DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL

In the case of	**Claim for**
BioniCare Medical Technologies, Inc. (Appellant)	Supplementary Medical Insurance Benefits (Part B)
**** (Beneficiaries)	**** (HIC Numbers)
Palmetto GBA – DME Regional Carrier (Contractor)	**** (ALJ Appeal Number)

The Administrative Law Judge (ALJ) issued a decision dated March 24, 2009, addressing coverage for the BioniCare Stimulator Model BIO-1000 (BIO-1000), and related supplies, which the appellant rented to 47 beneficiaries on various dates in 2004 and 2005.[1] The ALJ determined that the devices and/or supplies furnished to the beneficiaries were not medically necessary and, therefore, not covered by Medicare. The ALJ found that the appellant was liable under section 1879 of the Social Security Act (Act) for the non-covered items furnished to the beneficiaries because valid notice was not provided. 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). The Council admits the appellant's

[1] To preserve the beneficiaries' privacy, the Council will refer to beneficiaries by their ALJ-assigned numbers. Their full names, HICNs, and dates of service at issue are listed on Attachment A to this decision. Attachment A will not be provided to the beneficiaries, but will be provided only to the appellant and appellant's counsel.

request for review dated March 31, 2009, into the record as Exhibit (Exh.) MAC-1.

The Council has reviewed the record and the appellant's contentions. For the reasons set forth below, the Council modifies the ALJ's decision and reverses it in part. Specifically, the Council adopts the ALJ's ultimate conclusion that Medicare coverage is not warranted for the BIO-1000 devices and related supplies furnished to the beneficiaries, but modifies the decision to clarify that the overarching issue is whether the BIO-1000 device is a reasonable and necessary treatment for osteoarthritis of the knee, and to explain more fully why it is not. The Council finds insufficient evidence to demonstrate that the device was medically reasonable and necessary in accordance with section 1862(a)(1) of the Social Security Act (Act). On the issue of liability for the non-covered devices, the Council reverses the ALJ's finding on liability, related to beneficiaries 1, 2, 4, 5, 10-13, 15, 17-25, 27-41, 44, 45, and 47. The Council finds that these 36 beneficiaries received valid advance beneficiary notices (ABNs) and consequently are liable for the non-covered items. The appellant remains liable for the non-covered items provided to the remaining 11 beneficiaries (3, 6-9, 14, 16, 26, 42, 43, and 46) who did not receive ABNs.

BACKGROUND AND PROCEDURAL HISTORY

The appellant seeks Medicare Part B payment for the BIO-1000, a device that delivers pulsed electrical stimulation to the knee and is used in the treatment of osteoarthritis of the knee, and related supplies. For the claims at issue, the appellant billed Medicare for the rental of the BIO-1000 under HCPCS code E0762, and for related supplies under HCPCS code A4595.[2] The Durable Medical Equipment Medicare Administrative Contractor (DME MAC) denied coverage initially, and on redetermination on the ground that the effectiveness of the device in treating osteoarthritis had not been established in clinical studies. *See, e.g.*, Beneficiary 1 Claim File, Exh. 1 at 15.

[2] The Centers for Medicare & Medicaid Services (CMS) 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).

On reconsideration, the Qualified Independent Contractor (QIC) issued unfavorable decisions, based on its findings that medical necessity had not been established for each beneficiary. *See, e.g.,* Beneficiary 1 Claim File, Exh. 1 at 4-6. Additionally, the QIC found those beneficiaries who had signed ABNs liable for the non-covered charges. *Id.* at 6. For the claims involving beneficiaries who had not signed an ABN, the QIC found the appellant liable for the non-covered charges. *See, e.g.,* Beneficiary 3 Claim File, Exh. 1 at 8.

The ALJ found that the devices and/or supplies provided to the beneficiaries were not medically necessary and therefore not covered by Medicare. Dec. at 9-11. On the issue of liability, the ALJ concluded that although the appellant issued an ABN to 36 beneficiaries, the ABN was not valid and therefore the appellant was liable for the non-covered items. *Id*. at 11-12.

