampling methodology must be predicated on the actual statistical validity of the sample as drawn and conducted." MPIM, ch. 3, § 3.10.1.1. Manual authority also provides that medical review of claims *that are in a sample* must account for underpayments. *Id.* § 3.10.5.1. Accounting for an underpayment appearing in a sample is distinct requirement from the theory advanced by the appellant, and accepted by the ALJ, that a sample must somehow be designed to actively review all denied claims in order to capture underpayments. The MPIM provides acceptable methodologies for a reasonably economical and efficient review of an appellant's payment history. The MPIM

does not, however, require a contractor to actively pursue underpayments, but only to account for underpayments, that have been uncovered as the result of the audit, when calculating an overpayment

Appellant's challenges to the ALJ's sampling findings

The appellant's arguments challenging the ALJ's findings on sample size, precision and definition of the sample universe are not entirely persuasive. Neither before the ALJ, nor now, has the appellant identified any explicit error in the sampling methodology. Rather, the essence of the appellant's argument is that the sample was not drawn as the appellant would have drawn it. This argument, alone, does not provide a basis for the Council to find the sample invalid.

As quoted above, the MPIM states explicitly that it is not improper and, in fact, is required that the contractor consider "real-world economic constraints," such as "the level of available resources," when choosing a sampling methodology. See MPIM, ch. 3, §§ 3.10.2 and 3.10.4.3. Therefore, even if the PSC chose a particular sampling methodology because, for example, it required less staff resources than a stratified sample, that would not be a basis to conclude that the methodology is invalid. Further, the MPIM recognizes and accepts that a smaller sample size may affect the precision of the estimated overpayment. MPIM, ch. 3, at § 3.10.4.3. The MPIM does not prescribe a particular sample size or precision. Similarly, the MPIM does not prescribe any particular sampling design, but notes that any sample design that results in a probability sample, including simple random sampling, systematic sampling, stratified sampling, or cluster sampling is acceptable. MPIM, ch. 3, § 3.10.4.1. Thus, there is no support in Medicare's statistical sampling authorities for Dr. Yancey's absolute conclusions that this sample size, *per se*, was inherently too small, or that a sampling methodology that results in a relative precision percentage greater than 10% may never be used in calculating an extrapolated overpayment.

However, as recounted in the ALJ's decision, the precision of the sample was 29.94%, which is unusually high. Dec. at 12. Dr. Yancey asserted that the precision was so bad that the results should not have been projected to the population. The PSC's statistician, Dr. Dobbins, testified that he would not have chosen a 30% precision level. However, he further testified that the most important factors were adhering to the

Manual guidelines with respect to defining the universe, sampling frame, and sampling units. Dr. Dobbins agreed with the appellant's present statistician, Dr. Dorfshmid, that the Office of the Inspector General used a precision of no more than 25%. The ALJ found that the level of precision in the sample was "tenable."

Generally, we would agree that this relative level of (im)precision would ordinarily be reflected in the lower bound of the 90% confidence interval, as stated in the manual. As noted above, it is CMS's policy to allow for smaller sample sizes and less precise point estimates, but to offset such lack of precision by directing the contractors to give the benefit of the doubt resulting from any imprecision in the estimation of the overpayment to the appellant, not the agency. This is done by assessing the overpayment at the lower level of a confidence interval - generally, the lower level of a ninety percent one-sided confidence interval. This results in the assumption, in statistical terms, that there is a ninety percent chance that the actual overpayment is higher than the overpayment which is being assessed.

The unique facts of this case, though, give us pause in approving the exact extrapolation used here. The appellant has an active practice specializing in hematology and oncology. His patients may either have cancer or primary disorders of the blood. Side-effects of cancer treatment may also produce blood disorders.

The record indicates that the sample was primarily intended to review the appellant's claims for administration of drugs used to treat anemia, which is a deficiency of red blood cells. Thus, the sampling frame was defined as all claims with dates of service and payment between January 1, 2005, and October 31, 2007, that included a line item for codes Q0136, Q0137, J0881 and J0885. Q0136 and J0885 are codes for epoetin alfa (brand name Procrit); Q0137 and J0881 are codes for darbepoetin alfa (brand name Aranesp).⁶ Thirty claims with 128 line items were selected out of 6442 claims with 26,598 line items. Of these 128 line items, only 28 involved a claim for Procrit and only 2 claims involved Aranesp. With some variation in payment amount depending on the year, the Procrit payment

⁶ The codes were renumbered effective January 1, 2006, without significant change in definition.

amounts clustered around \$600. The Aranesp payments averaged about \$1050.

