DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-10-894

In the case of	**Claim for**
North Alabama Neurological, P.A. d/b/a Spine Neuro Center (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiary)	**** (HIC Number)
Cahaba GBA (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated January 21, 2010, which concerned gold fiduciary markers for stereotactic radiosurgery that were surgically implanted in the beneficiary's skull on June 2, 2009. The ALJ determined that the claims were not covered or payable by Medicare. The appellant has asked the Medicare Appeals Council to review this action.

The Council reviews the ALJ's decision *de novo.* 42 C.F.R. § 405.1108(a). The Council will limit its review of the ALJ's action to the exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. 42 C.F.R. § 405.1112(c).

The appellant submitted multiple enclosures with its request for review. As we will explain below, the Council finds good cause to admit non-duplicative documents into the record as Exhibit (Exh.) MAC-1. 42 C.F.R. § 405.1122(c). The Council excludes duplicative documents from the record and marks those documents for identification purposes only as Exh. MAC-2 (Excluded).[1] The Council also admits interim correspondence from the Council dated March 26, 2010, into the record as Exh. MAC-3.

[1] The Council notes that it is unnecessary for the appellant to submit duplicate documents at each level of appeal, which impedes expeditious review of the record.

The Council affirms the ALJ's decision that the services are not covered by Medicare. The Council modifies the ALJ decision to reflect additional legal and evidentiary bases for coverage denial and appellant liability for non-covered charges.

BACKGROUND

The record indicates that the 76 year old beneficiary was seen by Dr. J*** T. B*** on June 1, 2009, "in consultation for brain metastasis secondary to a non-small cell lung carcinoma." Exh. 2, at 37. The musculoskeletal/ neurological examination indicates that the beneficiary had "extensive hand intrinsic weakness and weakness of his grip and dorsal interossei on the right side," with the left side "completely normal." *Id.* The note states that a magnetic-resonance imaging (MRI) scan from Crestwood Hospital, dated May 28, 2009, reflected "a left posterior frontal ring-enhancing lesion about 2 cm in diameter," which "involves the left motor strip." *Id.* at 36. The MRI also indicated "a tiny left mesial occipital enhancing lesion measuring 4 mm in greatest dimension on axial images." *Id.* There was "some vasogenic edema associated with the larger mass." *Id.* The assessment and plan is stated as follows:

> He has two metastases, one on the left motor strip causing right hand weakness. Options include craniotomy with evacuation of this lesion followed by whole brain or focused radiation versus isolated focused ration through stereotactic radiotherapy. This was discussed with the patient. We have elected and he is in agreement with placement of gold fiducial markers. I discussed with him he would have three stab incisions under local anesthesia to monitor[] anesthesia care. It is a very nonpainful procedure and would not require general anesthetic. He is in agreement with this plan. After placement of the fiducial markers, *he will be free to undergo any sort of radiation therapy at any time.* . . .

Id. (emphasis supplied).

The record also contains an Operative Report, dated June 2, 2009, dictated by Dr. B*** reflecting the beneficiary's admission for outpatient surgery. Exh. 2, at 35-36. Pre and post operative diagnoses are "metastatic lung cancer to the brain," with the operation being "implantation of gold fiduciary

markers for stereotactic radiosurgery." *Id.* at 35. The procedure was described, in relevant part, as follows:

> [The beneficiary] is brought to the operating theatre where he was placed in horseshoe head holder. He did not receive any sedation. He had local anesthetic injected in left frontal, right frontal and right parietal regions. Stab incisions were then utilized. Stryker high speed drill is then used to drill through the outer cortex three times. The three gold markers were placed through the outer cortext into the inner spongy bone. The wounds were irrigated and closed with Monocryl. Demabond is then placed over the wound.

Id. at 35-34. The beneficiary was "then transferred to the Post-Anesthesia Care Unit and noted to be in good condition and was discharged later on that day." *Id.* at 34. The record contains no other clinical documents concerning the beneficiary's admission, surgery, post-surgery recovery, or discharge for the outpatient surgery.

