

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-1575

In the case of

Claim for

Excel Diagnostics, Ltd.
(Appellant)

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiary)

(HIC Number)

Trailblazer Health
Enterprises

(Contractor)

(ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated May 18, 2010, 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 allowed Medicare Part B coverage for high dose Indium In-111 pentetreotide injections ("Indium-111") (brand name: OctreoScan) furnished to the listed beneficiaries for the treatment of neuroendocrine cancer during various dates of service in 2006 and 2007.¹

The Council has carefully considered the record that was before the ALJ, as well as the memorandum from the Centers for Medicare & Medicaid Services (CMS) dated July 15, 2010, and the exceptions to the referral filed by counsel for the appellant dated August 9, 2010. The CMS memorandum and appellant's exceptions are entered into the record in this case as Exhibits (Exhs.) MAC-1 and MAC-2, respectively.

¹ The Attachment to this decision identifies the beneficiaries by name, HIC numbers, and dates of service. To protect the beneficiaries' privacy, the Council provides the complete Attachment only to the appellant and counsel.

As explained in further detail below, the Council substantially reverses the ALJ's decision. Specifically, the Council vacates the ALJ's determination that Medicare coverage is appropriate for 500-millicuries (mCi) therapeutic doses of Indium-111 furnished to each beneficiary, as billed by the appellant. The Council concludes that the appellant is not entitled to any additional payment beyond 6 mCi of Indium-111 per beneficiary, per date of service. The Council also concludes the appellant is liable for the non-covered services, and that liability for the overpayment may not be limited or waived. See sections 1879 and 1870 of the Social Security Act (Act).

BACKGROUND AND PROCEDURAL HISTORY

The appellant furnished injections of Indium-111 to various beneficiaries from February 26, 2006, through December 12, 2007. Indium-111 is a radiopharmaceutical which is approved for the diagnosis of certain types of cancer. The HCPCS code designated for billing diagnostic Indium-111 during the dates of service at issue was A9565,² defined as "Indium In-111 Pentetreotide, diagnostic, per millicurie (mCi)." The appellant, an Independent Diagnostic Testing Facility (IDTF), used Indium-111 for *diagnostic* purposes and submitted 32 claims to the contractor for the dates of service at issue. These claims were subsequently paid by the contractor, at a diagnostic level of 6 mCi per claim, and are not at issue before us. However, with regard to fifteen additional beneficiaries, the appellant also furnished high doses (approximately 500 mCi) of Indium-111 as part of an FDA-approved clinical trial for the *treatment* of neuroendocrine tumors. The appellant submitted 25 claims covering 25 dates of service for the 15 beneficiaries. The appellant billed both the diagnostic and therapeutic uses of Indium-111 throughout the period with code A9565. However, the appellant did not add a "CV" modifier to the 25 claims at issue to indicate that the drug was being used as part of a clinical trial pursuant to an Investigational New Drug Application (IND).

The appellant submitted the original 57 assigned Medicare claims, which were initially paid by the carrier, Trailblazer Health Enterprises (Trailblazer). On July 17, 2008,

² The Centers for Medicare & Medicaid Services developed the Healthcare Common Procedure Coding System (HCPCS) to establish "uniform national definitions of services, codes to represent services, and payment modifiers to the codes." 42 C.F.R. § 414.40(a). CMS also utilizes the American Medical Association (AMA)'s annual publication of Current Procedural Terminology (CPT) codes.

TriCenturion, a Program Safeguard Contractor for the Centers for Medicare & Medicaid Services (CMS), informed the appellant that a review of the 57 claims paid during the dates of service at issue revealed that all 57 claims should have been partially or fully denied. TriCenturion determined that as a result of the payment error on the 57 reviewed claims, there was an actual overpayment of \$746,112. Exh. 1, at 108. On August 28, 2008, Trailblazer sent the appellant a demand letter requiring reimbursement of the overpaid amount. Exh. 1, at 121.