In addition, 23 line items involved charges for injecting Procrit or Aranesp, 90722, \$13.66 mean average, or G0351, \$14.10 mean average.⁷ Consistent with applicable LCD requirement for frequent testing of hematocrit levels this, 15 line items also involved automated complete blood count laboratory tests, 85025, \$10.86 mean average, and 13 line items were for venipuncture to draw the blood sample, 36415, \$3.00. Thus, the services directly related to administration of the drugs chosen to define the frame were present in only another 51 line items.

The remaining 47 line items involved a wide variety of codes for various services and drugs, as might be expected in the appellant's active practice in hematology and oncology. The sample included 20 other codes, in addition to the 4 codes used to define the sample and the other 4 directly related codes. See e.g. Exh. 1 at 10, 128, and 193-241. These other 20 codes include codes for the antineoplastic agents docetaxel, J9170 \$1,445.54; and gemcitabine, J9201, \$941.58. Also included were claims for Neulasta, J2505, \$1674.75-1730.56, which is used to increase white blood cells. In addition, the other line items included various supplies used with infusion therapy. Notably, there were also 5 line items for evaluation and management services, coded 99213 and 99214.

The paid amounts for these other 20 codes ranged from \$.05 for saline infusion, to \$1730.56 for Neulasta. In other words, the amount paid for the most expensive service was more than 34,000 times the amount paid for the least expensive service.

A review of the diagnosis codes in the sample also confirms that many of these other 47 line items did not involve any variant of anemia as the primary diagnosis. Exh. 1 at 338-347. Antineoplastic chemotherapy encounter, V581.1, and chemotherapy encounter, V581, were the most frequently reported non-anemia codes.

It is clear that the sample was intended to review the appellant's claims for the anti-anemia drugs Procrit and Aranesp. However, by defining the sampling frame as all claims that included one of the 4 primary codes, the sample also included many line items that had nothing to do with these 2

⁷ These codes were also renumbered effective January 1, 2006, without significant change in definition.

drugs. The other 20 non-related codes appeared in the sample only between 1 and 5 times each. The sampling frame did not purport to include all claims for any of these other codes across the universe of the appellant's patients.

The MPIM provides that sampling units should be selected according to the design of the survey and the chosen method of statistical sampling. The sampling unit should be appropriate for the issue under review. They may be an individual line(s) within claims, individual claims, or clusters of claims (e.g., a beneficiary). For example, possible sampling units may include specific beneficiaries seen by a physician during the time period under review, a list of all claims for which fully or partially favorable determinations have been issued, or claims for a specific item or service. In principle, any type of sampling unit is permissible as long as the total aggregate of such units covers the population of potential mis-paid amounts. The ideal frame is a list that covers the target universe completely.

On the facts of this case, we conclude that the sampling frame was overbroad because it included many services that were unrelated to the anti-anemia drugs that were the intended target of the review. Moreover, the simple random sample used did not adequately take into account the enormous variations in the amounts paid for the services, the variations in the types of services included, or the differing diagnoses. Nor did the sample reflect a comprehensive or well-designed review of the other 20 codes in the unrelated 47 line items across the entire universe of the appellant's patients. In the parlance of section 3.10.2 of the MPIM, *supra* at 10, the sample design was improperly executed as it did not accurately measure the variables of interest.

Accordingly, we direct that the contractor effectuate this case by excluding all codes other than the 8 codes listed above directly related to the administration of Procrit and Aranesp from the recalculation of the extrapolated overpayment. These 8 codes include only Q0136, Q0137, J0881, J0885, 90722, G0351, 85025, and 36415. The contractor may also recoup the actual overpayment for the remaining codes in the sample.

