DEPARTMENT OF HEALTH AND HUMAN SERVICES DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of

Claim for

Robert E. Rothfield, M.D. (Appellant) Supplementary Medical Insurance Benefits (Part B)

* * * *

(Beneficiary)

* * * *

(HIC Number)

* * * *

First Coast Service Options (Contractor)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated July 6, 2009, concerning the insertion of breast prostheses following reconstruction surgery (CPT Code 19342-50) performed on the beneficiary on August 6, 2008. The ALJ determined that the procedure was cosmetic in nature and therefore not covered by Medicare. The ALJ further found the provider liable for the non-covered costs under section 1879 of the Social Security Act (Act). The appellant has asked the Medicare Appeals Council (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).

As set forth below, the Council reverses the ALJ's decision. The Council finds that the ALJ erred in finding the procedure cosmetic and not covered by Medicare. The Council finds that the breast reconstruction procedure at issue was not cosmetic and is covered by Medicare. The Council admits the following into the record:

- Exh. MAC-1 Appellant's Request for Review, dated August 13, 2009,
- Exh. MAC-2 Council's two interim letters regarding the appellant's submission of new evidence and failure to send a copy of the request for review to all other parties, each dated September 16, 2009,
- Exh. MAC-3 Appellant's September 18, 2009, response, informing the Council that no new evidence was submitted,
- Exh. MAC-4 Appellant's September 24, 2009, response, providing proof that the appellant supplied a copy of the request for review to all other parties,
- Exh. MAC-5 Appellant's October 2 and October 5, 2009, facsimile communications, and
- Exh. MAC-6 Appellant's letter dated October 5, 2009.

The appellant submitted additional evidence with his request for review. Exh. MAC-1. If an appellant submits any new evidence with its request for review, the appellant must show good cause for submitting the documentation at this late stage in the appeal proceedings unless the appellant is an unrepresented beneficiary or state agency. See 42 C.F.R. §§ 405.966(a)(2), 405.1018, 405.1122(c).

By a September 16, 2009, letter, the Council informed the appellant that he must explain whether any document submitted with his request for review constituted new evidence and, if so, good cause must be shown to submit it at this stage of appellate review. Exh. MAC-2. In his September 18, 2009, response, the appellant stated that "there was no new evidence submitted in this case." Exh. MAC-3. Additionally, by a letter dated October 5, 2009, the appellant stated that his appeal of the ALJ's decision "does not require any additional new evidence." Exh. MAC-6. Based on these statements, and having reviewed the record and the additional records submitted with the request for review, the Council is satisfied that the additional records represent duplicate copies of documentation previously admitted into the record. Therefore, the additional documents are not new evidence and are not admitted.

BACKGROUND

In 1997, the 51-year-old beneficiary with breast cancer underwent a bilateral mastectomy and breast reconstruction with silicone implants. Exh. 2 at 7. In or about 2007, she began experiencing pain and discomfort in her breasts and noticed a sudden change in the appearance and volume of her breasts. Exh. 2 at 16. An examination revealed that these symptoms were consistent with bilateral ruptured implants and free silicone within the tissues. *Id*.

On February 12, 2008, at 62 years of age, the beneficiary underwent surgery, which included the removal of the ruptured silicone implants, irrigation of the affected area, reconstruction of the breast pockets, and insertion of new silicone implants. Exh. 2 at 16. The surgeon stated that the "implant shell was practically disintegrated and the silicone gel was evacuated necessitating multiple glove changes and going through numerous amounts of lap sponges on both sides to clean out the visible silicone." *Id.* at 17. The surgeon also noted that the beneficiary exhibited significant contractures in the affected area which were addressed with open capsulotomies. As a result, the beneficiary required modification of the breast pockets. *Id.* at 16-18.

The beneficiary initially responded well to the February 12, 2008, implants, but later developed cellulitis in the area surrounding the incision line. Exh. 2 at 13. The beneficiary was hospitalized and treated with intravenous antibiotics, but her condition did not improve. Id. The surgeon opined that the infection "may be consistent with a reaction to the free silicone gel within the pocket." Id. Therefore, on March 17, 2008, the implants were removed intact, the area was irrigated with antibiotic solution, and several cultures and samples were obtained. Id. The surgeon noted some clear serous fluid surrounding the implants and placed drainage catheters in the wound and out through separate stab wound incisions. Id. Based on a review of the cultures and samples, a pathologist ruled out malignancy, but noted a "few foreign body giant cells" in the left breast sample. Id. at 11.

A few months later, after the infection had alleviated, the beneficiary presented to the appellant surgeon for a bilateral breast reconstruction. Exh. 2 at 7, 2. She underwent a lengthy medical clearance. *Id.* at 7. Then, on August 6, 2008, the appellant performed a breast reconstruction surgery, inserting saline breast implants. Axillary skin from the prior surgeries was excised. *Id.* The beneficiary responded well, and was discharged home on August 10, 2008.¹ *Id.* at 2. The August 6, 2008, procedure is the subject of this appeal.

The appellant submitted a claim to Medicare for the August 6, 2008, procedure, under CPT code 19342-50 (the delayed insertion of breast prosthesis following mastopexy, mastectomy or in reconstruction). The Medicare contractor denied the claim initially and upon redetermination, finding that the claim is not covered because the procedure was performed by a plastic surgeon. Exh. 1 at 12. The contractor found the beneficiary liable for the non-covered costs. Id. The Oualified Independent Contractor (QIC) found that the surgery was cosmetic and therefore not covered by Medicare. Exh. 1 at 4. The QIC determined that because the service is statutorily excluded from coverage, the limitation on liability provisions of section 1879 of the Act do not apply, and therefore the beneficiary was liable for the non-covered costs. Id. at 5.

