



OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE
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TRICARE
MANAGEMENT ACTIVITY

OGC-AC

DEC -5 2008

Formal Review Decision
in the Appeal of
Julia G., SSN: [REDACTED]
A TRICARE Prime Beneficiary

This formal review determination is authorized by Title 32, Code of Federal Regulations, Part 199 (32 CFR 199) which implements Chapter 55 of Title 10, United States Code. The beneficiary is appealing the denial of cost-sharing for an Alpha-Stem® 100 (Microcurrent Therapy) device which she began renting in May 2008. The beneficiary subsequently purchased the device on an unspecified date. The device was rented and purchased from Alpha-Stem®, a non-network, participating provider. The initial denial and reconsideration determination were issued by Humana Military Healthcare Services (HMHS), the TRICARE Managed Care Support Contractor (MCSC) for the State of Oklahoma. Based on review of the case file and applicable regulatory and policy criteria, a determination has been made to *overturn* the decision reached by HMHS in its August 12, 2008, reconsideration determination. The rationale for this decision is discussed in more detail below.

The TRICARE Management Activity (TMA), formerly the TRICARE Support Office (TSO), and Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS), no longer uses the acronyms CHAMPUS or OCHAMPUS however, most regulatory and policy instruments still contain these acronyms. For the purposes of this decision, when regulation, policy, or other documentation are quoted, any reference to CHAMPUS or OCHAMPUS is synonymous with TRICARE.

FACTUAL BACKGROUND

On April 15, 2008, Bruce M., M.D., submitted a preauthorization request to HMHS for the purchase of an Alpha-Stim® 100 (CPT: E1399). A second request was faxed by Dr. [REDACTED] on May 22, 2008. In support of his request, Dr. M. advised:

This is microcurrent therapy using alpha waves and the same basic therapy used in bone stimulators post-operatively. It has been shown in numerous studies to help pain as well as anxiety and insomnia. As a full-time chronic pain physician, I must address pain as well as sleep and mood disorders.

Therefore, I find this to be the ideal tool in treatment of this difficult population.

By decision dated May 28, 2008, HMHS denied the request finding:

The service is a non-covered benefit per TRICARE Policy Manual 6010.54-M, August 1, 2002, Chapter 1, Section 2.1, Unproven Drugs, Devices, Medical Treatments, and Procedures (1)(A)(B)(3)(4)(C), (C-23, April 28, 2005), Issue Date November 1, 1993, Authority 32 CFR 199.2 and 32 CFR 199.4(g)(15).

Your request for the Alpha Stim 100 is considered unproven. TRICARE does not cover unproven medical treatments or devices, therefore your request for Alpha Stim 100 is **denied** at this time.

By reconsideration determination dated August 12, 2008, HMHS upheld its prior denial:

After careful reconsideration of this case, including all additional information, the second reviewer **agrees** with the initial denial of the **Alpha-Stim 100 (Microcurrent Therapy)**. Based upon the opinion expressed by the second reviewer, this request is **denied** as **Alpha-Stem 100 (Microcurrent Therapy)** is not approved as a covered benefit per TRICARE Policy Chapter 1, Section 2.1. Therefore, the initial denial for the **Alpha-Stem 100 (Microcurrent Therapy)** is **upheld**.

On October 8, 2008, the beneficiary appealed the denial to TRICARE. The beneficiary stated:

Please consider this a formal appeal to your recent denial decision to obtain reimbursement for the Alpha Stim 100 device that was purchased to control my chronic back pain.

Prior to ever using the Alpha Stim 100 device, I consulted with Dr. M [REDACTED] about having the Radio Frequency Ablation procedure that had previously been performed on several occasions at the [REDACTED] [REDACTED] (Dr. H [REDACTED]). These RFA procedures were effective in alleviating my chronic pain; however, they needed to be performed every 4-6 months. Since moving from Florida to Oklahoma in July 2007 (after my husband's retirement from the Air Force), I had not been able to find a doctor in Oklahoma City to continue the RFA treatments. I even requested

authorization to travel back to the [REDACTED] but was denied. By the spring of 2008, I was in a considerable amount of pain and could barely function to perform every day activities. I was already being prescribed high doses of pain medication (Kadian, Roxicodone, and Valium) still the pain was too much to be of any use.

By early May 08 TRICARE approved treatments using the Alpha Stem 100 device during in-office visits. I honestly did not expect to receive any relief from this new procedure, and was surprised when I obtained a great deal of relief after each treatment. My pain level went from a 10 (on a scale from one to ten) to a 5. Unfortunately, the pain relief was temporary because the standard treatment protocol is to use the device daily for the first 21 days. TRICARE did not authorize that many visits.

10 USC § 1106 provides that a claim for payment for services provided shall be submitted within one year after the date that the service is provided. If claims are not filed within this time period, the service or treatment shall be denied. Although the beneficiary has yet to submit claims for the purchase of the device, she notes that the device cost \$800.00, which is in excess of the minimum amount required for review at this level of appeal.

ISSUES AND FINDINGS OF FACT

APPLICABLE AUTHORITY

TRICARE benefits are authorized by Congressional legislation incorporated in Chapter 55 of Title 10, United States Code, and implemented by the Secretary of Defense and the Secretary of Health and Human Services in 32, Code of Federal Regulations, Part 199 (32 CFR 199). Specific regulatory provisions pertinent to this case are set forth in the attachment to this Formal Review Decision.