Beneficiary-Specific Claims

As noted above, the appellant asked, if the Council were to reverse the ALJ regarding the exclusion of underpayments (zero

payments) from the sample, that the Council reexamine the ALJ's unfavorable beneficiary-specific claim determinations. The appellant's theory was that each additional unfavorable claim, when extrapolated, would have a larger impact on the ultimate overpayment, as opposed to an overpayment based simply on the sum total of individual unfavorable claims. Based on the sampling analysis above, the Council will, in this instance, reexamine the unfavorable claim determinations. In so doing, the Council incorporates by reference the ALJ's recitation of the beneficiaries' medical histories. *See generally* Dec. at 17-20.

Beneficiary 4 (R.D.)
DOS June 16, 2006

The claim for Beneficiary 4 involved an office visit billed under CPT/HCPCS⁸ code 99214 with a "-25" modifier. Generally, the 99214 billing code identifies an office or outpatient visit for the evaluation and management (E&M) of an established patient requiring at least two of the following three components: a detailed history, detailed examination and medical decision making of moderate complexity. The -25 modifier indicates a significant, separately identifiable, E&M service by the same physician on the day of a procedure or service, that is above and beyond the usual pre-operative and post-operative care associated with the procedure that was performed.

The QIC denied coverage for the service as billed finding that there "was no separately identifiable service to support the use of the 25 modifier." However, the QIC found that the appellant's documentation supported downcoded reimbursement under CPT code 99212. *See* Exh. 1 at 34.

At the ALJ hearing, counsel for the appellant first noted that the 99212 code was the lowest office visit billing code available. Counsel further asserted that the QIC had allowed coverage for claims involving a similar level of service, but under the rationale denying coverage here, the QIC should have denied them all. The appellant testified to the nature of

⁸ CPT (Current Procedure Terminology) codes were designed by the American Medical Association to describe medical and surgical services performed by providers. Based upon the CPT system, CMS developed the Healthcare Common Procedure Coding System (HCPCS) for processing, screening, identifying, and paying Medicare claims. *See* 42 C.F.R. §§ 414.2 and 414.40. For purposes of this decision, the content of the CPT codes are identical to their HCPCS counterparts.

services provided, essentially notifying and counseling the beneficiary regarding the severity of a newly diagnosed, potentially fatal, condition. See ALJ Hearing CD #2.

Examining this claim in the context of the coverage criteria for CPT code 99214, the ALJ found that the "office visit was a follow-up examination for an existing problem" with no evidence of medical decision making of moderate complexity, but rather "straightforward decision making for ongoing treatment." However, as had the QIC, the ALJ found that while the appellant had not satisfied the coverage criteria for CPT code 99214, it had established "payment at a lower level of 99212." Dec. at 17.

Before the Council, counsel for the appellant reiterates that the appellant's hearing testimony established that this service involved diagnosis and identification of a pre-existing boil on the beneficiary's shoulder to be "acute leukemia" and a corresponding consultation. Counsel contends that the appellant's testimony regarding the activities involved in this office visit demonstrates that the Medicare coverage criteria for reimbursement of a claim billed under CPT code 99214 had been satisfied. Exh. MAC-2 at 5-6.

Pursuant to section 1833(e) of the Act, an appellant bears the responsibility for documenting the medical necessity of its claim for coverage. See also 42 C.F.R. § 424.5(a)(6). The appellant's testimony is not supported by documentary evidence of record. As noted above, coverage for a claim billed under CPT code 99214 requires evidence of at least two, of three, criterion - a detailed history, a detailed examination, or medical decision making of moderate complexity, typically lasting at least twenty-five minutes.

The Council finds that the appellant's evidence does not meet the CPT code 99214 coverage criteria. The "History" block for the appellant's June 16, 2006 "Physician Progress Note" indicates that the beneficiary's weight is stable, the visit itself was a one-week follow-up and that the beneficiary had received Neulasta on June 6, 2006. The Note contains results for six undated "Labs" and, pertinent here, a comment indicating that the "shoulder mass" is "[illegible] better." There is no contemporaneous record of the time spent in consultation with the beneficiary or the beneficiary's family or the content of

such consultation.⁹ See generally Claim Folder for Beneficiary 4 and Exh. 4, Tab 6-1.