On June 1, 2009, Dr. B*** sent a copy of the clinical note to the referring physician. Exh. 2, at 32. On July 15, 2009, Dr. B*** wrote a letter "To Whom It May Concern," which stated as follows:

> [The beneficiary] had recently undergone a salvage craniotomy on the left with complete right hemiplegia due to metastatic carcinoma to his motor strip. He had hemorrhage into a tumor there and has not regained any sort of function since his last craniotomy surgery.
>
> He has one resected lesion and two other occipital lesions consistent with metastatic disease.
>
> Although his systemic cancer seems to be well controlled he has stage IV metastatic cancer to the brain.
>
> I feel, in my best opinion, that his life expectancy is limited likely in the next few weeks to months. I also do not foresee any dramatic improvements in his neurological condition which is complete right hemiplegia. I do not feel he is able to travel on a

> regular basis given his size and severe neurological deficit.
>
> I feel he would qualify for some Home Health Care in the near future to assist in his care.

Exh. 1, at 33.

Initial Determination

Appellant submitted three claims to Medicare for services with date of service June 2, 2009, under Current Procedural Terminology (CPT) code 21499,[2] with payment modifiers 76 and 7659 for the second and third claims, respectively. Exh. 1, at 12.[3] Each claim was billed in the amount of $1244.00, for a total amount billed of $3732.00. *Id.* On initial determination, Medicare contractor Palmetto Government Benefit Administrators (GBA) denied payment using denial code "CO-B12," for "services not documented in patient's Medicare record."

Redetermination

The appellant submitted a request for redetermination, dated July 15, 2009, in letter format signed by the appellant's "insurance specialist." Exh. 1, at 13. The appellant explained that the beneficiary had surgery for two brain lesions, with one "in the left side in his motor strip causing right handed weakness." *Id.* The appellant stated that "[t]his has been going on for a week" and that the beneficiary had also "been placed on steroids and has a 2 cm lesion." *Id.* The appellant maintained that "[i]t was recommended that the patient undergo surgery to have gold bead fiducials placed to aid[] in his treatment with stereotactic radiation." *Id.* According to the appellant, "**[t]here is not a valid CPT assigned to this procedure yet.**" *Id.* (emphasis in original).

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[2] The Centers for Medicare & Medicaid Services (CMS) has 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). HCPCS codes are divided into three levels, with Level I codes and descriptors being CPT codes that are 5-position numeric codes primarily representing physician services. HCPCS Codebook (Introduction).

[3] HCPCS code 21499 is listed in the category for "Surgery Codes – Musculoskeletal," defined as "unlisted musculoskeletal procedure, head." HCPCS Codebook. Modifier 76 is "repeat procedure by same physician," while Modifier 59 is "distinct procedural service." *Id.*

The appellant also stated that "[f]iducial markers are gold beads or stainless steel screws that are implanted in and/or around a soft tissue tumor to act as a radiologic landmark, to define the target lesion's position with millimeter precision." Exh. 1, at 13. The appellant then stated that the markers "are typically placed using a CT or other image-guided percutaneous method." The appellant explained that "**[i]n head and neck procedures, 3-6 fiducial seeds may be placed avoiding the need for separate future fiducial placement procedures.**" *Id.* (emphasis in original). The appellant further explained:

> Precision in localization is crucial to accurate radiotherapy. There are cases where implantables provide the best target, particularly in soft tissue such as the brain. Because the markers stay in place in the tumor, they reduce the likelihood of damage to surrounding tissue during therapy. Another benefit is that there is no waiting period required after they are placed in the brain because tumors in those areas do not move.

Id. The appellant requested that the contractor "review the attached information" and stated that she was "enclosing a copy of the operative report for your review." *Id.*

The Medicare contractor issued an unfavorable redetermination decision, dated July 23, 2009. Exh. 1, at 19-15. The contractor decided that the claim was not covered by Medicare and that the appellant was responsible for payment. *Id.* at 19. Palmetto explained: "After the review of the documentation submitted, we have determined that the documentation does not support medical necessity of service. Documentation does not clearly state what the unlisted code represents." *Id*. at 18.

QIC Reconsideration

The appellant submitted a reconsideration request form, dated July 30, 2009, to the Qualified Independent Contractor (QIC). Exh. 1, at 20. The item or service appealed was "implantation of gold fiducials" on the date of service. *Id.* The appellant stated its reason for disagreement as "Medicare stated service not documented – operation: implantation of gold fiduciary markers for stereotactic radiosurgery is listed on the op note & a detailed description of service was provided in letter attached to . . . appeal." *Id.* The request for reconsideration was signed by the appellant's insurance specialist. *Id.*

The QIC issued an unfavorable reconsideration decision, dated September 25, 2009. Exh. 1, at 29-23. The reconsideration states that a panel of clinicians had conducted an "on the record" review of all clinical data provided by the appellant. *Id.* at 28. The QIC decided that Medicare did not cover the claims and that the appellant was responsible for non-covered charges. *Id.* at 27.