APPLICABLE LEGAL AUTHORITIES

Durable Medical Equipment (DME)

Section 1832(a) of the Social Security Act (Act) provides that benefits under Medicare Part B include "medical and other health services." Section 1861(s)(6) of the Act defines "medical and other health services" as including DME. Section 1861(n) of the Act lists certain items that are classified as DME. Neither a transcutaneous electrical nerve stimulator (TENS) unit, nor the device at issue, is listed in section 1861(n). By its own terms, however, section 1861(n) is not an exhaustive list of those items that qualify as DME.

Medicare covers DME if it (1) meets the definition of DME; (2) is medically "reasonable and necessary;" and (3) the equipment is used in the beneficiary's home. Medicare Benefit Policy Manual (MBPM)(Pub. 100-02), Ch. 15, § 110. DME is defined as equipment that can withstand repeated use; is primarily and customarily used to serve a medical purpose; generally is not useful to an individual in the absence of an illness or injury; and is appropriate for use in the home. 42 C.F.R. § 414.202.

Medically Reasonable and Necessary

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). 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).

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 Determinations (LCDs) concerning the device. However, in determining whether the BIO-1000 is medically reasonable and necessary to treat osteoarthritis of the knee, 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. 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 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

I. ALJ Decision and Scope of Council Review

The ALJ denied the claims on medical necessity grounds, including:

> 1) The purpose of the device, deferring knee surgery, unreasonably defers timely treatment, since deferral of treatment increases complicating factors such as age.
>
> 2) To the extent that the device was prescribed for pain relief, other less expensive analgesics and electronic stimulators are available for that purpose.
>
> 3) The record does not document that the beneficiaries tried other therapeutic interventions (including medicinal therapies and less expensive electronic stimulators) before renting the device, and does not document the results of such trials.

Dec. at 9-11.

The Council does not dispute that the above concerns may be factors in determining whether the device is medically reasonable in individual cases. However, the Council finds that the ALJ did not fully explicate the overarching issue in the case, whether the device is a reasonable and necessary treatment for osteoarthritis of the knee.

Also, because the Council determines in this case that the BIO-1000 device is not medically reasonable and necessary, pursuant to Section 1862(a)(1)(A) of the Act, the Council will adjudicate

the applicability of the limitation of liability provisions in section 1879 of the Act, and the validity of the advance beneficiary notices (ABNs) signed by the beneficiaries.

In its request for review, the appellant's representative summarizes the exceptions to the ALJ's coverage decision by posing a series of questions to the Council:

1. Can an ALJ deem a DME device not to be covered based on the failure to provide additional documentation that has not been requested or prescribed by the DME MACs and for which Appellant was not provided notice?

2. Can an ALJ deem a device not to be covered based on the belief that other less expensive electrical stimulators were not tried?

3. Can an ALJ deem an ABN to be invalid if it provides a specific reason for denial that is accurate?

4. For the disputed claims, is the BIO-1000 reasonable and medically necessary and thus covered by Medicare?

Exh. MAC-1 at 1.

The burden is on the appellant to establish that the device in this case was medically reasonable and necessary when furnished to the beneficiary. The appellant argues that the BIO-1000 is reasonable and necessary because: it was approved by the FDA, CMS issued a HCPCS code for the device, scientific studies demonstrate the safety and effectiveness of the device, the general medical community has accepted the device, and many Medicare contractors and ALJs have determined that Medicare could pay for the device. We address each of these arguments below.

1. Additional Documentation and "Treating Physician Rule"

The appellant asserts that the denied claims could not be "based on a lack of medical documentation supporting medical necessity" because the DME MACs did not request additional documentation as required by MPIM, at § 5.7, 5.8. Exh. MAC-1 at 2-3. Further, the appellant contends that without a local coverage determination (LCD), or similar guidance on the issue, the

appellant cannot predict which, if any, additional medical records should be provided. *Id*.