The appellant appealed, and on redetermination Trailblazer partially allowed 27 of the 57 claims, but denied 30 claims finding that "the facts received did not justify the medical need for these services." Exh. 1, at 196. Trailblazer revised the amount requested for reimbursement downward to \$723,929.89. Exh. 1, at 196. Trailblazer subsequently issued two corrected redeterminations after the first determination was issued on March 3, 2009. In the third and final redetermination, issued on August 17, 2009, Trailblazer indicated that there were 58 claims submitted during the dates of service at issue.³ Trailblazer determined that all 58 claims could be partially paid for the Indium-111 that was used for diagnostic purposes. Specifically, Trailblazer found that 6 mCi of Indium-111 for each claim would be allowed. In the detailed explanations attached to the revised determinations, Trailblazer indicated that since the appellant was an IDTF, Medicare reimbursement would be limited to the amount of Indium-111 that is allowed for diagnostic purposes, 6 mCi according to the Medicare Claims Processing Manual. See Exh. 1, at 189. This resulted in a fully favorable resolution of 32 of the 57 claims. Trailblazer indicated that the resulting overpayment after the revised determination would be reduced to \$556,790.99, including \$32,014.76 in interest. Exh. 1, at 180. The only claims which remained in the appeal following the redetermination were the 25 claims in which the appellant also billed for the therapeutic use of Indium-111 in a quantity of approximately 500 mCi.

Upon reconsideration, Q²Administrators, the Qualified Independent Contractor (QIC), affirmed the contractor's determination with regard to the 25 claims. The QIC indicated that Indium-111 is only covered by Medicare as a diagnostic agent, with a limit of 6 mCi per diagnostic test. The QIC cited National Coverage Determination (NCD) 310.1 in determining that

³ One claim was later denied as a duplicate claim, reducing the number of claims in the original overpayment to 57.

Medicare would not cover the appellant's high dose therapeutic use of Indium-111 administered in the appellant's clinical trials. Exh. 1, at 45. The QIC held the appellant liable for all non-covered services. *Id.*

On appeal, and after conducting a hearing with the appellant's representative and counsel, the ALJ issued a "fully favorable" decision, granting coverage for the high dose Indium-111 therapeutic injections at issue. The ALJ addressed the 32 purely diagnostic claims and found that the QIC erred in denying the claims. The ALJ found that pursuant to Trailblazer's Local Coverage Determination (LCD) L18347, the diagnostic administration of Indium-111 at 6 mCi per test is covered by Medicare. Dec. at 7. The ALJ also found that the applicable NCD did not preclude Medicare coverage of the therapeutic administration of high doses of Indium-111. Thus, the ALJ concluded that the QIC erred in its denial of coverage and its affirmation of the overpayment which was assessed. The ALJ also found that Trailblazer, by determining that an IDTF cannot furnish therapeutic services, misinterpreted Medicare policy. The ALJ indicated that "an IDTF may bill for any CPT or HCPCS codes that are *solely* therapeutic." Dec. at 8 (emphasis in original). Liability was not addressed by the ALJ because he found that the services were approved and the overpayment determination was reversed.

APPLICABLE LEGAL AUTHORITY

Determining whether Indium-111 is Reasonable and Necessary

The provisions of the Act, the Medicare regulations, and the Medicare Program Integrity Manual (MPIM) set forth key points in the relevant analysis.

Section 1862 of the Act provides that:

(a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items and services -

(1)(A) which . . . are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.