The appellant's hearing testimony is not supported by documentary evidence. There is no detailed history, detailed examination, or contemporaneous documentation of time. Accordingly, the appellant's claim does not meet the coverage criteria coverage of services billed with CPT code 99214-25. However, as the ALJ found, the claim for Beneficiary 4 (R.D.) on June 16, 2006, may be reimbursed under CPT code 99212

Beneficiary 5 (L.De.)
DOS June 28, 2005

The claim for Beneficiary 5 involved administration of Procrit, for treatment of low hematocrit, billed under CTP code Q0136 and a therapeutic/diagnostic injection, billed under CPT code G0351.

Measured against the criteria in Local Coverage Determination (LCD) L8850 (*Synthetic Erythropoietin Substitutes*),¹⁰ the QIC found that there was no history and physical, nor progress note for the date of service. Accordingly, the QIC denied coverage for this claim based upon the inadequacy of the supporting documentation. Exh. 1 at 34-35.

In the request for hearing counsel for the appellant contended that primary erythropoietin deficiency can be caused by a variety of medical conditions and factors and that there were a number of indicators of this diagnosis in the beneficiary's medical records. The appellant asserted that -

In each of the cases where [as here] the beneficiary's diagnosis code was "Other specified anemias," 285.8, we provided to the QIC evidence of . . . factors to support the diagnosis of primary erythropoietin deficiency, which included lab results. . . However, . . . the QIC [did not] explain why the information submitted fails to support the code "Other specified anemias," 285.8. . . .

Exh. 1 at 4.

⁹ Exhibit 4, Tab 6-4 contains a summary of the appellant's December 30, 2008, consultation with Beneficiary 4.

¹⁰ See Exhibit 4, Tab 2.

Before the ALJ, counsel and the appellant largely restated this line of argument. See ALJ Hearing CD #2.

The ALJ noted that in 2004 and early 2005, the beneficiary's hematocrit and hemoglobin levels had actually decreased following administration of Procrit. Consequently, the ALJ concluded that the continued administration of Procrit was not medically reasonable and necessary. Dec. at 17-18.

Before the Council, counsel for the appellant asserts that the ALJ failed to consider that the appellant's argument that the beneficiary's medical history included "primary erythropoietin deficiency that required Procrit injections to combat . . . anemia." Counsel adds that the beneficiary's low creatinine clearance indicated that renal dysfunction was also contributing to primary erythropoietin deficiency. Counsel contends that "[o]ne noted decrease in hemoglobin and hematocrit levels" was not sufficient to override the appellant's medical judgment that the beneficiary had primary erythropoietin deficiency and asserts that the appellant's course of treatment complied with the LCD's coverage criteria. Exh. MAC-2 at 7.

The appellant's argument is based upon the LCD's guidance for "Treatment of Non-Dialysis-Related Anemias with EPO" which provided that "Medicare is establishing the following limited coverage for HCPCS [CPT] code J0885 [Injection Epoetin Alfa]" for several diagnostic codes including 285.8. See Exh. 4, Tab 2 (LCD L8850 at 7). At the hearing, counsel referenced the "Note" associated with code 285.8 which provides "By using diagnosis code **285.8***, the medical records **must** reflect the diagnosis of primary erythropoietin deficiency causing the anemia." *Id.* (emphasis in original).

Pursuant to section 1833(e) of the Act, an appellant bears the responsibility for documenting the medical necessity of its claim for coverage. See, also, 42 C.F.R. § 424.5(a)(6). The appellant's documentary evidence does not support this claim for coverage. The appellant's summary of an October 8, 1999 visit with the beneficiary identifies "mild anemia" and is otherwise undecided as to the beneficiary's then-current diagnosis. See Claim File for Beneficiary 4, Exh. 2 at 13-14. Otherwise, the appellant's documentation generally consists of lab test results and notes not contemporaneous to the June 28, 2005, date of service. The documentation does not contain a 285.8 diagnostic code or otherwise reflect a diagnosis of primary erythropoietin deficiency causing anemia.

Accordingly, the appellant's claim for coverage of services provided to Beneficiary 5 (L.De.) on June 28, 2005, billed under CPT codes Q0136 and G0351, remains denied.

Beneficiary 8 (C.G.)
DOS September 29, 2006

The claim for Beneficiary 8 involved administration of Procrit, billed under CTP code J0885 and drug injection charges, billed under CPT code 90772.

