

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Rocky Mountain
Anaplastology, Inc.

(Appellant)

Claim for

Supplementary Medical
Insurance Benefits (Part B)

(Beneficiary)

(HIC Number)

CIGNA Government Services -
DME MAC Jurisdiction C

(Contractor)

(ALJ Appeal Number)

INTRODUCTION

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated July 16, 2009, because there is an error of law material to the outcome of the claim. See 42 C.F.R. § 405.1110.

The Council has carefully considered the record that was before the ALJ, as well as the memorandum, with any attachments, from the Centers for Medicare & Medicaid Services (CMS) dated September 10, 2009. The Council has also considered written exceptions filed with the Council by the appellant on September 23, 2009. 42 C.F.R. § 405.1110(b)(2). The CMS memorandum and appellant exceptions are entered into the record in this case as Exhibits (Exhs.) MAC-1 and MAC-2, respectively.

The ALJ determined that the "facial template" provided by the appellant to assist the physician in placing implants during a surgical procedure, in preparation for later placement of an ear prosthesis, is covered by Medicare as "incident to" the physician's surgical services. For the reasons set forth below, the Council finds that the item is neither a service "incident to" physician services nor a facial prosthesis and is not covered by Medicare. The Council therefore reverses the ALJ decision.

BACKGROUND

This case involves Medicare coverage and payment for a "facial template" used by the surgeon during a surgical implant procedure. The only item or service at issue upon referral is the facial template, not the physician services, surgery, or ear prosthesis.

As indicated on her letterhead, the appellant is a "certified anaplastologist/ocularist specializing in artificial eyes, facial prosthetics and breast prostheses." Exh. MAC-2, at 1. A form "Certificate of Medical Necessity/Physician's Order for prosthetic services/durable medical equipment," on appellant letterhead, is signed by the physician, dated September 2, 2008, and includes a certification of medical necessity. Exh. 3, at 1. The start date for the written order is August 21, 2008, the HCPCS code is L8499 (unlisted procedure for miscellaneous prosthetic services), and the ICD-9-CM diagnosis code is 171.0 (malignant neoplasm of head, face, and neck - cartilage of ear/eyelid). *Id.* The type of prosthesis required is "template for surgeon," and the description of diagnosis is "malignancy external ear." *Id.*

A letter from the appellant to the surgeon, dated September 24, 2008, states that the appellant had prepared an "ear impression," "wax model," and "template" for use by the surgeon in placing 3 implants in the beneficiary's skull, in preparation for later placement of a "prosthetic." Exh. 3, at 2. The appellant stated that the "[t]emplate should lay flush on the model and the patient. If it does not, just wiggle the remaining ear tissues into the template until it does." *Id.* The appellant asked the physician to return the ear impression, wax model, and template after the implant surgery. *Id.* The record indicates that the implant surgery occurred on October 8, 2008. Exh. 4, at 5.

Initial Determination

The appellant submitted a claim to CIGNA Government Services, the Durable Medical Equipment Medicare Administrative Contractor (DME MAC) for Jurisdiction C, for \$865.00 under HCPCS code L8499,¹ with date of service September 16, 2008. Exh. 4, at 6.

¹ The 2008 HCPCS and CPT Code book defines HCPCS code L8499 as "unlisted procedure for miscellaneous prosthetic services."

The DME MAC denied payment because "this service/equipment/drug is not covered under the patient's current benefit plan" and the DME MAC found the beneficiary responsible for the amount. *Id.*

DME MAC Redetermination

The appellant requested a redetermination, arguing that "this template was a tool that Dr. Davis required for the surgery preformed [sic] on Weds. Oct. 8, 2008." Exh. 4, at 5. In a redetermination decision dated December 8, 2008, the DME MAC stated that "the item you requested is not covered" and, without discussion, cited LCD for Facial Prosthesis (L11556) "and its accompanying policy article" in support. *Id.* at 2.²

QIC Reconsideration

The appellant requested reconsideration by the Qualified Independent Contractor (QIC), stating as follows:

[The beneficiary] is my patient. He is scheduled to have me fabricate an artificial ear for him this month (January 2009). This is a routinely covered DME item. Prior to his surgery (also routinely covered - he had cancer), the surgeon requested that I fabricate a template to be used during the final surgery, so that correct placement of the needed implants would be indicated. ***Without this tool, the outcome of his treatment would have been adversely affected.***

All other aspects of this case have been approved (or will be, as they are routine). This "template" is merely a tool needed for the implementation of newer technology, that just hasn't, as yet, been assigned a specific code."