Historically, in making coverage determinations, CMS has interpreted the terms reasonable and necessary to mean that the item or service in question is safe and effective and not experimental. CMS has further determined that the relevant tests for applying these terms are whether the item or service has been proven safe and effective based on authoritative evidence, or alternatively, whether the item or service is generally accepted in the medical community as safe and effective for the condition for which it is used. 54 Fed. Reg. 4304 (Jan. 30, 1989); 60 Fed. Reg. 48417 (Sept. 19, 1995). See also 52 Fed. Reg. 15560 (Apr. 29, 1987). CMS explains, when discussing the differences between FDA and CMS review, that parties interested in the coverage of a drug or device may contact CMS with an inquiry on Medicare coverage while the particular drug or device is proceeding through the FDA premarket review process. Additionally, although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket approval review process) for at least one indication to be eligible for Medicare coverage, except for certain Category B devices, FDA approval/clearance alone does not generally entitle a drug or device to Medicare coverage. 68 Fed. Reg. 55634, 55636 (September 26, 2003).

The Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that specify whether specific medical items, services, treatment procedures, or technologies may be paid for by Medicare. In the absence of a specific NCD, the Medicare contractor is responsible for determining whether an item or service is reasonable and necessary. (See preface to Coverage Issues Manual (reprinted at 54 Fed. Reg. 34555 (Aug. 21, 1989))).

The foreward to the National Coverage Determinations (NCD) Manual, IOM Pub. No. 100-03, provides:

Where an item, service, etc. is stated to be covered, but such coverage is explicitly limited to specified indications or specified circumstances, all limitations on coverage of the items or services because they do not meet those specified indications or circumstances are based on § 1862(a)(1) of the Act. Where coverage of an item or service is provided for specified indications or circumstances but is not explicitly excluded for others, or where the item or

service is not mentioned at all in the CMS Manual System the Medicare contractor is to make the coverage decision, in consultation with its medical staff, and with CMS when appropriate, based on the law, regulations, rulings and general program instructions.

The coverage decisions in the manual will be kept current, based on the most recent medical and other scientific and technical advice available to CMS.

An ALJ and the Council are bound by statutes, e.g., the Act, and regulations, NCDs, and CMS Rulings. 42 C.F.R. §§ 405.1060(a)(4), 405.1063. Neither an ALJ nor the Council is bound by contractor local coverage determinations (LCDs), local medical review policies (LMRPs), or CMS program guidance such as program memoranda and manual instructions, "but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). An ALJ or the Council must explain its reasoning for not following an LCD or program guidance in a particular case. 42 C.F.R. § 405.1062(b).

In determining whether high volume (500 mCi) Indium-111 is medically reasonable and necessary to treat neuroendocrine cancer, individual adjudicators, including ALJs and the Council, take into account the same issues that CMS and its contractors consider when they make coverage determinations, including, when appropriate, factors that contractors use when they develop LCDs. CMS has provided guidance in the Medicare Program Integrity Manual (MPIM) (CMS Pub. 100-08) to assist contractors in developing LCDs. The MPIM instructs contractors that, "[i]n order to be covered under Medicare, a service shall be reasonable and necessary." MPIM, Ch. 13, § 13.5.1. The MPIM contemplates that, in making a determination as to whether an item or service is reasonable and necessary, contractors will analyze whether the item or service is safe and effective, and not experimental or investigational:

Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational . . .; and

- Appropriate, including the duration and frequency that is considered appropriate for the service. . . .

Id. The MPIM further instructs contractors to base LCDs on the strongest evidence available at the time the determination is issued. In order of preference, this includes:

- Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
- General acceptance by the medical community (standards of practice), supported by sound medical evidence based on:
 - Scientific data or research studies published in peer-reviewed medical journals;
 - Consensus of expert medical opinion (i.e., recognized authorities in the field); or
 - Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1.

The manual notes further:

Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.

Id.

In addition, the item or service must be reasonable and necessary for the beneficiary's condition on the dates of service at issue.