Section 1862(a)(1)(A) of the Act bars coverage of items and services that are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. Thus, the regulations clearly place the burden of substantiating a claim for payment on the entity making the claim by requiring appellant to provide additional documentation explaining the conditions necessitating the device and supplies at issue for each particular beneficiary. *See* 42 C.F.R. § 424.5(a)(6). The Council notes that the Secretary may require medical documentation, in addition to the CMN or letter of medical necessity (LMN), to support medical reasonableness and necessity for DME. *See Maximum Comfort v. Secretary of Health & Human Services*, 512 F. 3d 1081 (9th Cir. 2007), *petition for cert. denied*, 129 S.Ct. 115 (U.S. Oct. 6, 2008) (No. 07-1507); *accord MacKenzie Medical Supply, Inc. v. Leavitt,* 506 F.3d 341 (4th Cir. 2007); *Gulfcoast Medical Supply, Inc. v. Secretary, HHS,* 468 F.3d 1347 (11th Cir. 2006).[3] The MPIM also specifies that, for DME to be covered by Medicare, "the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered." MPIM Ch. 5, § 5.7. Further, the regulations require that a supplier submit all relevant evidence on or before the time when it requests reconsideration by the Qualified Independent Contractor (QIC). 42 C.F.R. § 405.966. The ALJ found that the record lacked sufficient documentation to meet the requirements of the MPIM; therefore, the device was not covered by Medicare. Dec. at 10-11 (citing MPIM, §§ 5.7-5.8).

As discussed further below, the Council finds that the appellant has not provided sufficient evidence that the devices at issue have been independently peer-reviewed with publication of the results in authoritative journals. It is the *appellant's* responsibility to adduce the strongest available evidence to demonstrate that the device is reasonable and necessary, and not experimental or investigational. *See* MPIM, CMS Pub. 100-8, Ch. 13, § 13.7.1. In this case the appellant has failed to make such a showing.

The Council has also considered the appellant's argument that a number of cases have upheld the "treating physician rule" that

[3] *See also* www.hhs/dab/macdecisions.

the treating physician's opinion is binding unless contradicted by substantial evidence. Exh. MAC-1 at 7. CMS Ruling 93-1, establishes that no presumptive weight will be given to a treating physician's medical opinion in determining the medical necessity of services. Rather, "[a] physician's opinion will be evaluated in the context of the evidence in the complete administrative record." CMS Ruling 93-1 (*eff*. May 18, 1993). CMS Ruling 93-1 was issued in response to litigation concerning coverage of Medicare Part A services, provides that no presumptive weight should be assigned to a treating physician's medical opinion in determining the medical necessity of inpatient hospital or skilled nursing facility services. Moreover, the Ruling adds parenthetically that the Ruling does not "by omission or implication" endorse the application of the "treating physician rule" to services not addressed in the Ruling, *e.g.* Medicare Part A services. However, the rule's relevance is quite attenuated because the Council finds the treatment or device has not been proven to be medically reasonable and necessary, safe and effective, and not investigational or experimental for any beneficiaries.

II. Medically Reasonable and Necessary

The appellant takes issue with recent decisions of the Council holding that the BIO-1000 was not medically reasonable and necessary in part because the Council was not persuaded that the evidence offered by the appellant demonstrated that the device was medically reasonable, and not experimental or investigational. Exh. MAC-1. In earlier decisions, the Council considered whether the BIO-1000 was reasonable and necessary when furnished to beneficiaries prior to 2006. The present case involves dates of service in 2004 and 2005. Therefore, in deciding whether the BIO-1000 was reasonable and necessary for the beneficiaries at issue in this appeal, the Council has reexamined the appellant's arguments and evidence as they pertain to furnishing the devices and related supplies in 2004 and 2005.

1. FDA Clearance and HCPCS Coding

In its request for review, the appellant argues that FDA clearance establishes that the BIO-1000 is safe and effective and not experimental or investigational:

> Under Medicare regulations, pursuant to the FDA's determination that the BIO-1000 is a class II device, CMS deems it to be a "Category B" device which means that it is "non-experimental/investigational."

