

Corporate Medical Policy

Electrical Bone Growth Stimulation

File Name: electrical_bone_growth_stimulation
Origination: 4/1981
Last Review: 6/2023

Description of Procedure or Service

Electrical bone growth stimulation is a medical technique to promote bone growth in difficult to heal fractures by applying a low electrical current to the fracture site. A variety of invasive and noninvasive interventions are used to treat fracture non-union including immobilization, casting, open or closed surgical reduction, pins, screw fixation, intramedullary rods and bone grafting. Bone growth stimulators, which may be non-invasive or invasive, may be used instead of, or in addition to, other interventions to promote bone healing.

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the probability of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion.

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

1. Invasive stimulation involves the surgical implantation of a cathode at the fracture site with the production of direct current (DC) electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site, but carry increased risks associated with implantable leads.
2. Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using either pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours per day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed into a back brace or directly onto the skin and are worn for 6–8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Patient compliance may be an issue with externally worn devices.
3. Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply obviating the need for a surgical procedure to remove the generator when treatment is finished.

Regulatory Status

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The following implantable device was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process in 1986: The OsteoStim® (Electro-Biology), which may also be marketed under the trade name SPF (Biomet).

The noninvasive OrthoPak® Bone Growth Stimulator (BioElectron, now Zimmer Biomet) received U.S. Food and Drug Administration (FDA) premarket approval in 1984 for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all noninvasive devices) include Physio-Stim® from Orthofix Inc., first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System® from Electrobiology, now Zimmer Biomet, which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. No distinction was made between long and short bones. The FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis. As of September 2020, under consideration is the reclassification of noninvasive electrical bone growth stimulators from Class III to the lower-risk Class II category. In 1994, the SpinaLogic Bone Growth Stimulator® (Regentek, a division of dj Orthopedics [formerly OrthoLogic]) was approved as a combined magnetic field portable device. This device is secured with a belt around the waist. In 1996, the Spinal-Stim Lite® (Orthofix) was approved as a spinal adjunct to the Physio-Stim®. The Spinal-Stim Lite® device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery. In 1999, the SpinalPak® bone growth stimulator system (Bioelectron, a subsidiary of ElectroBiology), a capacitive coupling system, was approved for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels. In 2004, the Stim® (Orthofix), a pulsed electromagnetic field system, was approved as an adjunct to cervical fusion surgery in patients at high risk for nonfusion. In 2020, the ActaStim-S Spine Fusion Stimulator (Theragen, Inc.), was approved as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. This device is secured with a belt around the waist.

No semi-invasive electrical bone growth stimulator devices with FDA approval or clearance were identified.

This policy discusses the use of bone growth stimulators on the appendicular skeleton and spine.

Related Policies:

Ultrasound Accelerated Fracture Healing Devices
Bone Morphogenetic Protein
Lumbar Spine Fusion Surgery

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Electrical Bone Growth Stimulation when it is considered medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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When Electrical Bone Growth Stimulation is covered

1. Non-invasive electrical bone growth stimulation may be considered medically necessary as treatment of fracture non-unions or congenital pseudoarthroses in the **appendicular skeleton**.

The diagnosis of fracture non-union must meet ALL of the following criteria:

- a. at least 3 months have passed since the date of the fracture;
 - b. serial radiographs for the preceding 3 month period have confirmed that no progressive signs of healing have occurred;
 - c. the fracture gap is one centimeter or less; and
 - d. the patient can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.
2. Either invasive or non-invasive methods of electrical bone growth stimulation may be considered medically necessary as an *adjunct* to **lumbar spinal fusion** surgery for patients with any of the following risk factors for subsequent failed fusion:
 - a. one or more previous failed spinal fusion(s);
 - b. grade III or worse spondylolisthesis;
 - c. fusion to be performed at more than one level;
 - d. current tobacco use;
 - e. diabetes;
 - f. renal disease;
 - g. alcoholism;
 - h. steroid use.
 3. Non-invasive electrical bone stimulation may be considered medically necessary as a treatment for patients with failed **lumbar spinal fusion**. Failed spinal fusion is defined as a spinal fusion which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial X-rays over a course of 3 months.

When Electrical Bone Growth Stimulation is not covered

1. For any conditions or medical criteria other than those cited above.
2. Investigational applications of electrical bone growth stimulation in the **appendicular skeleton** include, but are not limited to:
 - immediate post-surgical treatment;
 - treatment of fresh fractures,
 - delayed union
 - arthrodesis
 - failed arthrodesis
 - stress fractures
3. Implantable and semi-invasive electrical bone growth stimulators are considered investigational in the appendicular skeleton.