Uses of Chemotherapy Drugs for a Medically Accepted Indication

Section 1861(t)(2)(A) establishes coverage under Part B Medicare for drugs used in an anticancer chemotherapeutic regimen when used for a "medically accepted indication." A medically accepted indication is defined as:

- (B) ... any use which has been approved by the Food and Drug Administration for the drug, and includes another use of the drug if -
- (i) the drug has been approved by the Food and Drug Administration; and
 - (ii)(I) such use is supported by one or more citations which are included (or approved for inclusion) in one or more of the following compendia: the American Hospital Formulary Service - Drug Information, the American Medical Association Drug Evaluations, the United States Pharmacopoeia-Drug Information, and other authoritative compendia as identified by the Secretary, unless the Secretary has determined that the use is not medically appropriate or the use is identified as not indicated in one or more such compendia, or
 - (II) the carrier involved determines, based upon guidance provided by the Secretary to carriers for determining accepted uses of drugs, that such use is medically accepted based on supportive clinical evidence in peer reviewed medical literature appearing in publications which have been identified for purposes of this subclause by the Secretary.

Chapter 15, section 50.4.5.A of the Medicare Benefit Policy Manual (MBPM) (CMS Pub. 100-02) lists the publications identified by the Secretary as providing peer-reviewed support for determining off-label chemotherapy drug coverage. However, the section also instructs contractors, in reviewing such publications, to consider:

- Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
- Whether the administered chemotherapy regimen is adequately represented in the published evidence.
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
- Whether the study is appropriate to address the clinical question. The contractor will consider:

1. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question.
2. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and
3. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

The criteria for determining whether a service is medically reasonable and necessary under section 1862(a)(1) of the Social Security Act and its implementing provisions, and the MBPM instructions for determining coverage of an off-label use of a drug, contain similar considerations. The MBPM instructions, however, reflect the statutory requirements specific to extending chemotherapy drug coverage to off-label uses.

DISCUSSION

The primary issue in this case is whether Medicare covers 500 mCi doses of Indium-111, furnished in a clinical trial, for therapeutic purposes to treat neuroendocrine cancers. As explained below, the Council finds that Medicare will cover up to 6 mCi of Indium-111 per claim for diagnostic purposes, but will not cover the additional volume of the drug used for therapeutic purposes.

1. Basis for Referral

Before the Council, the appellant contends that CMS's referral memorandum does not identify findings or conclusions in the ALJ decision that would meet the "error of law" standard as a basis for the referral. The appellant argues that the referral objections go to the sufficiency of the evidence in establishing whether the services furnished during the clinical study were medically reasonable and necessary, and not whether there was an error of law that was material to the outcome of the claims at issue in the ALJ's decision. Specifically, the appellant argues that CMS's arguments go to the weight of the evidence supporting the medical reasonableness and necessity of Indium-111 pentetreotide injections, i.e., questions of "substantial

evidence," and do not state a basis for identifying any error of law. Exh. MAC-2, at 3-4.

The Council disagrees and finds that CMS's objections go to both the sufficiency and weight of the evidence and to the proper application of law. The weight of the evidence supporting medical reasonableness and necessity was not the only allegation in the agency's referral memorandum. Other exceptions raised by CMS were whether an IDTF can bill for both diagnostic and therapeutic uses, whether the applicable local coverage determination (LCD) limits the amount of Indium-111 that can be considered medically reasonable and necessary, and whether the costs of using Indium-111 therapeutically qualify as routine costs covered in a clinical trial pursuant to National Coverage Determination (NCD) Manual (CMS Pub. 100-04), section 310.1. Thus, the referral raised errors of law material to the outcome of the claims, and own motion review is therefore appropriate.

2. Whether an IDTF may bill for therapeutic services

CMS contends that the ALJ erred in determining that the appellant, an IDTF, may furnish and bill for drugs it provided to treat the beneficiaries' cancer, as well as to diagnose the beneficiaries' cancer. Exh. MAC-1, at 15. Specifically, CMS asserts that the appellant may not bill incident to a physician's services. CMS asserts that the medical treatment of cancer is a physician's service and most chemotherapy regimens are only covered when furnished incident to a physician's services. Further, CMS asserts, IDTF services must be ordered by a treating physician, which CMS notes may not generally be the same physician as the IDTF's supervising physician. Thus, CMS argues, an IDTF is restricted to furnishing diagnostic tests, and may not provide treatment or related therapeutic services. CMS cites to restrictions on IDTFs provided in Trailblazer's Part B Diagnostic Radiology manual. According to Trailblazer's manual, "an IDTF can only bill for diagnostic tests" and "an IDTF is not allowed to bill for any CPT or HCPCS codes that are solely therapeutic." See <http://www.trailblazerhealth.com/Publications/Default.aspx>.