Exh. MAC-1 at 5, *citing* 42 C.F.R. § 405.201(b). The appellant appears to argue that, because under the quoted provision the BIO-1000 may be deemed "non experimental/ investigational," CMS would be precluded from excluding the device from Medicare coverage on the ground that its use is not yet proven effective for Medicare beneficiaries or generally accepted in the medical community. The appellant misreads the relevant authority.

The regulations state that "CMS *may consider* for Medicare coverage" FDA approved devices "that have been categorized as non-experimental/investigational." 42 C.F.R. § 405.201(a)(2) (emphasis added). The regulations further clarify that CMS uses FDA categorization "*as a factor* in making Medicare coverage decisions." 42 C.F.R. § 405.201(a)(1) (emphasis added). Thus, under Medicare regulations, the fact that a device may be deemed non-experimental/investigational by virtue of its FDA classification means, as a threshold matter, only that it is eligible to be considered for Medicare coverage.

This conclusion is reinforced by statements published by CMS in the Federal Register. On September 26, 2003, the Department of Health and Human Services (HHS), under the joint signature of the Secretary of HHS and the CMS Administrator, issued a notice describing the revised decision-making process that CMS uses to make an NCD. 68 Fed. Reg. 55,634 (September 26, 2003). In addition to describing the new process, the notice discussed the difference between CMS review of a medical device as compared to reviews conducted by the FDA. *Id*. at 55,636. In pertinent part, the notice explains that:

> Both CMS and the FDA review scientific evidence, and may review the same evidence, to make purchasing and regulatory decisions, respectively. However, CMS and its contractors make coverage determinations and the FDA conducts premarket review of products under different statutory standards and different delegated authority (67 FR 66755, November 1, 2002). Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of coverage under section 1862(a)(1)(A)

> of the Act. CMS adopts FDA determinations of safety and effectiveness, and CMS evaluates whether the product is reasonable and necessary for the Medicare population. Although an FDA-regulated product must receive FDA approval or clearance (unless exempt from the FDA premarket review process) for at least one indication to be eligible for coverage [discussion of Category B devices omitted] FDA approval/clearance alone does not generally entitle that device to coverage.

Id.

Moreover, FDA clearance does not preclude CMS, or its contractors, in analyzing whether a particular item or service is medically reasonable and necessary, from making an independent inquiry into whether the item or service is safe and effective and not experimental or investigational. *See* MPIM, Ch. 13, § 5.1. Nor does it preclude CMS or its contractors from inquiring whether the item or service is supported by "[p]ublished authoritative evidence derived from definitive randomized clinical trials or other definitive studies." *Id.* at § 7.1. If FDA clearance were dispositive of these issues, there would be no need for the MPIM provisions cited above.

Accordingly, the FDA clearance that the BIO-1000 obtained does not, by itself, establish that the device meets Medicare coverage requirements; i.e., that it has been shown to be a medically reasonable and necessary treatment for osteoarthritis of the knee. The Council finds that the evidence, as summarized below, does not establish that, at the time the devices were furnished in 2004 and 2005, the BIO-1000 met medical necessity standards for Medicare coverage.

Similarly, the appellant argues that CMS has recognized the effectiveness of the BIO-1000 because it has issued a HCPCS code for the device. Exh. MAC-1 at 5. The appellant appears to equate the issuance of a HCPCS code with a favorable Medicare coverage determination. CMS has made clear in several policy statements, however, that there is no link between the issuance of a HCPCS code and a determination that an item or service is covered by Medicare. For example, in the *Innovators' Guide to Navigating CMS* (Aug. 25, 2008), CMS stated unequivocally: "Coding is distinct from coverage of a new technology; assignment of a new code does not automatically imply coverage

by any payer." *Id.* at 18.[4] Therefore, the fact that CMS issued a HCPCS code for the BIO-1000 does not provide any further support to the appellant's claims for coverage.