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4. Investigational applications of electrical bone growth stimulation in the **spine** include, but are not limited to:
 - Semi-invasive electrical bone growth stimulators as an adjunct to lumbar fusion and for failed lumbar fusion.
 - Invasive, semi-invasive, and noninvasive electrical stimulation as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

Policy Guidelines

Fresh Fractures:

A fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.

Delayed Union:

Delayed union is defined as a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

Nonunions:

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: “A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months.” This time frame is not based on physiologic principles, but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (ie, degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

For individuals who have fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of clinical trials. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration has approved noninvasive electrical bone growth stimulation for the indications of fracture nonunions and congenital pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their own controls. There is also evidence from two small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. However there are few nonsurgical options in this population, and the pre-post studies of patients with nonhealing fractures support the efficacy of the treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have delayed fracture union who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. RCTs on the delayed union of fractures were limited by small sample sizes and did not show a significant difference in outcomes between study groups. The evidence is insufficient to determine that the technology results in an improvement

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in the net health outcome.

For individuals who have fresh fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of five RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have stress fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This well-conducted RCT found that, although an increase in the hours of use per day was associated with a reduction in the time to healing, there was no difference in the rate of healing between treatment and placebo. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes two small RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Although the results of one trial suggest benefits to the bone stimulation in decreased time to union, clinical outcomes were not assessed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive electrical bone growth stimulation, the evidence includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are at high risk of lumbar spinal fusion surgery failure who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews, a TEC Assessment, and RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials indicate that in patients with risk factors for failed fusion surgery, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have failed lumbar spinal fusion surgery who receive noninvasive electrical bone growth stimulation, the evidence includes a TEC Assessment and studies where patients served as their own controls. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Data indicate that noninvasive electrical stimulation improves the fusion rate in this population. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who are undergoing cervical spinal fusion surgery or who have failed cervical spine fusion who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The only controlled trial published to date had methodologic limitations and the efficacy of electrical stimulation in the cervical spine has not been established. An open-label multicenter cohort study provided evidence to demonstrate that patients at high risk for arthrodesis following anterior cervical discectomy and fusion procedures reported statistically significant improvements in fusion rates with pulsed electromagnetic field stimulation. However, limitations in the study design, including use of a historical control group, lack of blinding, and no restrictions on surgical methods used by surgeons, preclude definitive assessments of treatment efficacy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

NOTE: Patients with implanted electronic devices should consult their physician before using these electrical bone growth stimulation devices.

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Billing/Coding/Physician Documentation Information

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. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 20974, 20975, E0747, E0748, E0749

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

Consultant Review - 8/94

BCBSA Medical Policy Reference Manual - 12/95

FDA Approval letter dated 6/12/98

BCBSA Medical Policy Reference Manual - 9/23/98

Consultant Review - 3/99

Medical Policy Advisory Group - 5/99

Specialty Matched Consultant Advisory Panel - 11/1999

Medical Policy Advisory Group - 12/2/1999

Specialty Matched Consultant Advisory Panel - 8/2001

BCBSA Medical Policy Reference Manual - 12/18/2002; 7.01.07

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 12/17/03

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 02/25/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 3/07/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 3/15/05

Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion Fractures (September 2005). Retrieved 2/16/07 from <http://www.cms.hhs.gov/coverage/download/id30M.pdf>

Centers for Medicare and Medicaid Services. NCD for Osteogenic Stimulators, Manual Section Number 150.2. Retrieved 2/19/07 from

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 8/14/08

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 9/16/10

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 9/16/10

Griffin XL, Costa ML, Parsons N, Smith N. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. *Cochrane Database of Systematic Reviews* 2011, Abstract. Retrieved on June 20, 2011 from <http://onlinelibrary.wiley.com/doi/10.1002/clsyst.1933>

Specialty Matched Consultant Advisory Panel review 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 9/1/11

Specialty Matched Consultant Advisory Panel review 7/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 9/13/12

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 10/11/12

Medical Director review 10/2012

Specialty Matched Consultant Advisory Panel review 7/2013

Medical Director review 7/2013

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 10/10/13

Shi HF, Xiong J, Chen YX et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. *BMC Musculoskelet Disord* 2013; 14:35. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3556314/>

Beck BR, Matheson GO, Bergman G et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. *Am J Sports Med* 2008; 36(3):545-53.

