BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: Durable Medical Equipment (DME)

ORIGINAL EFFECTIVE DATE: 01/08/14
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

ELECTRICAL STIMULATION FOR TREATMENT OF ARTHRITIS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Pulsed electrical stimulation using surface electrodes has been investigated for the treatment of arthritis. Electrical stimulation is provided by an electronic device that noninvasively delivers a sub-sensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field.

Devices include, *but are not limited to*, the BioniCare Bio-1000™ stimulator.

ELECTRICAL STIMULATION FOR TREATMENT OF ARTHRITIS (cont.)

Criteria:

- Electrical stimulation for the treatment of osteoarthritis or rheumatoid arthritis is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Resources:

Resources prior to 01/08/14 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 1.01.27 BCBS Association Medical Policy Reference Manual. Electrical Stimulation for the Treatment of Arthritis. Re-issue date 12/12/2013, issue date 04/25/2006.

FDA 510K Summary for BioniCare Bio-1000™:

- FDA-approved indication: For use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee and for overall improvement of the knee as assessed by the physician's global evaluation (clinical studies).