The QIC noted that, on the date of service, the beneficiary had readings of 12.7 for Hemoglobin and 37.6 for Hematocrit. The QIC found that there was no history and physical (H&P) to support the diagnosis and determine whether the service satisfied the LCD's coverage guidelines, nor a progress note for the date of services. Exh. 1 at 35.

As with Beneficiary 5, in the request for hearing counsel for the appellant argued that primary erythropoietin deficiency can be caused by a variety of medical conditions and factors and that there were a number of indicators of this diagnosis in the beneficiary's medical records. Counsel also questioned the foundation for the QIC's conclusion. See Exh. 1 at 4. At the ALJ hearing, the appellant generally testified that the Procrit treatments helped the beneficiary. See ALJ Hearing CD #2.

The ALJ cited a March 11, 2004, Physician Progress Note in the beneficiary's record indicating that the beneficiary was to receive "Procrit 40,000 U SQ, weekly." The ALJ indicated that the lab report for the date of service showed a HGB level of 12.7 and a HCT level of 37.6. Additionally the ALJ noted the presence in the record of a 2002 lab report. The ALJ surmised that it appeared "that there was only one treatment prior to the date of service" and concluded that the record was insufficient to support the medical necessity of the beneficiary's Procrit treatment. Dec. at 18.

Counsel for the appellant contends that, per the LCD, for a diagnosis of "285.8 - Other specified anemias" there must be a diagnosis of primary erythropoietin deficiency. Counsel further asserts that the appellant's testimony supports a finding that the patient had primary erythropoietin deficiency. Additionally, counsel generally references the appellant's testimony and a December 29, 2008, note from the appellant

(Exhibit 4, Tab 10-3) recounting his initial ("March of 2004") examination of the beneficiary as further support for coverage. Exh. MAC-2 at 7-8.

Other than the lab results cited by the ALJ, there is no contemporaneous evidence in the record pertinent to the date of service at issue. Specifically, there is no diagnosis of primary erythropoietin deficiency anemia satisfying the LCD coverage criteria for diagnosis code 285.8. Accordingly, the appellant's claim for coverage of services provided to Beneficiary 8 (C.G.) on September 29, 2006, billed under CPT codes J0885 and 90772, remains denied.

**Beneficiary 11 (M.S.)
DOS February 5, 2007**

The claim for Beneficiary 11 involved the administration of Procrit, billed under CTP code J0885.

Based upon the coverage criteria in LCD L8850, the QIC denied coverage finding that -

there was not . . . [history and physical] included in the case file, the only progress note date (*sic*) 2/4/02 was illegible. Unable from the . . . [documentation] submitted to determine the medical cause for the anemia. Without . . . [supporting documentation we are] unable to determine if . . . [this claim] meets the LCD [requirements] for coverage.

Exh. 1 at 37.

In its request for an ALJ hearing, the appellant did not associate the claim for this beneficiary with any specific aspect of its global argument. *See generally* Exh. 1 at 1-9. At the hearing, the appellant testified that the beneficiary had chronic anemia which may have stemmed from chemotherapy treatment for breast cancer. The appellant did contend that the appellant had primary erythropoietin deficiency which was responsive to Procrit. However, counsel for the appellant also conceded that the documentation associated with this beneficiary was not as adequate as the appellant would have liked. To support the claim for coverage, the appellant read the appellant's medical history into the record. *See* ALJ Hearing CD #3.

The ALJ cited an October 6, 2006, physician's progress note in the beneficiary's record indicating that the beneficiary was to receive "Procrit 80,000 for HCT <41." The ALJ noted the beneficiary's HGB/HCT levels at that time were 12/37. On the date of service they were 13.4/40.4. The ALJ denied coverage finding that other "than an illegible flow sheet report . . . the record contains no documentation to reflect the beneficiary's more recent HGB/HCT levels to support medical" necessity. Dec. at 18-19.

Counsel for the appellant does not dispute the ALJ's characterization of the evidence. Rather, counsel references the appellant's hearing testimony "that there were a number of indicators supporting the diagnosis of primary erythropoietin deficiency." Counsel asserts that given the appellant's testimony regarding the beneficiary's medical history and his determination that the beneficiary's "low EPO values were inadequate for her to battle anemia" there was sufficient evidence in the record to support coverage for this claim. Exh. MAC-2 at 8.

