

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL
Docket Number: M-13-1562

In the case of

Claim for

D.D.H.
(Appellant)

Medicare Advantage (MA)
(Part C)

(Enrollee)

(HIC Number)

Health Net Medicare Programs/
Health Net of Arizona, Inc.
(MA Organization (MAO)/
MA Plan)

(ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated October 29, 2012. In that decision, the ALJ found that Health Net Medicare Programs, a Medicare Advantage Organization (MAO) that offers the Health Net of Arizona, Inc. Medicare Advantage (MA) plan in which the beneficiary is enrolled, is not required to authorize or cover sacroiliac joint fusion surgery with the iFuse Implant System for the beneficiary's sacroiliac joint problems and pain. The enrollee has asked the Medicare Appeals Council (Council) to review this action.

The regulation codified at 42 C.F.R. § 422.608 states that "[t]he regulations under part 405 of this chapter regarding MAC [Medicare Appeals Council] review apply to matters addressed by this subpart to the extent that they are appropriate." The regulations "under part 405" include the appeal procedures found at 42 C.F.R. part 405, subpart I. With respect to Medicare "fee-for-service" appeals, the subpart I procedures pertain primarily to claims subject to the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 70 Fed. Reg. 11420, 11421-11426 (March 8, 2005). The Council has determined, until there is amendment of 42

C.F.R. part 422 or clarification by the Centers for Medicare & Medicaid Services (CMS), that it is "appropriate" to apply, with certain exceptions, the legal provisions and principles codified in 42 C.F.R. part 405, subpart I, to this case.

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 Council has made the enrollee's request for review (including its eleven-page statement) a part of the record as Exhibit (Exh.) MAC-1. No response to the request for review has been received from the MAO.

The Council has carefully considered the enrollee's request for review and the administrative record. For the reasons stated below, the Council modifies the ALJ's decision, concurring in the ALJ's decision and expanding on its reasoning. The Council agrees with the ALJ that pursuant to the rules governing Medicare coverage (explained below), the iFuse Implant System surgery must be considered experimental and investigational. Therefore, Medicare does not cover it, and the MA organization and plan are not required to cover it.

APPLICABLE LEGAL AUTHORITIES

Managed Care Organizations

A managed care organization offering an MA plan must provide enrollees with "basic benefits," which are all items and services covered by Medicare Part A and Part B available to beneficiaries residing in the plan's service area. 42 C.F.R. § 422.101(a). An MA plan "must provide enrollees in that plan with coverage of the basic benefits by furnishing the benefits directly or through arrangements, or by paying for the benefits." 42 C.F.R. § 422.100(a). In providing "basic benefits," an MA organization must comply with national coverage determinations (NCDs) issued by CMS, "[g]eneral coverage guidelines included in original Medicare manuals and instructions unless superseded by operational policy letters or regulations in [part 422] or related instructions; and . . . [w]ritten coverage decisions of local Medicare contractors." 42 C.F.R. § 422.101(b). At its discretion, an MA plan may also offer additional (or "supplemental") benefits beyond those covered by original Medicare. 42 C.F.R. § 422.102.

Consistent with section 1852(a)(1)(A) of the Act, 42 C.F.R. § 422.101(a) specifies that an MAO must provide coverage of all Medicare-covered services available to original Medicare beneficiaries residing in a plan's service area.

Medically Reasonable and Necessary Medical Services

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. 15,560 (Apr. 29, 1987). 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 device to Medicare coverage. 68 Fed. Reg. 55634, 55636 (Sept. 26, 2003).¹

The Act vests in the Secretary the authority to make coverage decisions. Under that authority, CMS issues National Coverage Determinations (NCDs) that state 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 Medicare contractor has not issued any Local Coverage

¹ The Federal Register publications are available on line at: <https://www.federalregister.gov/>

Determinations (LCDs) concerning sacroiliac joint fusion surgery with the IFuse Implant System. However, in determining whether this surgery is medically reasonable and necessary, 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 (CMS Pub. 100-08) (MPIM) to assist contractors in developing LCDs.² The MPIM instructs contractors that, “[i]n order to be covered under Medicare, a service shall be reasonable and necessary.” MPIM, Ch. 13 at § 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:

² The Medicare policy manuals, including the Medicare Program Integrity Manual, are available online at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs.html>

ALJs and the Medicare Appeals Council are not bound by 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).

- o Scientific data or research studies published in peer-reviewed medical journals;
- o Consensus of expert medical opinion (i.e., recognized authorities in the field); or
- o Medical opinion derived from consultations with medical associations or other health care experts.