In its rationale, the QIC stated that there was "currently no national coverage determination (NCD) or local coverage determination (LCD)" for the codes billed by the appellant. Exh. 1, at 27. The QIC then stated that "[w]hen there is no NCD or LCD, services are evaluated individually for coverage based on Medicare's general medical reasonableness and necessity criteria." *Id.*; *see* Section 1862(a)(1)(A) of the Social Security Act (Act). The QIC cited the Medicare Program Integrity Manual (MPIM) as providing conditions for a medical necessity determination, including that "the service must be safe and effective, and not be experimental or investigational." *Id.*, *citing* MPIM, Pub. 100-08, Ch. 13, § 13.5.1.[4] In relevant part, the QIC stated that individual coverage determinations were based on documentation of medical necessity through clinical trials or studies and general acceptance within the relevant medical community, as supported by sound medical evidence. *Id.*, *citing* MPIM Ch. 13 § 13.7.1. The QIC concluded:

> We reviewed the clinical records you supplied to your carriers, as well as those you sent to us with your appeal. You submitted multiple office notes and a procedure report. You did not submit documentation from the published medical literature supporting coverage of the [21499 claims] in this case. Therefore, we are unable to reverse your carrier's denial.

Exh. 1, at 27-26. The QIC found the appellant liable for the non-covered charges under section 1879 of the Act. *Id.* at 26.

ALJ Decision

The appellant requested an ALJ hearing by filing the form "Request for Medicare Hearing By An Administrative Law Judge," dated October 2, 2009,. Exh. 1, at 31. The appellant checked the box indicating that it did not wish to have a hearing and

[4] Manuals issued by CMS can be found at http://www.cms.hhs.gov/manuals.

requested an on the record determination. *Id.* The appellant also checked the box indicating that it had "no additional evidence to submit." *Id.* The appellant stated its reason for disagreeing with the QIC reconsideration, as follows: "Medicare denied stating that service was not documented in medical records. On more than one occasion op note has been sent and clearly worded "Implantation of gold fiduciary markers for stereotactic radiosurgery. The patient has metastatic lung cancer." *Id.*

The appellant also enclosed procedural and clinical documents, which the ALJ marked as excluded from evidence on grounds that they were duplicative and not material. The appellant subsequently filed a form "Waiver of Right to an Administrative Law Judge (ALJ) Hearing," dated November 17, 2009, stating that "I believe conclusion can be made based on the written documentation." Exh. 3, at 38.

The ALJ issued an unfavorable decision, dated January 21, 2010. In his "Findings of Fact," the ALJ noted that the contractor denied payment on the grounds that the documentation did not establish what services were being represented by the unlisted codes, and the QIC denial was based on the appellant's "failure to file published medical literature supporting medical necessity for the services at issue." Dec. at 2. The ALJ also noted that the appellant had submitted the operative report and letters to support coverage. *Id.*

In his "Analysis," the ALJ rejected the appellant's argument that the operative report provided sufficient documentation of the unlisted procedure to establish coverage. Dec. at 4. The ALJ stated that an unlisted procedure had no "automatic valuation under the fee schedule," and that the appellant was required to "provide[] adequate information to establish a reasonable payment." *Id.* The ALJ also found that the operative report failed to satisfactorily explain why separate procedures were billed, medical necessity, or the role of payment modifiers used. *Id.*

The ALJ stated that he had considered the "supplementary information" in the record, but that "as a whole," the evidence failed to provide Medicare contractors with enough detail to make an informed payment determination. Dec. at 4. He therefore found that "the claim must continue to remain denied." *Id.* Under his "Conclusions of Law," the ALJ stated that the appellant "has not established coverage and payment for the

unlisted services provided to the beneficiary on June 2, 2009 and billed by Appellant under CPT code 21499." *Id.* at 5.