The appellant asserts that for the beneficiaries who were given the high doses of Indium-111, the services furnished by the IDTF were not solely therapeutic, but were used for a combination of diagnostic and therapeutic services in those beneficiaries. Thus, the appellant contends, the services furnished to the fifteen beneficiaries at issue on twenty-five dates of service

were not restricted by the provisions of Trailblazer's manual. The appellant also asserts that Trailblazer lists many IDTF-billable radiopharmaceuticals and drugs, some of which are listed as "therapeutic" rather than "diagnostic" in their descriptions. Further, according to the appellant, Trailblazer instructed the appellant to use HCPCS code A9565, the code described for diagnostic use of Indium-111, to bill Indium-111 even though it was being used for both diagnostic and therapeutic purposes. Exh. MAC-2, at 7.

The Council finds that, generally, IDTFs are diagnostic testing facilities, not treatment facilities. However, the Council understands that there may be situations where the delineation may not be clear or explicitly stated in a contractor's policies or guidelines directing the use of particular codes by an IDTF. Moreover, the Council also acknowledges that there may have been some diagnostic role to the treatments furnished to the beneficiaries at issue, as recognized by the contractor. Regardless, the IDTF issue is not dispositive of the issues in this case, and therefore we will not address whether and when an IDTF can bill as a general matter for therapeutic CPT/HCPCS codes. Under the facts of this case, it is clear that the appellant was using Indium-111 in a manner that had not been FDA-approved or found covered by the contractor in its local coverage policy, and which was moreover the subject of a clinical trial; thus, it is not covered for reasons unrelated to the status of the facility as an IDTF.

3. Whether the Treatment was Reasonable and Necessary

According to the appellant, the therapeutic use of Indium-111 was medically reasonable and necessary, and not experimental or investigational. To support its argument, the appellant notes that Indium-111 was approved for marketing in, and used as a diagnostic agent since, 1994. Exh. MAC-2, at 8. The appellant asserts that Indium-111 is considered by the FDA as an "orphan drug" to treat certain types of neuroendocrine tumors, which have been given "orphan disease" designation. *Id.* The appellant states that "the purpose of [the appellant's] use of Indium-111 pentetate is not to bring a [new] drug to market, but rather to use an existing radiopharmaceutical for treatment of patients with a rare condition." *Id.* The appellant asserts that it is a standard practice of medicine for a physician to prescribe marketing-approved drugs for off-label uses. *Id.* at 9. Counsel further argues that Trailblazer's Medical Director, Dr. Charles Haley, was "intimately" involved in reviewing the

therapeutic use of Indium-111 by the IDTF prior to the appellant billing for the radiopharmaceutical.

By contrast, CMS asserts that "[n]owhere in the record does Dr. Haley or anyone else speaking on behalf of the carrier state, imply, or aver that the use of Indium In-111 to treat cancer will be covered and/or paid." Exh. MAC-1, at 19. CMS asserts that Dr. Haley informed the appellant that Medicare contractors do not pre-approve or pre-authorize coverage. Further, Dr. Haley informed the appellant that the claims would be judged under medical reasonableness and necessity criteria. CMS quotes a March 22, 2006, e-mail in which Dr. Haley responds to an inquiry by the appellant by stating that "Medicare expects [the appellant] to perform services that are 'reasonable and necessary' for the care of the patient." Exh. MAC-1, at 3. CMS notes the appellant's claim that it is the only provider to use Indium-111 to treat neuroendocrine cancer patients; thus, CMS asserts, the "[t]herapeutic administration of Indium-111 for therapeutic use is not the standard of care, is not generally accepted by the medical community, is not generally covered in [the United States]," and is thus experimental and investigational. Moreover, according to CMS, the appellant admits that Indium-111 was being administered to these patients under an Investigational New Drug Application (IND) reviewed by the FDA, and thus, CMS contends, the status of this drug is investigational. *Id.*