Patel DS, Roth M, Kapil N. Stress fractures: diagnosis, treatment, and prevention. *Am Fam Physician*. 2011 Jan 1;83(1):39-46. <http://www.aafp.org/afp/2011/0101/p39.html>

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 1/9/14

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Medical Director review 7/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 10/9/14

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 12/11/14

Specialty Matched Consultant Advisory Panel review 6/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 4/14/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 4/14/2016

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 4/13/2017

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 4/12/2018

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 4/8/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 4/8/2019

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Medical Director Review 6/2023

Policy Implementation/Update Information

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- 4/81 Original Policy
- 11/81 Reaffirmed
- 12/83 Reaffirmed
- 5/99 Medical Policy Advisory Group
- 7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 2/01 System coding changes.
- 6/01 Removed "The presence of iron-containing internal fixation devices in the area to be stimulated." from When Electrical Bone Growth Stimulation is Not Covered section of the policy. Coding format change. E0760 removed from coding.
- 10/01 Specialty Matched Consultant Advisory Panel - 8/01. No changes.
- 5/03 Specialty Matched Consultant Advisory Panel review. Revised under "when it is covered" section, number 1.b., changed the term "non-progressive" to "no progressive". Code E0760 removed from the Billing/Coding section.
- 3/04 Benefits Application and Billing/Coding sections updated for consistency.
- 8/26/04 Code descriptions removed. References added. Definition for non-union corrected in Medical Terms and definition for delayed union added.
- 6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to the policy statement. SUR6240 added as key word.
- 6/18/07 Routine biennial review. Information added to Description for clarity. Specialty Matched Consultant Advisory Panel review 5/18/07. No changes to policy coverage criteria. (adn)
- 7/20/09 Routine biennial review. Specialty Matched Consultant Advisory Panel review 5/21/09. No change to policy statement. (adn)
- 8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Removed Medical Policy number. Updated references. Updated the "Policy Guidelines" section. Existing medically necessary policy statements modified by adding lumbar (spine) to the statements. Steroid use added as another high-risk condition for non-fusion. Added the following criteria to "When Not Covered" section: "3. Implantable and semi-invasive electrical bone growth stimulators are considered investigational. 4. Invasive, semi-invasive, and noninvasive electrical stimulation are considered investigational as an adjunct to cervical fusion surgery and for failed cervical spine fusion." (mco)
- 8/16/11 Description section updated. References updated. Specialty Matched Consultant Advisory Panel review 7/2011. No changes to policy statements. (mco)
- 11/8/11 References updated. No changes to Policy Statements. (mco)
- 8/7/12 Specialty Matched Consultant Advisory Panel review 7/2012. No changes to Policy Statements. (mco)
- 11/27/12 Added related policy to Description section. Revised the following statement in the "When not Covered" section: "2. Investigational applications of electrical bone growth stimulation in the

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appendicular skeleton include, but are not limited to, immediate post-surgical treatment., and treatment of fresh fractures, delayed union or failed arthrodesis. Delayed union is defined as a decelerating fracture healing process, as identified by serial x-rays. 3. Semi-invasive electrical bone growth stimulators are considered investigational as an adjunct to lumbar fusion and for failed lumbar fusion.” References updated. Medical Director review. Policy noticed on 11/27/12 for effective date 2/26/13. (mco)

7/30/13 Specialty Matched Consultant Advisory Panel review 7/2013. Medical Director review 7/2013. No changes to Policy Statements. (mco)

11/26/13 References updated. No changes to Policy Statements. (mco)

2/25/14 Description section updated. Policy Guidelines and References updated. Use of electrical bone growth stimulation for stress fractures and arthrodesis added to “When not Covered” section. “When Covered” section updated to include the following criterion: “The patient can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.” Medical Director review 2/2014. Policy noticed on 2/25/14 for effective date 4/29/14. (mco)

8/12/14 Specialty Matched Consultant Advisory Panel review 7/2014. Medical Director review 7/2014. No changes to Policy Statements. (mco)

1/27/15 Reference added. Related policies added. (sk)

2/24/15 Reference added. (sk)

7/28/15 Specialty Matched Consultant Advisory Panel review 6/24/2015. (sk)

5/31/16 References added. Policy Guidelines updated. (sk)

7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. (sk)

7/28/17 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/28/2017. (sk)

7/13/18 References added. Policy Guidelines updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 6/27/2018. (sk)

9/10/19 References added. Specialty Matched Consultant Advisory Panel review 7/30/2019. Contradictory statement “Invasive methods of bone growth stimulation may be considered medically necessary when used as an adjunct to surgical treatment of non-union of major long bone fractures” removed from When Covered section of policy. (sk)

6/30/20 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/17/2020. (sk)

3/8/22 References added. Specialty Matched Consultant Advisory Panel review 6/16/2021. (sk)

7/26/22 Description section updated. Regulatory Status updated. Specialty Matched Consultant Advisory Panel review 6/29/2022. (sk)

8/1/23 Reference added. Minimal edits to Policy Guidelines to include updated definition of nonunion. Specialty Match Consultant Advisory Panel review 6/2023. (rp)

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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.