2. Medical Reasonableness and Necessity

The burden is on the appellant to establish that the device in this case was medically reasonable and necessary when furnished to the beneficiaries. Accordingly, the Council has considered whether the evidence the appellant submitted is sufficient to establish that the BIO-1000 was a medically reasonable and necessary device when it was provided to the beneficiaries.

We note at the outset that throughout the record, the purpose of the BIO-1000 device has been described in a number of ways. The first generic description is that the BIO-1000 alleviates the pain and other symptoms that beneficiaries experience with osteoarthritis of the knee. The second description suggests that the medical benefit of the device is that its use may ultimately result in regeneration of the knee cartilage.

The Council finds that there is little objective evidence in the record that using the BIO-1000 results in regeneration of cartilage in humans.[5] Therefore, if we were to determine that appellant's argument that BIO-1000 is a medically reasonable treatment for osteoarthritis rests solely on the claim that it regenerated cartilage; i.e., it cured the defect causing the knee pain, its contention that the device is medically reasonable and necessary for "treatment" of osteoarthritis would clearly fail for lack of substantial evidence. However, since it appears that appellant's primary argument for coverage is more general; i.e., that the BIO-1000 is effective in alleviating the pain and symptoms associated with osteoarthritis, we evaluate the case primarily in those terms.

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[4] The guide is available at: http://www.cms.hhs.gov/CouncilonTechInnov/Downloads/InnovatorsGuide8_25_08.pdf.

[5] A chart entitled "Differentiation between BioniCare Technology and Bone Stimulators and TENS" states that the BioniCare technology has demonstrated cartilage regeneration in **animals**. Master Exhs. (on CD) at M-75.

a. Appellant's Evidentiary Submissions

i. Affidavits

The appellant submitted affidavits from Michael Rodeman, Vice-President of Operations for RS Medical and Karen Boston-Wright, HealthCare Solutions, Inc. *See* Master Exhs. (on CD) at M-75. As relevant here, Mr. Rodeman and Ms. Boston-Wright assert generally that the BIO-1000 is not a TENS unit and has not been found to be experimental or investigational in many cases. *Id*. The Council concurs with the assertion that the BIO-1000 is not a TENS unit, but disagrees with the assertion that the device is not experimental or investigational for the reasons stated below.

ii. Studies on Humans

The appellant submitted several articles regarding studies that it asserts demonstrate the efficacy of the BIO-1000 in treating osteoarthritis of the knee. *See* Master Exhs. (on CD) at M-75. The Council notes at the outset that much of the literature was authored, at least in part, by individuals connected with BioniCare, including Dr. Zizic who has served as the President and CEO of BioniCare since 2003. For example, two of the authors of a three-month study, published in 2007, to evaluate the safety and efficacy of the device in patients with osteoarthritis of the knee were employees of BioniCare. (Drs. Zizic and Caldwell.) *See* D. Garland, et al., "A 3-month, randomized, double-blind, placebo-controlled study to evaluate the safety and efficacy of a highly optimized, capacitively coupled, pulsed electrical stimulator in patients with osteoarthritis of the knee," OSTEOARTHRITIS AND CARTILAGE (2007), in Master Exhs. (on CD) at M-75. The study was supported by a grant from BioniCare Medical Technologies. It was designed to include patients from two orthopedic surgery practices and one rheumatology practice.

The appellant argues that the above studies should not be discounted simply because individuals affiliated with BioniCare were co-authors. The Council accords these studies less weight based upon guidance in the MPIM. According to the MPIM,

> [L]imited 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.

MPIM, Ch. 13, § 7.1. Therefore, in the Council's view, whether the authors of a study have a potential financial interest in the outcome is a legitimate inquiry in determining the appropriate weight to be given a study.

iii. Studies on Animals

The appellant has also relied on studies that used BIO-1000 technology on animals. For example, the record contains the results of a study entitled "Pulsing Direct Current-Induced Repair of Articular Cartilage in Rabbit Osteochondral Defects," published in the *Journal of Orthopaedic Research* in 1990. *See* Master Exhs. (on CD) at M-75. The article does not purport to correlate the results of the rabbit studies to the repair of human cartilage, and the Council finds no basis in Medicare coverage standards for relying on the study in this appeal.