After considering the CMS referral memorandum and the appellant's exceptions, the Council finds that the drug at issue has not been approved for coverage by the FDA for therapeutic uses at or around 500 mCi, nor is such use currently contemplated in the listed compendia, nor is it the standard of care in the industry; thus, this use is not covered by Medicare. The Council does not equate the contractor's approval of Indium-111 for diagnostic purposes at 6 mCi to constitute or contemplate approval of the drug for therapeutic purposes at 500 mCi. Moreover, the clinical trial that was conducted by the appellant was based on an IND; thus, by definition, it was not a use of Indium-111 which was generally accepted as the standard of care for this particular drug. The appellant indicated that no one else in the U.S. was using Indium-111 for therapeutic purposes. An unproven use of a drug which does not fall under the standard of care in the U.S., is the subject of a IND, and is used at a high dosage not contemplated by current coverage provisions of the contractor for diagnostic use is, by definition, experimental or investigational.

The appellant asserts that the ALJ properly evaluated coverage based on Medicare law and policy. The ALJ noted in his decision that radiopharmaceutical therapeutic use is supported by *the European Journal of Cancer, Journal of the National Cancer Institute, and Radiation Oncology*. In his decision, the ALJ found medical documentation supported medical reasonableness and necessity in this case.

However, CMS contends that the ALJ erred in not evaluating coverage under the peer reviewed literature standard in section 1861(t)(2) of the Act.⁴ With respect to the ALJ's statement that "the successful therapeutic use of radiopharmaceuticals in the treatment of tumors has been reported in several [peer-reviewed medical journals]," we find that the ALJ did not discuss how the clinical trials in peer-reviewed literature were bases for coverage under Medicare standards per the guidelines of MBPM, chapter 15, section 50.4.5.A. The ALJ did not discuss protocols or conditions of the studies that were included in the peer-review articles at issue. We agree with CMS that the ALJ did not discuss how the clinical trials in peer-reviewed literature were bases for coverage under the Medicare manual guidelines.

4. *Whether therapeutic Indium-111 is covered by NCD 310.1*

The appellant asserts that NCD 310.1 provides that routine costs of clinical trials, as well as reasonable and necessary items and services used for diagnostic and therapeutic purposes in a clinical trial, are covered by Medicare. Further, the appellant asserts that NCD 310.1 does not restrict coverage of an investigational item otherwise covered outside of a clinical trial. Exh. MAC-2, at 11. The appellant cited the exception in NCD 310.1, which states that "routine costs of a clinical trial exclude the investigational item or service itself, 'unless otherwise covered outside of the clinical trial.'" The appellant points out that Indium-111 is otherwise covered by Medicare, and the appellant contends that the use of the radiopharmaceutical for treatment is covered under the provisions of the NCD.

CMS asserts that the routine costs of a clinical trial specifically exclude costs of a non-covered chemotherapeutic agent. According to CMS, furnishing Indium-111 to treat cancer has never been a covered service, and the IND status indicates that the use of the Indium-111 in high doses as a cancer

⁴ The Council shall assume, without deciding, that drugs used in a chemotherapeutic regimen include radiopharmaceuticals.

treatment is investigational and not proven to be safe or effective. Exh. MAC-1, at 22. CMS also asserts that routine costs exclude the investigational item itself, which in this case is the Indium-111. Further, CMS asserts that Indium-111 is not "otherwise covered outside of clinical trial" when using 500 mCi for therapeutic use when it is normally used at 6 mCi for diagnostic purposes. CMS points out that the clarifying "not otherwise covered outside of clinical trial" language in the NCD was added July 7, 2007, which was after a majority of dates of service at issue.⁵ See Exh. MAC-1, at 21.