The Council agrees with the ALJ's determination that the evidence of record is inadequate to support the appellant's claims for coverage for this service. The appellant's documentation does not reflect that a diagnosis of primary erythropoietin deficiency is causing the beneficiary's anemia.

Accordingly, the appellant's claim for coverage of services provided to Beneficiary 11 (M.S.), on February 5, 2007, billed under CPT code J0885, remains denied.

**Beneficiary 12 (R.S.)
January 6, 2006**

The claim for Beneficiary 12 involved the administration of pegfilgrastim (Neulasta) injection treatments billed under CPT code J2505.

The QIC noted that the administration of Neulasta occurred on the same day as the administration of cytotoxic chemotherapy drugs. The QIC denied coverage as "not within the FDA approved guidelines for usage." Exh. 1 at 37. Specifically, the QIC noted, "the FDA label shows the administration should not occur within 14 days before and 24 hours after administration of cyotoxic (*sic*) chemotherapy." *Id.* at 20.

In the request for hearing, counsel for the appellant contended that "FDA labeling does not control Medicare coverage." Exh. 1 at 5. Counsel argued that the QIC disregarded the fact that Medicare "regularly covers off-label uses of FDA-approved drugs where the treatment is reasonable and necessary, particularly in the context of . . . chemotherapy." Exh. 1 at 5. Further, counsel cited CMS's admonishment to Medicare contractors to "not deny coverage solely on the absence of FDA-approved labeling for the use."¹¹ *Id.* Counsel noted that the beneficiary lived more than 100 miles from the appellant's clinic and was at risk for developing neutropenic fever after returning home and not being able to access the clinic for proper treatment. Given these factors, counsel contended that the appellant exercised reasonable medical judgment in administering the Neulasta on the same day as the administration of cytotoxic chemotherapy. *Id.* at 5-6.

At the hearing, counsel for the appellant reiterated the above arguments. The appellant and associated physician witness testified to the beneficiary's fragile physical nature and the distance between his residence and the clinic (a one-way trip of either 120 or 131 miles). The appellant stated that the administration of Neulasta at issue was not done without full consideration of the beneficiary's health and safety, both as to the contemporaneous injection itself and the issues involved had the beneficiary been required to return to the clinic the day following chemotherapy.

The ALJ found that the "record contains physician orders dated December 29, 2005 and October 4, 2006 for Neulasta 6mg SQ." However the ALJ determined that "according to administration records, the beneficiary received Neulasta treatments on the same days as cytotoxic chemotherapy treatments, which is not within the FDA approved guidelines." The ALJ found that "this off-label use should be allowed because the drug's off-label use is supported by 'peer-reviewed' literature." However, the ALJ then denied coverage because the appellant did not provide such supporting literature. Dec. at 19.

While the ALJ did not cite the "peer-reviewed literature" upon which he was relying, the Council notes that the appellant's request for an ALJ hearing cites supportive articles in both the *Journal of Clinical Oncology*, which the MBPM (at chapter 15,

¹¹ See Medicare Benefit Policy Manual (MBPM) (IOM Pub. 100-02), ch. 15, § 50.4.

section 50.4.5.C) identifies as "peer reviewed medical literature" for purposes of off-label use of drugs in an anti-cancer regimen and the Journal of Supportive Oncology. See Exh. 1 at 5, n.18.

Counsel for the appellant asserts that "the standard for . . . [this] claim is not whether the physician submits peer-reviewed literature supporting off-label use. Rather, for drugs that are not used as 'anti-cancer agents' the standard is whether the use is "medically accepted as explained by the Medicare Benefit Policy Manual" Exh. MAC-2 at 8-9. Counsel referenced testimony from the appellant and associated physician-witnesses that administration of Neulasta on the same day as chemotherapy was consistent with accepted standards of medical practice. Additionally, counsel noted that it was more practical to provide the beneficiary with Neulasta on the date of service in issue; otherwise, the beneficiary would have had to make a 130-mile [one-way] trip to the clinic the next day for the injection. Exh. MAC-2 at 8-9.

Chapter 15, section 50.4.2 of the MBPM provides -

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the carrier determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. . . .

