



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

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Coverage Policy Number 0256

Subject **BioniCare® Bio System™**

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Hyperlink to Related Coverage Policies

Electrical Stimulators

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2008 CIGNA

Coverage Policy

CIGNA does not cover pulsed electrical stimulation devices (i.e., BioniCare® Bio-1000™ System) for any indication because they are considered experimental, investigational or unproven.

General Background

Osteoarthritis (OA) is the most prevalent form of arthritis, affecting over 21 million people in the United States. It is defined as a deterioration of the cartilage that covers the ends of the bones in the joints, causing pain and decreased mobility. It generally affects women more than men and usually those over the age of 45.

Rheumatoid arthritis (RA), which affects over 2.1 million people in the United States, is an autoimmune disease which causes inflammation of the joints. It, too, results in pain and decreased mobility and is the most serious and debilitating type of arthritis, occurring most frequently in women (Arthritis Foundation, 2005).

The goals of treatment for OA and RA are decreased pain and joint damage and improved function. Standard treatments include: diet, medication, physical and/or occupational therapy, and/or surgery (Arthritis Foundation, 2005). Recently, there has been an increased interest in alternative treatments such as pulsed electrical stimulation (PES).

The BioniCare® Bio-1000™ System (BioniCare Medical Technologies, Inc., Sparks, MD) is a noninvasive device that delivers low-amplitude pulsed electrical stimulation intended to reduce the level of pain and symptoms

associated with OA of the knee and RA of the hand. Proponents theorize that pulsed electrical stimulation can facilitate bone formation and cartilage repair and alter inflammatory cell function (Hayes, 2005). There is currently insufficient evidence to prove this theory or the BioniCare system's efficacy.

The system has three major components:

1. a signal generator (a nine-volt, battery-powered unit that provides the therapeutic electrical signal)
2. a signal applicator, designed to fit the treatment site and the individual, that wraps the joint and holds the contact elements
3. snap-in, replaceable contact elements

The contact elements are placed over the affected area and held in place with the applicator. Small electrical currents are then delivered. The device is usually worn 6–10 hours a day, most often done while the patient is sleeping.

U.S. Food and Drug Administration (FDA)

The U. S. Food and Drug Administration (FDA) (2003) approved the BioniCare Bio-1000 System as substantially equivalent (510K) to a predicate transcutaneous electrical nerve stimulator (TENS) class II device (i.e., the term "predicate device" refers to an FDA-approved device to which equivalence is drawn). The BioniCare System, Model Bio-1000 has been approved by the FDA for use as an adjunctive therapy in reducing the level of pain and symptoms associated with OA of the knee and for overall improvement of the knee as assessed by the physician's global evaluation. In 2005, the device was also approved by the FDA as an adjunctive therapy in reducing the level of pain and stiffness associated with rheumatoid arthritis of the hand (FDA, 2005). In June 2006, in response to BioniCare's request for a clarification of classification for the BioniCare Bio-1000 System, the FDA reclassified the BioniCare System as a "transcutaneous electrical stimulator for arthritis" from the previous classification as a TENS device that was based on a similar safety profile (BioniCare, 2006).

Literature Review

Garland et al. (2007) conducted a randomized, double-blind, controlled study to evaluate the clinical effectiveness of the Bio-1000 device in patients with knee OA. A total of 58 patients with moderate to severe knee OA were included in the study. Primary outcome measures included: (1) the percent change from baseline on a 0–100 visual analog scale (VAS) measuring patient global evaluation of arthritis symptoms in the treated knee, (2) the percent change from baseline of pain and other symptoms, and (3) the percent change from baseline on the Western Ontario and McMaster Universities (WOMAC) pain, stiffness, and function subscales. Patients were randomly assigned an active (n=39) or placebo (n=19) device in a 2:1 active to placebo ratio. All differences in each of the five categories favored the active group over the placebo group. According to the study, based on the percentage of patients in each treatment group who experienced 50% or greater improvement in each primary outcome, three of five primary outcome measures showed a statistically significant difference. The exceptions were WOMAC stiffness (p=0.08) and function (p=0.14). This study suggests that the use of pulsed electrical stimulation in the treatment of patients with knee OA may improve symptoms when compared to placebo. This study is limited by the small sample size.