Similarly, a study entitled "Up-regulation of Chondrocyte Matrix Genes and Products by Electric Fields," published in *Clinical Orthopaedics & Related Research* in October 2004, studied the effect of "capacitively coupled" electrical signals on chondrocytes isolated from the articular surface of fetal *bovine* metacarpophalangeal joints. Master Exhs. (on CD) at M-75 (emphasis added). While the study concluded that the procedure had some effect *in vitro*, it only suggested that it may be used *in vivo* as a noninvasive modality to promote cartilage healing or ameliorate the effects of osteoarthritis, or both.

In summary, the Council finds that the above and similar animal studies have no probative value in determining whether BIO-1000 is medically reasonable and necessary for the treatment of osteoarthritis in humans.

b. Acceptance in the Medical Community

The appellant argues that the BIO-1000 is generally accepted in the medical community and is, therefore, medically reasonable and necessary. *See* Exh. MAC-1 at 7-8. The Council does not find that the evidence establishes that the device has general acceptance in the medical community.

According to the request for review, more than 3000 physicians have prescribed the BIO-1000. *See* Exh. MAC-1 at 7. An

affidavit from appellant's witness Michael Rodeman, dated February 19, 2007, avers that, as of December 31, 2005, over 3900 physicians had prescribed the device and as many as 1500 commercial payers had reimbursed for it. Master Exhs. (on CD) at M-75. Even accepting these statements at face value, there is no evidence in the record explaining the reasons the physicians decided to prescribe the BIO-1000 device.[6] For this reason, the fact that a number of physicians prescribed the device does not demonstrate that the general medical community accepts that the BIO-1000 is reasonable and necessary for the treatment of osteoarthritis.

Moreover, to the extent that the appellant produced affidavits from prescribing physicians averring that the BIO-1000 is effective for their patients, or that one or more independent medical experts may have opined in proceedings before other ALJs that the device was safe and effective and not experimental or investigational,[7] such individual opinions do not establish acceptance by the general medical community. As stated in the MPIM:

> 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 . . . are not sufficient evidence of general acceptance by the medical community.

MPIM Chap. 13, § 13.7.1. For these reasons, the Council concludes that the appellant has not proven that the BIO-1000 device has gained general acceptance within the medical community.

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[6] If, hypothetically, a physician prescribed the device because a patient had failed all other treatments, and the physician regarded the BIO-1000 as a last resort, the fact that the physician prescribed the device would not necessarily prove that the physician believed the device was effective.

[7] In the request for review, the appellant argues that three ALJs other than the ALJ who issued the decision presently under review retained independent medical experts to opine on the BIO-1000. Exh. MAC-1 at 6. Neither the curricula vitae, written reports, nor testimony of these experts is in the present record, nor has this evidence been presented to the Council. Accordingly, the Council finds that the above assertions do not provide a basis for determining coverage in this case.

c. Effect of ALJ and Contractor Decisions

The appellant similarly asserts that the BIO-1000 must be regarded as medically reasonable and necessary because some Medicare contractors and ALJs have concluded that claims for the device may be paid. Exh. MAC-1 at 7. This argument is unpersuasive because the Council conducts a *de novo* review of ALJ decisions, which includes a review of the determinations of various Medicare contractors. Prior decisions of ALJs and contractors are not precedential, nor are they binding on the Council.