Id. at § 13.7.1. The Manual further explains:

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

Background

The record shows that the beneficiary first injured her sacroiliac joint in a fall onto concrete in 1974. Exh. MAC-1 at 1; Exh. 3 at 21-33. The resulting damage to the joint has caused severe pain, and loss of functionality and mobility. *Id.* Physicians have treated the injury for years; however, without very much improvement. *Id.* In recent years, the beneficiary's medical condition has worsened. Exh. 3 at 21, 28. The beneficiary's physicians have recommended the iFuse Implant System surgery for her sacroiliac joint. *Id.* at 21, 28; Exh. 17 at 110-11.

The beneficiary has been seeking MA plan approval for sacroiliac joint fusion surgery with the iFuse Implant System. See Exh. 1. The beneficiary and her surgeon state that in January 2012, the Medicare contractor paid the beneficiary's surgeon for performing two identical procedures for two other beneficiaries

who needed the surgery for the same type of reason. See Exh. 18 at 113-14.

The MA plan denied the beneficiary authorization for the procedure on the ground that it is experimental and investigational. Exh. 1 at 1, 3, 5. The Qualified Independent Contractor and the ALJ both denied coverage for the same reason. Exh. 11 at 90-92; Dec. at 4-5.

In her request for review, the beneficiary asserts that her sacroiliac joint injury is causing her a series of debilitating medical problems, and that she has a substantial need for the surgery, which is reasonable and necessary for her. Exh. MAC-1. She also asserts that this surgical procedure would be a cost-effective form of treatment for her. *Id.* She contends that the Medicare contractor in her geographical area has covered the procedure for at least two other beneficiaries. *Id.* Finally, she contends that without a physical evaluation during the appeals process, Medicare cannot determine whether the surgery is reasonable and necessary for her. *Id.*

Analysis

Although it appears that the beneficiary is correct in stating that the Medicare contractor paid for or covered two similar procedures (E27280)³ for other beneficiaries in January 2012, that fact does not affect the determination in this case. Medicare coverage decisions and appeals are not determined on the basis of precedent. Instead, each case or each matter is decided on its own merits. The Council decides this case based on the legal authorities set forth above and the reasoning explained below.

Section 1862(a)(1)(A) of the Social Security Act (Act) provides that Medicare will only cover items and services that are determined 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, the Centers for Medicare and Medicaid Services (CMS) has interpreted the terms "reasonable and necessary" to

³ CPT (Current Procedure Terminology) codes were designed by the American Medical Association to describe medical and surgical services performed by providers. The CPT code system has been incorporated into the Healthcare Common Procedure Coding System (HCPCS) developed by CMS for processing, screening, identifying, and paying Medicare claims. See 42 C.F.R. §§ 414.2 and 414.40.

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. 15,560 (Apr. 29, 1987).

In practical terms, this means that to qualify for Medicare coverage, an item or service (including a surgical procedure) must meet the requirements of a National Coverage Determination (NCD) or a Local Coverage Determination (LCD), or both. Or, if there is no NCD or LCD (as in this case), then *for the surgical procedure* (not simply the titanium insert device), there must be 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 in published, peer-reviewed medical journals, consensus of expert medical opinion, or medical opinion derived from consultations with medical associations or other health care experts. Pub. 100-08, Medicare Program Integrity Manual (MPIM), Chapter 13, §§ 13.5.1, 13.7.1. It is the responsibility of the party seeking Medicare coverage to furnish this information and evidence. See § 1833(e) of the Act.

In this case, evidence of this type has not been submitted. Nor is such evidence available at this time, based on the Council's review of the current medical literature. Therefore, there is no basis for ordering Medicare coverage of this surgical procedure.

The Council acknowledges that the beneficiary has researched and weighed the potential surgery at issue here, and that she is proceeding on the basis of medical advice. However, the Council is affirming the denial of coverage in this case for broader, legal and medical reasons, not based on medical reasons applicable to the beneficiary alone. The Medicare statute provides a medical coverage program of limited, defined benefits. Not all items and procedures are covered, and the requirements for coverage include those designed to ensure that relatively new devices, procedures, and treatments will have

thoroughly demonstrated their safety and efficacy prior to being covered by Medicare.

DECISION

For the foregoing reasons, the Medicare Appeals Council finds that the MAO is not required to pay for or otherwise cover the sacroiliac joint fusion surgery with the iFuse Implant System for the beneficiary's sacroiliac joint.

The ALJ's decision is modified as explained above.

MEDICARE APPEALS COUNCIL

/s/ Stanley I. Osborne, Jr.
Administrative Appeals Judge

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

Date: August 22, 2013