



## Corporate Medical Policy

### BioniCare Stimulator

**File Name:** bionicare\_stimulator  
**Policy Number:** DME0015  
**Origination:** 11/2004  
**Last Review:** 3/2009

**Active policy, no longer scheduled for routine literature review.**

#### Description of Procedure or Service

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Electrical stimulation has been used to improve functional status and relieve pain related to osteoarthritis and rheumatoid arthritis unresponsive to other standard therapies. Electrical stimulation is provided by a non-invasive electronic device that delivers a low voltage, monophasic electrical field to the target site of pain.

The BioniCare® BIO-1000 stimulator has been FDA cleared for marketing as a type of transcutaneous electrical nerve stimulation (TENS) device for use in osteoarthritis of the knee and rheumatoid arthritis of the hand. The BioniCare® system consists of an electronic stimulator device with electrical leads that are placed over the affected area and held in place with a lightweight, flexible wrap and velcro fasteners. The battery-powered device delivers small electrical currents of 0.0 to 12.0 volt output. It is recommended that the device be worn for at least 6 hours per day. Patients are reported to often wear the device while sleeping.

The BioniCare® stimulator device is contraindicated in patients with demand-type pacemakers and may interfere with other electronic devices.

Note: TENS (Transcutaneous Electrical Nerve Stimulator) is addressed in policy SUR6770 and Interferential Stimulation is addressed in policy DME 0155

#### Policy

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**Active policy, no longer scheduled for routine review.**

**BCBSNC does not provide coverage for the BioniCare® Stimulator device. It is considered investigational. BCBSNC does not provide coverage for investigational services.**

#### Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

#### When BioniCare Stimulators are covered

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Not applicable.

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## Policy: BioniCare Stimulator

### When BioniCare Stimulators are not covered

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BCBSNC does not provide coverage for the BioniCare® Stimulator device. It is considered investigational. BCBSNC does not provide coverage for investigational services.

### Policy Guidelines

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A review of the literature has not found adequate evidence to indicate the use of electrical/electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes. Only one published study on the use the BioniCare® Stimulator device for osteoarthritis of the knee has been identified. No published studies for rheumatoid arthritis were identified.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: E0762*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Scientific Background and Reference Sources

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BCBSA TEC Assessment [Electronic Version]. January 1997.

ECRI Hotline Response, 5/25/2004. Pulsed electrical stimulation for treatment of OA of the knee. Retrieved on September 27, 2004 from [http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc\\_id=7846&q=oa+of+knee+electrical+stimulation&anm](http://www.ta.ecri.org/Hotline/Prod/summary/detail.aspx?doc_id=7846&q=oa+of+knee+electrical+stimulation&anm).

BCBSA TEC Medical Policy Clearinghouse News [Electronic Version]. October 15, 2004.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.09, 11/09/2004.

Pelland L, Brosseau L, Casimiro L, Robinson VA, Tugwell P, Wells G. Electrical stimulation for the treatment of rheumatoid arthritis. Cochrane Database of Systematic Reviews 2002, Issue 2. Art. No.:CD003687. DOI: 10.1002/14651858.CD003687.

U.S. Food and Drug Administration. 510(k) Summary (June 2003). BioniCare® Stimulator. Retrieved 6/12/06 from <http://www.fda.gov/cdrh/pdf3/k030332.pdf>

California Technology Assessment Forum (October 2005). Interferential Stimulation for the Treatment of Musculoskeletal Pain. Retrieved 6/12/06 from <http://www.ctaf.org/ass/viewfull.ctaf?id=65198186094>

ECRI Target Report #890 (January 2006) Transcutaneous electrical joint stimulation for knee osteoarthritis. Retrieved 6/12/06 from [http://www.target.ecri.org/summary/detail.aspx?doc\\_id=8773&anm](http://www.target.ecri.org/summary/detail.aspx?doc_id=8773&anm)

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 4/25/06.

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.27, 1/10/08.

### Policy Implementation/Update Information

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- 11/11/04 New policy issued. BioniCare® stimulators are considered investigational. References added. Notification 11/11/2004. Effective 1/20/2005.
- 4/7/05 Specialty Matched Advisory Panel [MPAG] review on 3/10/2005. No changes made to policy criteria. Reference added.
- 03/02/06 CPT code E0762 added to Billing/Coding section.
- 4/9/07 Description of electrical stimulation added for clarity. Statement in Policy Guidelines section was deleted and replaced with the following: A review of the literature has not found adequate evidence to indicate the use of electrical/electromagnetic stimulation for the treatment of arthritis will result in improvements in health outcomes. Only one published study on the use the BioniCare® Stimulator device for osteoarthritis of the knee has been identified. No published studies for rheumatoid arthritis were identified. References updated. Specialty Matched Consultant Advisory Panel review 3/15/07. No changes to policy coverage criteria. (adn)
- 12/31/07 Typo corrected. (adn)
- 4/27/09 Routine biennial review. Specialty Matched Consultant Advisory Panel review meeting 3/26/09. No changes made to policy criteria. Policy status changed to: "Active policy, no longer scheduled for routine literature review."

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.