In further support of its contention that the BIO-1000 has been viewed as medically reasonable and necessary by some Medicare contractors, the appellant has submitted an affidavit that purports to describe discussions in 2007 with several medical directors as to possible coverage for the BIO-1000 device. *See* Exh. M-76 at 51-54. The content of the affidavit is almost entirely hearsay. It purports to describe what other persons (specifically contractor medical directors) said or thought. *See, e.g.,* Pilley Affidavit at paras. 7, 11, 12, 13, 30-32.[8]

To the extent that Dr. Pilley's affidavit offers his own opinions and conclusions about possible Medicare coverage of the BIO-1000 device, whether the device is efficacious and safe, whether it is experimental or investigational, and what coverage criteria should govern its use, Dr. Pilley makes clear that he never reviewed an actual case involving the BIO-1000 in his capacity as the Medical Director for one DME Payment Safeguard Contractor (PSC). Para. 33. Further, only the DME MACs, and not the DME PSCs, may adopt local coverage policies. *See* MPIM, Ch. 13, Local Coverage Determinations, §§ 13.1.3 and 13.2.4. Dr. Pilley never explained the foundation for his affidavit to the extent that it purports to describe the coverage policy of the DME MACs responsible for processing claims and establishing coverage policy. Rather, Dr. Pilley's affidavit contains numerous largely unsupported statements of personal opinion. *E.g.*, "I . . . did not consider it experimental" (para. 7), "In

[8] Although counsel for appellant asserts that Dr. Pilley testified at the ALJ hearings in this case as well as providing an affidavit, in fact there is no evidence that he testified at the hearings in this case. The Council has reviewed the audio recordings of all hearing sessions, and there is neither any testimony by Dr. Pilley nor any reference to him testifying. *See* CD Recordings of Hearings on February 10 and 26, 2009. Therefore, the ALJ never had an opportunity to ask Dr. Pilley any questions about the matters asserted in his affidavit.

my opinion" (para. 8), "I favored coverage" (para. 9), "I personally believe" (para. 15), "I believe that" (para. 16), "I did not and do not believe" (paras 17 and 18), and "It was my opinion" (para. 34).

Moreover, section 1842(c)(2) of the Act provides that the DME MACs shall pay no less than ninety-five percent of "clean claims" within less than twenty-eight days. In view of the huge volume of Medicare claims processed each year, the vast majority of all claims are allowed without any individual review. Typically, individual review is given only to claims that are selected for review based on a processing edit. *See, generally,* Medicare Program Integrity Manual, Pub. 100-08, Chapter 1 - Overview of Medical Review (MR) and Benefit Integrity (BI) Programs. Thus, the fact that some claims were allowed in the past does not demonstrate an affirmative coverage policy. Nor has appellant introduced evidence that some claims were in fact allowed after individual consideration and review of a beneficiary's medical condition by a DME MAC. The very fact that the claims at issue were denied belies any assertion that CMS or its contractors had an affirmative uniform policy of coverage.

For these reasons, the Pilley affidavit does not provide credible evidence of a policy on the part of CMS or its contractors with respect to Medicare coverage, or non-coverage, for the BIO-1000 device.

In further support of its argument that the BIO-1000 device is not experimental or investigational, the appellant also submitted statements from six individuals and entities who commented on a Draft LCD of Non-Coverage for the BIO-1000, provided at a public meeting on October 13, 2008. *See* Bio-100 LCD Comments (submitted on CD), as Exh. M-83. The appellant asserts that no one presented any evidence at the meeting that the BIO-1000 was experimental or investigational. Exh. MAC-1 at 7. This argument misses the mark. According to Dr. Zizic's statement, the stated basis of the draft LCD was that "[t]here is insufficient published literature to support that any indication for these devices is medically necessary." *See* Dr. Zizic's Comments (submitted on CD) in Exh. M-83. The absence of any medically supported use is an indicia that a device is experimental or investigational. In any case, the Draft LCD is not in the record, and the statements do little more than restate the views of the appellant, its employees, and consultants in favor of coverage. The Council gives no extra

weight to these statements, or any weight to a draft LCD that was not in existence on the date of the services at issue.