Request for Review

The appellant filed a request for review, dated March 16, 2010. Exh. MAC-1, at 1-2. The appellant argued that it billed CPT codes 21499, 21499-76, and 21499-76-59 to account for the three times that Dr. B*** had used a Stryker drill to drill through the beneficiary's outer cortex before implanting each of the three gold markers "into the inner spongy bone." *Id.* at 1. The appellant stated that "Code 21499 was used three times due to the fact that there were three holes drilled into the patient's skull to implant three gold fiduciary markers." *Id.* The appellant stated that Medicare billing experience indicated that it could not bill multiple quantities, due to the risk of having them denied as duplicate billing. *Id.* The appellant thus used modifiers to represent the separate processes for each of the holes drilled and markers placed. *Id.* The appellant also stated that it based its pricing on the closest comparable cranial procedure, but reduced the price as "implantation of gold markers is not as invasive." *Id.* The appellant enclosed a letter from Dr. B***, dated February 3, 2010, concerning medical necessity. *Id.* at 2. The appellant also enclosed "literature from the manufacturer CIVCO. This enclosure shows the intentions of use of the product by the manufacturer." *Id.* The appellant concluded by stating that it felt that it had addressed all issues raised by the ALJ. *Id.*

In his letter, Dr. B*** stated that the beneficiary had undergone "placement of gold fiduciary markers for stereotactic radial surgery as the standard of care for single solitary metastasis and non-small cell carcinoma." Exh. MAC-1, at 3. Dr. B*** stated that "other standard treatments include surgical resection of this lesion, which was discussed with the patient." *Id.* Dr. B*** asserted that, given the beneficiary's age and the location of the tumor "directly in his motor strip," the beneficiary's risk of developing right hemiplegia post-operatively was "quite high." *Id.* The beneficiary "therefore has elected through consultation with his radiation oncologist as well as me . . . [gold] fiduciary marker implantation for stereotactic radial surgery was the standard of care chosen for this individual with his family." *Id.* According to Dr. B***, "[i]t is impossible to perform stereotactic radial surgery without marker implantation to be accurate and therefore this was medically necessary to treat his metastasis to his brain."

Id. Dr. B*** also wrote that "it is standard care for focused radiation and implantation of fiduciary markers and the benefits in order to try to prevent [the beneficiary] from acquiring a formal craniotomy to treat this lesion." *Id.*

APPLICABLE LEGAL STANDARDS

Medicare is a defined benefit program. The primary coverage authority for items or services provided to a Medicare beneficiary is the Social Security Act (Act). MPIM Ch. 13, § 13.1. "Contractors use Medicare policies in the form of regulations, NCDs, coverage provisions in interpretive manuals, and LCDs to apply the provisions of the Act." *Id.*[5] Coverage denials in both NCDs and LCDs are based upon section 1862(a)(1) of the Act, the exclusion for services "not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* §§ 13.1.1, 13.5.1. In the absence of applicable statutory, regulatory, or administrative authority, Medicare contractors may give individual consideration to coverage of items or services billed. *Id.* § 13.5.

As the QIC noted, a contractor may cover an item or service only if it is reasonable and necessary under section 1862(a)(1)(A) of the Act. Exh. 1 at 27-26, *citing* MPIM Ch. 13, § 13.5.1. The MPIM contemplates that, in making an individual 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 the coverage determination on the strongest evidence available at the time the determination is issued. In the order of preference, this includes:

[5] National Coverage Determinations (NCDs) and Local Coverage Determinations (LCDs) may be found in the Medicare Coverage Database maintained by CMS at http://www.cms.gov/mcd/overview.

- 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 MPIM further notes:

> 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.

DISCUSSION

The ALJ found that the record documentation was insufficient to establish a reasonable payment amount. Dec. at 4. The ALJ stated that the operative report did not explain why three procedures were separately payable or medically necessary. *Id.* The ALJ concluded that the record, as a whole, failed to provide enough information to make a payment determination. *Id.* The Council concludes that the ALJ erred in his analysis. The issue for decision was whether the surgical procedure on the date of service was reasonable and necessary under the Medicare

coverage criteria discussed above. The Council's research does not indicate that contractor Palmetto GBA issued an LCD concerning stereotactic radiosurgery. However, the fiscal intermediary (FI) for Alabama, Wisconsin Physicians Service Insurance Corporation, issued "Cranial Stereotactic Radiosurgery (SRS) and Cranial Stereotactic Radiotherapy (SRT)," LCD L30318 (original effective date July 17, 2009). LCD L30318, in turn, references relevant CMS coverage policy as the Medicare Claims Processing Manual (MCPM). *Id.*, *citing* MCPM, Pub. 100-04, Ch. 13, § 70 (Radiology Services and Other Diagnostic Procedures). The Council sees no reference in either the LCD or the MCPM to indicate that placement of three implanted gold fiducials is reasonable and necessary under section 1862(a)(1)(A) of the Act as a precondition to SRS or SRT.