Based upon the appellant's and supporting witnesses' testimony, the beneficiary's medical history, the referenced medical literature and the beneficiary's residential/travel circumstances, the Council finds that the January 6, 2006, administration of Neulasta to this beneficiary was reasonable under accepted standards of medical practice. Accordingly, the appellant's January 6, 2006, claim for Beneficiary 12 (R.S.), billed under CPT code J2505, **is covered by Medicare.**

**Beneficiary 13 (W.W.)
December 12, 2006**

The claim for Beneficiary 13 involved an office visit billed under CPT code 99213-25. This code identifies an office or

outpatient visit for the evaluation and management of an established patient requiring two of three key components - an expanded problem focused history; an expanded problem focused examination and medical decision making of low complexity. The problems presented are of low to moderate severity and a physician is typically expected to consult with the patient or patient's family for fifteen minutes. The "-25" modifier identifies a significant, separately identifiable E&M service by the same physician on the day of a procedure.

The Medicare contractor down-coded this claim allowing reimbursement under CPT code 99212 (problem focused history; problem focused examination and straightforward medical decision making) with a "-25" modifier. The Contractor indicated that, pursuant to the LCD, "the medication should be withheld when the HCT reaches 36 percent. The lab results furnished relate the patient's HCT was 36.7." Exh. 1 at 163. "Therefore, the documentation fails to establish the medical necessity for the administration of Procrit because the required indications are not met . . . Therefore, 99213 will be downcoded to 99212 25 and allowed for payment." *Id.* Without further discussion, the QIC agreed with the Medicare contractor's conclusions. Exh. 1 at 38.

In its request for hearing, the appellant questioned whether "the QIC even reviewed the documentation . . . showing that both visits met the criteria for a 99214 visit."¹² Exh. 1 at 7-8. Otherwise, the appellant emphasized to the ALJ that

Medicare Evaluation and Management Guidelines are, as the name confirms, guidelines, not a condition to payment. The position taken by many people that "if it is not written, it wasn't done" is one of the situations where conventional wisdom is mistaken . . . [U]nder Medicare law, the question is whether a service was actually provided as billed. If you conclude that the evidence . . . supports the conclusion that the code accurately reflects the services, the claims should be paid, even if the service was not documented in accordance with the Guidelines.

¹² The appellant's argument in its request for ALJ hearing was directed at claims for two distinct beneficiaries, one of whom, Beneficiary D.G., involved a claim billed with CPT code 99214-25. See Exh. 1 at 35. The claim for Beneficiary W.W. was billed under CPT code 99213-25. *Id.* at 38.

Exh. 1 at 8.

At the ALJ hearing, counsel for the appellant noted that CPT code 99213 represented "the second lowest office visit you have." The appellant's testimony and counsel's argument referenced the appellant's progress note for the date of service and how the entries there, which reflect examinations made and prescriptions written, satisfied the CPT coding criteria. See ALJ Hearing CD #3.

The ALJ noted that the record contains an E&M documentation score sheet with history and examination reports, a complexity of medical decision making chart and notes that the beneficiary received an iron supplement. Recounting the elements in CPT code 99213, the ALJ found that the examination in issue required only straightforward decision making for routine care. Accordingly, the ALJ denied the appellant's claim for coverage at the higher rate of reimbursement associated with CPT code 99213, but affirmed coverage at the downcoded rate associated with CPT code 99212-25.¹³ Dec. at 19-20.

Counsel for the appellant notes that coverage for E&M services billed under CPT code 99213 involve satisfaction of two of the following three elements: (1) a limited number of diagnoses or management options; (2) a limited amount and/or complexity of data to be reviewed; and (3) low risk of complications and/or morbidity or mortality. Counsel recounts that on the date of service the appellant performed a review and examination of the affected body area - forearms, as well as "multiple other systems," including, but not limited to, ears, nose, throat, cardiovascular, respiratory, breast, abdominal/GI, lymphatic, hematologic and immunologic. Counsel referenced the appellant's testimony that the beneficiary's iron level had "drifted low" and his decision to prescribe an iron supplement, ferrous fumarate, to ensure that the beneficiary's Procrit dosage remained effective. Counsel asserts that this combination of services satisfies the coverage criteria for CPT code 99213. Exh. MAC-2 at 9-10.