ISSUE(s): Whether the Alpha-Stem® 100 is medically necessary, appropriate or otherwise coverable under the TRICARE Basic Program.

Medically or psychologically necessary is defined in pertinent part as the frequency, extent and types of medical services or supplies which represent appropriate medical care and that are generally accepted by qualified professionals to be reasonable and adequate for the diagnosis and treatment of illness, injury, pregnancy, and mental disorders or that are reasonable and adequate for well-baby care.

Title 32, Code of Federal Regulations, Part 199 (32 CFR 199), which governs the administration of the TRICARE Program, contains certain provisions for benefit coverage.

32 CFR 199.4 (g)(15) provides:

By law, CHAMPUS can only cost-share medically necessary supplies and services. Any drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established, as described in this paragraph (g)(15), is unproved and cannot be cost-shared by CHAMPUS.

The Alpha-Stem® 100 is a microcurrent electromedical device classified as a transcutaneous electrical nerve stimulator (TENS). The device is a precision medical instrument which generates low intensity electrical currents up to 600 millionths of an ampere (600 microAmperes) in modified square waves of variable frequencies. The device was originally introduced in 1981.

In its reconsideration determination of August 12, 2008, HMHS referenced TRICARE Policy Manual, Chapter 1, Section 2.1 as its reason for denying cost-sharing. The referenced policy states that TRICARE can only cost-share medically necessary supplies and services. TRICARE regulations and program policies restrict benefits to those drugs, devices, treatments, or procedures for which the safety and efficacy have been proven to be comparable or superior to conventional therapies. Any drug, device, medical treatment, or procedure whose safety and efficacy has not been established is unproven and is excluded from coverage. There is no specific reference to the Alpha-Stem® 100 in TRICARE regulation or policy.

Matters concerning relatively new medical procedures and treatment regimens are referred to the Director, Medical Benefits and Reimbursement Branch (MB&RB), which is the TMA entity tasked with the responsibility of maintaining continuous updates on current standards of medical procedure and recommending changes to TRICARE regulation and policy where indicated by the acceptable standard of care, interpreting the regulation in light of current health care technology, and promulgating program policy interpretations which, together with the regulation, govern the administration of the TRICARE Program. The TRICARE Policy Manual constitutes the vehicle by which TRICARE officials determine what services and supplies may or may not be covered.

By position paper dated June 19, 1999, MB&RB advised:

We conducted an extensive literature search and determined that the Alpha-Stim®, a brand of TENS may be considered for cost sharing to treat acute and chronic pain when other methods of pain control have not been successful...

The position paper went on to find that the conventional medical treatment of acute pain is aimed at relieving the symptoms and not curing the underlying cause. MB&RB focused its attention to microcurrent electrical therapy (MET) for pain management:

MET works because of its ability to stimulate cellular physiology and growth. Studies also demonstrate its ability to enhance amino acid transport and protein synthesis. Correct application of MET to an injured site augments the endogenous current flow, allowing cells in the traumatized area to regain their capacitance. Resistance is reduced, allowing bioelectricity to flow through and reestablish homeostasis. This process helps initiate and perpetuate the many biochemical reactions that occur in healing...

The Alpha-Stim® uses microcurrent electrical therapy (MET) for those suffering from chronic or acute pain. It is a brand of transcutaneous electrical nerve stimulator and is classified as a combination TENS and Cranial Electrical Stimulation (CES). The current is applied by easy-to-use self-adhesive electrodes or hand held probes. Absolute contraindications have not been established.

MB&RB acknowledged that the Alpha-Stim® 100 is the equivalent to the Alpha-Stim® 350 and the Alpha-Stim® CS that were cleared for marketing by the United States Food and Drug Administration (FDA) for long term relief of acute and chronic pain and acceleration of the healing process in 1983, 1988, 1989, and 1992. MB&RB found that the Alpha-Stim® 100 may be used for acute or chronic head pain, pain in upper extremities, back pain, pain in lower extremities, pain in the face, and pain of auricular points as well as other conditions. There are no significant adverse side effects to therapeutic electrical-medical technology, according to MB&RB.

With receipt of this appeal case, MB&RB was once again contacted with regard to its position regarding authorization of the Alpha-Stim® 100. On December 3, 2008, MB&RB referenced its June 18, 1999, position paper advising that nothing has changed since its last review. MB&RB also advised that on August 11, 2005, it issued a similar position paper regarding the BioniCare® TEN stimulation device. In that memorandum, MB&RB advised:

Based on the above conclusions, we do not share the same opinion as the contractor. We believe that the BIO-1000 System, as transcutaneous electrical nerve stimulation that blocks pain through electrodes applied to the skin, requested by the beneficiary, does meet the DME requirements.

The beneficiary has established that other methods of pain control have not been successful. MB&RB has found that the Alpha-Stim® 100 is no longer considered to be unproven and can therefore be cost-shared in this case.

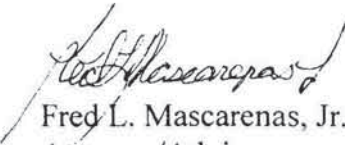
FORMAL REVIEW DECISION

For the reasons noted herein, it is determined that the beneficiary meets TRICARE coverage criterion for cost-sharing the Alpha-Stim® 100 in this case.

APPEAL RIGHTS

Because this decision finds in favor of the beneficiary, further appeal is not afforded.

Submitted by:



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