The Council notes that the QIC reconsideration set forth relevant documentary standards for individual coverage considerations. Exh. 1, at 27-26, *citing* MPIM Ch. 13, §§ 13.5.1, 13.7.1. On appeal to the ALJ, the appellant stated that it previously submitted the operative report, which adequately explained the purpose of the procedure performed. *Id.* at 31. The appellant also stated that it would submit no additional evidence and waived its right to an ALJ hearing. *Id.* The appellant submitted no published authoritative evidence from definitive randomized clinical trials or sound medical evidence referenced in the MPIM, as quoted in the reconsideration.

As noted, the ALJ's decision focused not on medical necessity standards as set forth in the Act and MPIM, but on the amount of payment. As the Council has stated, the ALJ erred in his analysis. The Council has thus admitted into the record non-duplicative evidence submitted by the appellant with the request for review. That evidence consists of three pages from a manufacturer's catalog and a letter from Dr. B***. The Council finds that neither the manufacturer literature nor the letter from Dr. B*** establishes that the outpatient surgical procedure performed on June 2, 2009, is reasonable and necessary under the MPIM standards or establishes general acceptance within the medical community.

Moreover, the record contains no documentation to indicate that the beneficiary actually had stereotactic radiation or radiosurgery, as referenced in the appellant's requests for redetermination, reconsideration, ALJ hearing, and Council review. Exhs. 1, at 13, 20, 31; Exh. MAC-1, at 1. Dr. B*** states that the implantation of gold fiduciary markers for

stereotactic radial surgery on June 2, 2009, was performed, in part, "to try to prevent him from acquiring a formal craniotomy to treat this lesion." Exh. MAC-1, at 3. On June 1, 2009, Dr. B*** had stated that he had discussed both a craniotomy and stereotactic radiotherapy with the beneficiary, who agreed to "placement of gold fiducial markers" in a relatively uncomplicated outpatient surgical procedure the following day. Exh. 1, at 36. Dr. B*** wrote that "[a]fter placement of the fiducial markers, [the beneficiary] will be free to undergo any sort of radiation therapy at any time." *Id.* The office note, and the record as a whole, gives no indication that the beneficiary selected radiation therapy over a craniotomy as a course of treatment.

On July 15, 2009, Dr. B*** wrote that the beneficiary "had recently undergone a salvage craniotomy on the left with complete right hemiplegia due to metastatic carcinoma to his motor strip. He had hemorrhage into a tumor there and has not regained any sort of function since his last craniotomy surgery." Exh. 1, at 33. Dr. B*** opined that the beneficiary then had limited life expectancy and did not foresee any "dramatic improvements in his neurological condition which is complete right hemiplegia." *Id.* Dr. B*** stated that the beneficiary likely qualified for home health services. *Id.*

The Council has considered the record and the exceptions presented. The Council finds that the documentation submitted does not establish that the implantation of three gold fiducial markers in outpatient surgery performed on June 2, 2009, was reasonable and necessary for the treatment of the beneficiary's condition. Section 1862(a)(1)(A) of the Act. The Council further finds that the appellant knew or should have known that the services were not covered by Medicare and is thus liable for the non-covered charges. Section 1879 of the Act; 42 C.F.R. § 411.406(e). The ALJ's decision is modified to reflect the additional legal and evidentiary bases for coverage denial and appellant liability.

DECISION

It is the decision of the Medicare Appeals Council that the services billed to Medicare under CPT codes 21499, 21499-76, and 21499-76-59, for date of service June 2, 2009, are not covered by Medicare. The appellant is liable for the non-covered charges.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

/s/Constance B. Tobias, Chair
Departmental Appeals Board

Date: November 22, 2010