III. LIMITATION ON LIABILITY

The ALJ addressed liability and found that although some of the beneficiaries were provided ABNs, the notices "did not provide the beneficiaries with adequate advance notice of probable non-payment." Dec. at 12. Therefore, the ALJ concluded that none of the beneficiaries were responsible for the costs of the non-covered items pursuant to section 1879 of the Act. *Id*. However, as set forth below, the Council reverses the ALJ's decision and finds that the appellant issued valid ABNs to beneficiaries 1, 2, 4, 5, 10-13, 15, 17-25, 27-41, 44, 45, and 47. Consequently, these 36 beneficiaries are responsible for the related non-covered costs.

Section 1879 of the Act provides that a beneficiary or supplier may be liable for the cost of an item or service that is not "reasonable and necessary" based upon prior knowledge of non-coverage. Act at § 1879(a); 42 C.F.R. §§ 411.400, 411.404, 411.406; Medicare Claims Processing Manual (MCPM), Pub. 100-04, Ch. 30, § 40. A beneficiary is deemed to have knowledge of non-coverage if the supplier provides written notice to the beneficiary explaining why it believes that Medicare will not cover the item or service. 42 C.F.R. § 411.404(b). A supplier is deemed to have knowledge of non-coverage, in part, when it informs the beneficiary before furnishing the item or service that it is not covered. 42 C.F.R. § 411.406(d)(1). A supplier also has actual or constructive knowledge of non-coverage based upon "[i]ts receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from [Medicare contractors]" and "[i]ts knowledge of what are considered acceptable standards of practice by the local medical community." 42 C.F.R. §§ 411.406(e)(1),(3).

The Council finds that the appellant in this case knew or had reason to know that Medicare would not cover the device during the period at issue, pursuant to 42 C.F.R. §§ 411.406(e)(1),(3). Therefore, the appellant is liable for the non-covered items unless it notified the beneficiaries in writing that the items likely would not be covered by Medicare.

1. Beneficiaries Who Received No Notice

The ALJ was correct in finding that the claim files for beneficiaries 3, 6-9, 14, 16, 26, 42, 43, and 46 do not contain any evidence that the beneficiary received written notice of Medicare's non-coverage. Dec. at 11. Without evidence that the beneficiaries knew or could reasonably have been expected to know that Medicare would not cover the BIO-1000, these beneficiaries' liability for the non-covered items is waived pursuant to section 1879 of the Act. The appellant is liable for the non-covered costs arising from the claims of these beneficiaries.[9]

2. Beneficiaries Who Signed Valid ABNs

Each of the claim files for beneficiaries 1, 2, 4, 5, 10-13, 15, 17-25, 27-41, 44, 45, and 47 contains a signed ABN that states:

> [The] BIO-1000 System is a newly released product which has not yet received certification from Medicare as a covered benefit/product for treatment, and therefore, may be considered experimental.

See, e.g., Beneficiary 2 Claim File, Exh. 2 at 3. The Council finds that this statement constitutes adequate prior written notice that Medicare would not cover the BIO-1000 device or supplies. Therefore, the Council finds that for these 36 beneficiaries, liability is not limited. Each of these beneficiaries is responsible for the non-covered costs of the device and/or any related supplies pursuant to section 1879 of the Act.[10]

DECISION

It is the decision of the Medicare Appeals Council that Medicare does not cover the BIO-1000 devices at issue pursuant to section 1862(a)(1)(A) of the Act. Further, the appellant is liable for the non-covered costs arising from the claims of beneficiaries 3, 6-9, 14, 16, 26, 42, 43, and 46 because they were not furnished with an Advance Beneficiary Notice (ABN).

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[9] The initials and dates of service for these beneficiaries are listed in Table 1, below.

[10] The initials and dates of service for these beneficiaries are listed in Table 2, below.

Beneficiaries 1, 2, 4, 5, 10-13, 15, 17-25, 27-41, 44, 45, and 47 received and signed a valid ABN; they are responsible for the non-covered costs of the device and/or any related supplies under section 1879 of the Act.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson
Administrative Appeals Judge

/s/ Susan S. Yim
Administrative Appeals Judge

Date: July 13, 2009