Exh. 5, at 2 (emphasis in original).

In a reconsideration decision dated March 16, 2009, the QIC also denied coverage, stating: "According to Medicare guidelines evaluation of the patient, pre-operative planning, cost of materials, labor involved in the fabrication and fitting of the prosthesis, modifications to the prosthesis, repair due to normal wear or tear and follow-up visit are included in the allowance for the facial prosthesis and are not separately

² Local Coverage Determinations (LCDs) and policy articles can be found using the search function in the Medicare Coverage Database at <http://www.cms.hhs.gov/mcd/overview.asp>.

billable. We find the template was part of the pre-operative planning, therefore, no separate billing will be allowed." Exh. 6, at 1B.³ The QIC found the appellant liable for the non-covered item and referred the appellant to LCD L11556 "for more information." *Id.*

ALJ Decision

The appellant requested an ALJ hearing by letter dated April 29, 2009, writing:

When the Medicare guidelines for "pre-operative" planning for a silicone ear prosthesis were created, the intent was that the ear was removed in the best possible manner to fabricate the prosthesis. This usually had no impact on the prosthetist, as the surgeon's intent was to remove the cancer and save a life. If anything (if the prosthetist were lucky), it involved merely a conversation between the surgeon and the prosthetist.

[The beneficiary] had implants placed in the boney area around his ear. This was a surgical procedure approved and paid for by Medicare. The surgical template was a request from the doctor. It was not a template for placement of the prosthesis, but a template for the implants. It required several hours of work - and was not something given consideration at the time of the original writing of the Medicare guidelines, because of FDA regulations.

Because it was used as a surgical device during surgery, I do not believe it should be considered part of the prosthetic component.

I feel I am being penalized for billing Medicare directly, rather than billing through a third party (the doctor).

Exh. 7, at 1.

The ALJ conducted a telephone hearing on June 16, 2009, at which the appellant testified. Dec. at 2. In her decision, the ALJ found that the beneficiary had his right ear removed as a result of malignancy and, after the wounds had healed, the surgeon performed implant surgery, after ordering a facial template from the appellant to assist surgical placement of the implants. *Id.* "The template was made by creating an impression of the

³ The reverse side of a cited exhibit page is designated by the letter "B."

Beneficiary's face and making a wax model for the surgeon so that he can determine the location for the ear implant." *Id.* The appellant testified that CMS did not consider facial templates at the "time of the original writing of the Medicare guidelines because the [FDA] had not approved the device" and no specific HCPCS code was assigned. *Id.* "The Appellant argued that the facial template was used as a surgical device during the surgery and should not be considered as part of the prosthetic component." *Id.* The ALJ found the appellant's testimony and documentation credible. *Id.*

The ALJ quoted from Policy Article A25513 (related to LCD L11556), as follows:

The following services and items are included in the allowance for a facial prosthesis and, therefore, are not separately billable to or payable by Medicare under the prosthetic device benefit:

- Evaluation of the patient
- Pre-operative planning
- Cost of materials
- Labor involved in the fabrication and fitting of the prosthesis
- Modifications to the prosthesis made at the time [of] delivery of the prosthesis or within 90 days thereafter
- Repair due to normal wear or tear within 90 days of delivery
- Follow-up visits within 90 days of delivery of the prosthesis.

Dec. at 5, *citing* LCD L11556.

The ALJ's analysis focused on Medicare coverage of services or supplies "incident to" a physician's service. The ALJ recounted appellant's testimony that "facial templates for implant surgeries were not considered at the time of the original writing of the Medicare guidelines because the [FDA] had not approved the device. Accordingly, there is no specific code to cover the service provided." Dec. at 5. The ALJ concluded, without citation of supporting authority, that "[t]he facial template is not a service included in the allowance for a facial prosthesis but a service incident to a physician's service. The facial template was not part of the preoperative planning but

was a service necessary for the implant surgery." *Id.* at 6. The ALJ then found the facial implant "medically reasonable and necessary" and covered by Medicare.

Agency Referral

The Council received a referral memorandum from CMS on September 14, 2009. Exh. MAC-1. CMS argued that the facial template prepared by the appellant does not meet the definition of services "incident to a physician's professional services, of kinds which are commonly furnished in physician's offices and are commonly either rendered without charge or included in the physician's bills" Exh. MAC-1, at 1, *citing* section 1861(s)(2)(A) of the Act, 42 C.F.R. § 410.26(b).