Neither an ALJ, nor the Council, "are not bound by LCDs, . . . or CMS program guidance such as program memoranda and manual

¹³ The ALJ did not separately address use of the -25 modifier. However, as the ALJ characterized his action as "affirming" the QIC reconsideration, which included the "-25" modifier, the Council concludes that the ALJ intended to characterize payment for the claim as that available for a 99212-25 coding.

instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1060(a). Moreover, as discussed above, an appellant bears the responsibility for documenting the medical necessity of its claim for coverage. See section 1833(e) of the Act and 42 C.F.R. § 424.5(a)(6).

The appellant's argument appears to be that the totality of its evidence is sufficient to overcome what may be, in the Council's characterization, more specific deficiencies in that evidence noted by the ALJ. However, the ALJ's consideration and ultimate opinion on the evidence for this beneficiary represents just the opposite determination, that the totality of the evidence does not support the claim for coverage as billed.

We decline to embrace the appellant's suggestion that he need not contemporaneously document his services. The Secretary of the Department of Health and Human Services is charged with general administration of the Medicare program and authorized to write regulations and guidance to assist in that administration. See §§ 1871 and 1874 of the Act. Pertinent here, these regulations and guidance were created to enable CMS to assess claims for Medicare coverage against measurable criteria. A physician must furnish sufficient information to determine whether payment is due and the amount of payment. 42 C.F.R. § 424.5(a)(6). If for no other reason than administration of so vast a program, it is more than reasonable to require parties seeking Medicare payment to adhere to documentary criteria as a prerequisite to reimbursement. Standing alone, the appellant's assertions that he met the coverage criteria because he testified that he did, are not persuasive. *Ipse dixit* is not a reliable rule of law or standard of medical documentation.

Based on its review of the record, the Council finds that the appellant's claim for services provided to Beneficiary 13 (W.W.) on December 12, 2006, does not meet the coverage criteria for coverage of services billed with CPT code 99213-25. However, as the ALJ found, the claim may be reimbursed under CPT code 99212-25.

Liability

The ALJ found that, pursuant to section 1879 of the Act, the appellant was liable for the non-covered costs at issue in this case. Additionally, the ALJ found that the appellant's liability for the overpayment could not be waived pursuant to

section 1870 of the Act. See Dec. at 20. Neither CMS, nor the appellant, has challenged the ALJ's findings. Accordingly, they remain undisturbed.

FINDINGS

The Council has carefully considered the entire record and makes the following findings:

1. The PSC did not err by not including all underpaid (zero payment) claims in the sampling frame.
2. The sampling frame as drawn in this case is overbroad.
3. The Medicare contractor is directed to recalculate the extrapolated overpayment by excluding all codes other than those eight directly related to the administration of Procrit and Aranesp. Those eight codes include only Q0136, Q0137, J0881, J0885, 90722, G0351, 85025, and 36415.
4. The contractor may also recoup the actual overpayment for the remaining codes in the sample.
5. The Council has reviewed the six unfavorable coverage findings issued by ALJ and has found no reason to reverse five of those determinations.
6. Consistent with the beneficiary-specific analysis above, the claims for Beneficiaries 5 (L.De.), 8 (C.G.) and 11 (M.S.) remain denied.
7. Consistent with the beneficiary-specific analysis above, the claims for Beneficiaries 4 (R.D.) and 13 (W.W.) are denied as originally claimed, but is covered as down-coded.
8. Consistent with the beneficiary-specific analysis above, the claim for Beneficiary 12 (R.S.) is covered.
9. Consistent with the ALJ's decision, the appellant is liable for the non-covered charges and the overpayment amount pursuant to sections 1879 and 1870 of the Act.
10. The beneficiary-coverage determinations for the thirteen beneficiaries at issue before ALJ, including the six subsequently reviewed by the Council (identified by **bold**

type-face), are set out in the Beneficiary List attached to this decision.

DECISION

Consistent with the analysis and findings discussed above, the Medicare Appeals Council reverses the ALJ's decision in part. The contractor may extrapolate the overpayment to include only codes Q0136, Q0137, J0881, J0885, 90722, G0351, 85025, and 36415. The appellant is liable for non-covered charges and is not entitled to waiver of recoupment of the overpayment.

MEDICARE APPEALS COUNCIL

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

/s/ Gilde Morrisson
Administrative Appeals Judge

Date: August 11, 2011