Farr et al. (2006) conducted an open-label, prospective investigation of efficacy and safety of pulsed electrical stimulation in 288 patients who had failure, contraindication or intolerance to other nonsurgical modalities for OA. Primary outcome measures included patient and physician global evaluation and patient assessment of knee pain. Outcomes were measured using a five-point Likert scale (1 = no symptoms; 5 = very severe symptoms). The authors reported significant improvement in all efficacy variables (p<0.001) and that effect sizes were larger in patients who used the device for more than 750 hours versus those who used it for shorter periods (p<0.001). In a subgroup of 86 patients who recorded daily nonsteroidal anti-inflammatory drug (NSAID) use at baseline and during treatment, a reduction in NSAID use was reported. Thirty-nine of 86 (45.3%) reduced their NSAID use by 50% or more, and 16 of the 86 (18.6%) discontinued NSAIDs entirely. The most common adverse event was a transient rash. This study suggested that pulsed electrical stimulation may improve symptoms in some patients with OA who have failed other nonsurgical treatment modalities. This study is limited by lack of randomization, blinding, and control.

Mont et al. (2006) conducted a prospective, four-year, open-label, multicenter study to examine whether pulsed electrical stimulation enabled patients with osteoarthritis of the knee to defer surgery. Twenty-three centers recruited 157 patients with moderate-to-severe knee osteoarthritis between 1993 and 1997. All patients had

received a recommendation for total knee arthroplasty (TKA). Entry criteria included that knee pain was aggravated with activity and relieved by rest and of moderate (4–7) or severe (>7) intensity on a 10-point visual analog scale. The primary outcome was time elapsed from time of study to TKA. Of the 157 patients, 131 (83%) treated with pulsed electrical stimulation deferred TKA for the first year, 75% for two years, 65% for three years, and 60% for four years. This data was compared to an historical, matching control group in which 67%, 51%, 46%, and 35% deferred TKA for 1–4 years, respectively. The control group consisted of 101 OA patients treated with TKA between 1980 and 1983 and followed for five years or longer or until TKA was performed on the second knee. The difference between the treatment group and the control group was statistically significant ($p=.0011$). The authors reported there was no significant difference in the use of NSAIDs or analgesics between the two groups ($p<.05$). A hidden timer measured compliance with the device. The mean daily treatment time was 5.9 ± 2.7 hours for the treatment group and 5.7 ± 2.7 hours for the control group. The data suggests that the use of pulsed electrical stimulation may allow deferral of TKA in some patients with OA. This study is limited, however, by its lack of blinding, randomization and the use of an historical control group.

Hulme et al. (2003) conducted a Cochrane review to evaluate the effectiveness of pulsed electrical stimulation on improving outcomes for patients with osteoarthritis (OA) of the knee. Only three studies were included in the review for a total of 259 OA patients. Although the review suggested that the small- to-moderate effect on outcomes was statistically significant, further, large-scale studies to confirm whether these results confer to clinically important benefits are necessary.

Pelland et al. (2002) conducted a Cochrane review to determine the effectiveness of electrical stimulation (ES) for improving muscle strength and function in RA patients. All trials and studies comparing ES to placebo or another active intervention in RA patients were selected. Only one randomized controlled trial (RCT) met inclusion criteria. This trial compared the effect of ES protocols to hand function. The results demonstrated that ES was beneficial in terms of muscle strength and fatigue resistance of the first dorsal interosseous when compared to the no-treatment group. The authors concluded that although there was a beneficial effect of ES, the conclusion is limited by small sample size and the low methodological quality of the trial, thus substantiating the need for more well-designed studies to provide further evidence of the efficacy of ES in the treatment of RA.

Zizic et al. (1995) conducted a multicenter, double-blind, randomized trial to evaluate the safety and effectiveness of pulsed electrical stimulation devices. Seventy-eight patients were treated with skin-surface electrodes; 41 patients used an active device, while 37 (the placebo group) used an inactive device. All patients had chronic OA of the knee. The study measured three primary efficacy variables:

1. physician's global evaluation of the function of the treated knee
2. patients' evaluation of the pain of the affected knee
3. patients' evaluation of the function of the affected knee

The authors determined that intermittent, pulsed electrical stimulation, delivered at night for four weeks, provided short-term improvement in knee pain, function, flexion and duration of morning stiffness for patients with OA of the knee. This study has a small sample size, subjectively determined outcome and lack of long-term outcome.

Summary

There is insufficient evidence in the published, peer-reviewed scientific literature to support the efficacy of the BioniCare pulsed electrical device.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
	No specific codes

HCPCS Codes	Description
E0762	Transcutaneous electrical joint stimulation device system, includes all accessories

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

***Current Procedural Terminology (CPT®) ©2007 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	12/15/2007	0256	BioniCare® Bio System™
Great-West Healthcare	1/23/2008	06.334.02	Pulsed electrical Stimulation (PES) for Osteoarthritis of the Knee (BioniCare)

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.