The Council agrees with CMS that Indium-111 cannot be considered a routine cost of a clinical trial under NCD 310.1, under the facts presented here, when the radiopharmaceutical is the investigational item itself. Indium-111, as used as a therapeutic agent at high dosage, is the subject of the IND investigation and thus may not be considered a routine cost of a clinical trial. Moreover, 500 mCi of therapeutic Indium-111 cannot be considered "otherwise covered outside of the clinical trial" because it is not comparatively similar to the 6 mCi of Indium-111 that is approved for diagnostic purposes as an imaging agent. It is clearly being tested (1) as part of an Investigational New Drug Application, (2) for treatment rather than diagnostic purposes, and (3) at a dosage so significantly in excess of that contemplated for diagnostic purposes that it cannot in any manner be considered "otherwise covered" outside of the clinical trial.

6. *Liability*

The appellant contends that liability should be limited or waived under sections 1879 and 1870 of the Act. Counsel asserts that the appellant is not at fault for the overpayment on the grounds that the appellant contacted the Trailblazer Medical Director prior to billing for the Indium-111 used in the clinical study, and the appellant also submitted articles and other information to establish that the furnished services were medically reasonable and necessary and not investigational or experimental. Lastly, the appellant asserts that the claims were paid for two and one-half years before the overpayment action, and that requiring the IDTF to reimburse Medicare for the paid claims would be unfair. Exh. MAC-2; Exh. 1, at 17 (Request for ALJ Hearing). In response, CMS asserts that the

⁵ The language was actually added and became effective on July 9, 2007. See NCD 310.1 (Routine Costs in Clinical Trials).

appellant billed without the required "QV" modifier which would have identified that the services furnished were part of a clinical trial. Exh. MAC-1, at 1. Moreover, CMS asserts, the Medical Director never informed the appellant that the drug would be covered by Medicare, but instead informed the appellant that the contractor does not pre-authorize drug coverage.

The Council finds that there is no limitation of liability or waiver of the overpayment under sections 1879 and 1870 of the Act. The Council agrees with CMS that the appellant was never given implicit or explicit approval for coverage by the Medical Director of Trailblazer. The Medical Director informed the Director of the IDTF that the claims would be processed under medical reasonableness and necessity standards and that no prior approval could be granted by the contractor. Moreover, the appellant did not bill with the required QV modifier to alert the carrier that these were claims related to the clinical investigation of the use of Indium-111 to treat cancer. In summary, it was simply not reasonable for the appellant to assume that the high volume, 500 mCi therapeutic use of Indium-111 would be covered as a routine cost of a clinical trial where (1) its therapeutic use was the subject of the clinical trial itself, (2) it was not the standard of care to use Indium-111 for the treatment (rather than diagnosis) of cancer, and (3) the dose administered for therapeutic use bore no similarity to the approved diagnostic (6 mCi) dose of this drug.

However, the Council notes that Dr. Haley found that 6 mCi of Indium-111 could be covered for diagnostic purposes under the applicable LCD even in the claims where high doses were also being administered for therapeutic purposes. Thus, the Council finds that 6 mCi of the drug are covered with regard to each of the claims, as the beneficiaries at issue were being diagnosed as well as treated with Indium-111.

DECISION

It is the decision of the Medicare Appeals Council that the appellant is entitled to Medicare coverage and payment for 6 mCi of Indium-111 per claim for dates of service from February 26, 2006, through December 12, 2007. However, the Council finds that the additional dose of the drug used for therapeutic services furnished by the appellant is not covered by Medicare, and that the appellant is liable for the cost of the non-covered items under section 1879 of the Act. Recovery of the resulting

overpayment is not waived under section 1870 of the Act. The Council therefore substantially reverses the ALJ's May 18, 2010 decision.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Clausen J. Krzywicki
Administrative Appeals Judge

Date: October 14, 2010