CMS noted that Medicare Part B services include:

- Physicians services, including surgery, consultation, office and institutional calls, and services and supplies furnished incident to a physician's professional service.
- Prosthetic devices, other than dental, which replace all or part of an internal body organ.

Id. at 3-4, *citing* Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 15, § 10.⁴

CMS also noted that Medicare regulations define "incident to" services as follows:

1. Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.
2. Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
3. Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).
4. Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).
5. Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the

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

auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

6. Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.
7. A physician (or other practitioner) may be an employee or an independent contractor.

Id. at 4-5, quoting 42 C.F.R. § 410.26(b).

CMS then noted that regulations define a prosthetic device as "replac[ing] all or part of an internal body organ" *Id.*, quoting 42 C.F.R. § 410.36(a).

CMS framed the initial issue on referral as whether the facial template falls within a "covered benefit category." Exh. MAC-1, at 5. CMS stated that the appellant did not argue "that the template is a prosthetic device or a 'template for placement of the prosthesis, but a template for the implants.'" *Id.* at 6. CMS also noted appellant's argument that the template was a surgical device used by the surgeon during surgery and "should not 'be considered a part of the prosthetic component.'" *Id.*

CMS argued, however, that the facial template does not meet the definition of "incident to" services. "A custom-designed device ordered for use during surgery is not of a type commonly furnished in the physician's office or commonly furnished without charge or included in the bill of a physician." Exh. MAC-1, at 6. CMS also argued that the appellant's service does not meet the requirement of "direct supervision of the physician" and that "incident to services or supplies must represent an expense incurred by the physician or legal entity billing for the services or supplies." *Id.* at 6-7, citing 42 C.F.R. § 410.26, MBPM Ch. 15, § 60.2. CMS concluded that even if the facial template had been payable by Medicare as an "incident to" service, it would have to have been billed by the physician, not the appellant.

CMS finally argued that the facial template would not be paid separately by Medicare, because it would fall within "global surgery" billing requirements. Exh. MAC-1, at 7, citing 42 C.F.R. Parts 414, 416, and 419. CMS noted that the appellant furnished services to the physician for use during surgery performed on October 8, 2008. *Id.* CMS pointed out that the appellant did not furnish services to the beneficiary on the

September 16, 2008, date of service, a date "well before the October 8, 2008 surgery at which the physician reportedly used the template." *Id.* According to CMS, outpatient surgery and physician services also fall under the global surgical policy, which "generally includes all intra-operative services, pre-and post-operative visits, and supplies" *Id.*, citing Medicare Claims Processing Manual (MCPM), CMS Pub. 100-04, Ch. 12, § 40 and National Correct Coding Policy Manual for Medicare Services.

CMS concluded by recognizing appellant's argument that the facial template was a tool required by the physician for the implant surgery. Exh. MAC-1, at 7. CMS argued that the template does not meet the definition of a covered prosthetic or orthotic. *Id.*, citing 42 C.F.R. § 410.36, MBPM Ch. 15, §§ 120, 130. CMS also argued that the facial template does not fall within the definition of an "incident to" service, which "plainly exclude[s] custom made items ordered for and used solely during surgery." *Id.* Additionally, CMS argued that the facial template, used during the surgical procedure, would fall within the global surgical package for the implant surgery. *Id.* at 8.

Appellant's Exceptions

The Council received written exceptions from the appellant on September 23, 2009. Exh. MAC-2. The appellant argued that "[i]t would appear that the medical necessity of this claim is not in question, nor is it in question that the claim should be paid by Medicare." *Id.* at 1. The appellant summarized the issue as "this claim was billed incorrectly." *Id.*

The appellant stated that "[t]he rationale is that this procedure should be have been included as a service payable as an incident to a physician's service." Exh. MAC-2, at 1. The appellant also stated that neither she nor referring physicians have "figure[d] out how to do this," and that "this is a relatively new procedure, and as such, the billing for it has not, as yet, been established." *Id.*

The appellant also argued that the facial template is "*highly customized*" and its "design . . . must be done prior to surgery *in the presence of the patient.*" Exh. MAC-2, at 1 (emphasis in original). "*Because direct patient contact is required, it was not assumed it should be billed through the physician.*" *Id.* (emphasis in original). The appellant requested an "exception"

to the billing process, that the claim be paid, and that the Council provide guidance for submission of future claims. *Id.* at 2.

DISCUSSION

The Facial Template Is Not A Service Or Supply "Incident To The Service Of A Physician."