Citing the Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, Ch. 16, Section 120 (cosmetic surgery exclusion), the ALJ found that the surgery was not covered by Medicare. Dec. at 5. The ALJ stated: "The evidence establishes that on the date of service in question the beneficiary underwent a revision of a previous reconstruction surgery. Saline implants were placed inside the beneficiary's breasts, and the excess axillary skin stria was removed. Both procedures were cosmetic in nature, and Medicare does not cover cosmetic procedures." *Id.* The ALJ then applied the limitation on liability provision of section 1879 of the Act and found that the beneficiary's liability was waived. He held the appellant liable for the non-covered costs. *Id.*

DISCUSSION

The appellant contends that the ALJ erred in finding the procedure cosmetic. The appellant agrees that the excision of the skin stria was cosmetic; however, as appellant explained, "Medicare was not billed for this procedure," and it is not at issue. Exh. MAC-1. Further, the appellant argues that "the

¹ The record also reflects that the beneficiary developed cellulitis in her right breast sometime after the August 6, 2008, procedure. On October 1, 2008, the appellant surgeon removed the right breast implant. Exh. 2 at 5. The appeal now before us does not concern the October 1, 2008, procedure; only the August 6, 2008, procedure is at issue in this appeal.

placement of the saline implants is not in any way cosmetic. This was a straightforward reconstructive procedure, a revision of the previous reconstruction she had many years ago." Exh. MAC-6. The Council agrees that the breast reconstruction procedure at issue is not cosmetic and is covered by Medicare.

Cosmetic and Noncosmetic Procedures

Section 1862(a)(10) of the Social Security Act provides that:

no payment may made under part A or part B for any expenses incurred for items and services where such expenses are for cosmetic surgery or are incurred therewith, except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

The MBPM provides guidance concerning the cosmetic surgery exclusion. The MBPM states: "No payment can be made under either the hospital insurance or supplementary medical insurance program for certain items and services, when the following conditions exist," and lists among them cosmetic surgery. MBPM, CMS Pub. 100-02, Ch. 16 at § 10. Section 10 cross-refers to section 120, which provides:

Cosmetic surgery or expenses incurred in connection with such surgery is not covered. Cosmetic surgery includes any surgical procedure directed at improving appearance, except when required for the prompt (i.e., as soon as medically feasible) repair of accidental injury or for the improvement of the functioning of a malformed body member. For example, this exclusion does not apply to surgery in connection with treatment of severe burns or repair of the face following a serious automobile accident, or to surgery for therapeutic purposes which coincidentally also serves some cosmetic purpose.

MBPM, CMS Pub. 100-02, Ch. 16 at § 120.

Medicare guidelines specifically address circumstances where breast reconstruction and prostheses are covered. The guidelines clarify that breast reconstruction following a mastectomy is not an excluded cosmetic procedure. It may be covered by Medicare. The Medicare National Coverage Determination (NCD) Manual, Chapter 1, Part 2, § 140.2 - Breast Reconstruction Following Mastectomy, explains: During recent years, there has been a considerable change in the treatment of diseases of the breast such as fibrocystic disease and cancer. While extirpation of the disease remains of primary importance, the quality of life following initial treatment is increasingly recognized as of great concern. The increased use of breast reconstruction procedures is due to several factors:

A change in epidemiology of breast cancer, including an apparent increase in incidence;

Improved surgical skills and techniques;

The continuing development of better prostheses; and

Increasing awareness by physicians of the importance of postsurgical psychological adjustment.

Reconstruction of the affected and the contralateral unaffected breast following a medically necessary mastectomy is considered a relatively safe and effective noncosmetic procedure. Accordingly, program payment may be made for breast reconstruction surgery following removal of a breast for any medical reason.

Id. (emphasis added).

As the above provision clearly states, Medicare may cover breast reconstruction surgery following removal of a breast for any medical reason. In this case, the beneficiary had a bilateral mastectomy due to breast cancer. Exh. 2 at 16. At that time, silicone implants were placed. Id. The subsequent rupture of the silicone implants created an additional medically necessary condition requiring the removal and reconstruction of the breasts using new intact silicone implants. Id. The second set of implants became infected, and treatment of the infection, removal of the implants, and reconstruction surgery using saline implants followed. Id. at 2, 13. The Council concludes that the August 6, 2008, procedure at issue was not cosmetic. On the contrary, the procedure was medically necessary and is covered by Medicare, consistent with NCD Manual, Chapter 1, Part 2, section 140.2.²

² The ALJ denied coverage for the procedure at issue, applying MBPM, Ch. 16, § 120, which is derived from section 1862(a)(10) of the Act. Where services are statutorily excluded from coverage under the Act (i.e., excluded as

DECISION

It is the decision of the Medicare Appeals Council that the breast reconstruction surgery performed by the appellant on the beneficiary on August 6, 2008, is covered by Medicare. The ALJ's July 6, 2009, decision is hereby reversed.

MEDICARE APPEALS COUNCIL

/s/ Susan S. Yim Administrative Appeals Judge

/s/ Gilde Morrisson Administrative Appeals Judge

Date: December 16, 2009