The Council first finds that the ALJ erred in concluding that the custom facial template is covered by Medicare Part B as a service or supply "incident to" a physician's service. "Incident to" services must, in part, meet the following requirements:

- Be an integral, though incidental, part of *the physician's service* in diagnosis or treatment of an injury or illness
- Be commonly furnished without charge or included in the *bill of a physician*
- Be of a type commonly furnished in the office or clinic of *a physician*
- Be furnished under the direct supervision of *the physician* (or other practitioner)
- Be furnished by *the physician, practitioner with an incident to benefit, or auxiliary personnel*

42 C.F.R. § 410.26(b)(emphasis supplied).

The creation of the facial template by the appellant for later use as a guide by the surgeon during implant surgery does not fall within these requirements. The "incident to" benefit does not apply to durable medical equipment, prosthetics, or orthotics, but applies instead to an item or service commonly provided by a physician and as a part of a physician's service. The record makes clear that the custom facial template created by the appellant is not (1) a service or supply commonly provided by a physician in a noninstitutional setting; (2) "incidental to" a physician's service; or (3) furnished under the direct supervision of the physician or by a physician, "incident to" practitioner, or auxiliary personnel. The facial template thus does not meet Medicare coverage requirements for "incident to" services.

The Facial Template Is Not A Prosthetic Device Covered Under Medicare Part B Regulations Or The DME MAC's Local Coverage Policies.

The appellant's form certificate of medical necessity refers to the facial template as a prosthesis. Exh. 3, at 1. The appellant also billed Medicare for the item under HCPCS code L8499 for "unlisted procedure for miscellaneous prosthetic services." The appellant has maintained throughout the appeals process, however, that the facial template is not a component of the ear prosthesis referenced in the appellant's letter to the physician, but falls within the definition of "incident to services."

The appellant appears to have made this distinction in order to prevent coverage denial based upon the contractor Article, which includes pre-operative planning and other items and services in the allowance for a facial prosthesis. Facial Prostheses - Policy Article (A25513). This argument assumes, however, that the facial template falls within the coverage parameters established by LCD L11556 and Article A25513. The Council finds that it does not.

First, the facial template does not meet the definition of a prosthetic device under Medicare regulations. The record indicates that the beneficiary would receive an ear prosthesis after the October 8, 2008, implant surgery, to replace the ear removed as the result of cancer. The appellant created the facial template to guide surgical placement of implants for the ear prosthesis, not to "replace all or part of an internal body organ" 42 C.F.R. 410.36(a)(2). The template similarly fails to fall within coverage requirements for a "facial prosthesis" under the LCD, which is "covered where there is loss or absence of facial tissue due to disease, trauma, surgery, or a congenital defect." LCD L11556.

Moreover, the facial template does not meet the definition of any of the HCPCS codes listed under the LCD or Article. The appellant billed for the template using HCPCS L8499, for "unlisted procedure for miscellaneous prosthetic services." The LCD lists HCPCS codes including the following items provided by a non-physician: nasal prosthesis (L8040); midfacial prosthesis (L8041); orbital prosthesis (L8042); upper facial prosthesis (L8043); hemi-facial prosthesis (L8044); *auricular prosthesis* (L8045)(removable superficial prosthesis, which restores all or

part of the ear); partial facial prosthesis (L8046); nasal septal prosthesis (L8047); and unspecified maxillofacial prosthesis, by report (L8048). While the ear prosthesis would appear to fall within the LCD's ambit, the facial template would not. The Council finds that the facial template does not meet the definition of a facial prosthesis subject to coverage under the LCD L11556 and Policy Article A25513.

Because the Council finds that the facial template does not fall within a defined benefit category, the Council need not and does not reach the issue of whether the item is paid for in the global surgery package for implant surgery performed on October 8, 2008.

Limitation on Liability Provisions Do Not Apply

The Council finds that the facial template does not fall within the definitions of services or supplies "incident to a physician's service" or a prosthetic device and is not covered by Medicare. Because the coverage denial is not based upon section 1862(a)(1) of the Social Security Act (Act), the limitation on liability provisions of section 1879 do not apply.

DECISION

It is the decision of the Medicare Appeals Council that the facial template provided by the appellant does not meet the definition of a service or supply "incident to a physician's services" or a prosthetic device and is thus not covered by Medicare. The decision of the ALJ is reversed.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim
Administrative Appeals Judge

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

Date: December 8, 2009