

### Clinical Policy: Osteogenic Stimulation

Reference Number: LA.CP.MP.194

Date of Last Revision: 08/24

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

#### **Description**

Electrical osteogenic stimulation can be performed invasively or non-invasively. Invasive osteogenic stimulators provide electrical stimulation directly to the non-healing fracture or bone fusion site through percutaneously placed cathodes or by implantation of a coiled cathode wire. Noninvasive osteogenic stimulators deliver an electrical current to the fracture site via capacitive coupling (CC), pulsed electromagnetic field (PEMF), or combined magnetic field technology (CMFT) through treatment coils that are placed externally around the fracture. An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing.

This policy outlines the medical necessity criteria for electrical and ultrasonic osteogenic stimulators to enhance the bone healing process.

#### Policy/Criteria

- **I.** It is the policy of Louisiana Healthcare Connections that *noninvasive electrical osteogenesis stimulators* are **medically necessary** when any of the following apply:
  - A. Nonunion of long bone fracture (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, phalanges, metacarpal or metatarsal bone) and at least 90 days have passed since the date of fracture or the date of surgical treatment of the fracture and all of the following:
    - 1. The bone is not infected:
    - 2. The two portions of the bone involved in the non-union are separated by less than one centimeter (cm);
    - 3. The bone is stable at both ends by means of appropriate fracture care and immobilization;
    - 4. Serial imaging has confirmed that fracture healing has ceased for three or more months prior to starting treatment with the noninvasive electrical bone growth stimulator. Serial imaging must include a minimum of two sets of images, each including multiple views of the fracture site, separated by a minimum of 90 days;
  - B. Failed fusion of a joint, other than the spine, in which a minimum of six months has elapsed since the last surgery;
  - C. Congenital pseudoarthrosis;
  - D. As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed fusion surgery or for those undergoing a multilevel spinal fusion (involving three or more vertebrae);
  - E. Risk of delayed or non-union of fractures due to the following conditions or comorbidities (list may not be all inclusive):
    - 1. Alcoholism;
    - 2. Chemotherapy;
    - 3. Diabetes:



- 4. Obesity;
- 5. Osteoporosis;
- 6. Renal disease:
- 7. Tobacco use;
- 8. Steroid use.
- **II.** It is the policy of Louisiana Healthcare Connections that *invasive electrical osteogenesis stimulators* are **medically necessary** when any of the following apply:
  - A. Nonunion of long bone fracture and all of the following:
    - 1. The bone is not infected;
    - 2. The two portions of the bone involved in the non-union are separated by less than one cm;
    - 3. The bone is stable at both ends by means of appropriate fracture care and immobilization;
    - 4. Serial imaging has confirmed that fracture healing has ceased for three or more months prior to starting treatment with the invasive bone growth stimulator. Serial imaging must include a minimum of two sets of images, each including multiple views of the fracture site, separated by a minimum of 90 days;
  - B. Failed spinal fusion in which a minimum of nine months has elapsed since the last surgery and/or as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis;
  - C. Following a multilevel spinal fusion (involving three or more vertebrae);
  - D. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site;
  - E. Risk of delayed or non-union of fractures due to the following conditions or comorbidities (list may not be all inclusive):
    - 1. Alcoholism;
    - 2. Chemotherapy;
    - 3. Diabetes;
    - 4. Obesity:
    - 5. Osteoporosis;
    - 6. Renal disease;
    - 7. Tobacco use;
    - 8. Steroid use.
- **III.** It is the policy of Louisiana Healthcare Connections that *ultrasonic osteogenesis stimulators* are **medically necessary** when any of the following apply:
  - A. Used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh, closed fractures when there is high risk for delayed fracture healing or nonunion and at least one of the following risk factors exist:
    - 1. Fracture associated with extensive soft tissue or vascular damage;
    - 2. Fresh (seven days or less in duration), closed or grade I open, short oblique or short spiral tibial diaphyseal fractures treated with closed reduction and cast immobilization in skeletally mature patients;
    - 3. Fresh, closed fractures of the distal radius (Colles' fracture) treated with closed reduction and cast immobilization in skeletally mature patients;



- 4. Fresh Jones fracture (5th metatarsal);
- 5. Fresh fractures of the scaphoid;
- 6. Nonunion of bones other than the skull or vertebrae in skeletally mature patients, and excluding those that are related to malignancy when the following are met:
  - a. Documented by a minimum of two sets of imaging obtained prior to starting treatment, separated by a minimum of 90 days;
  - b. The two portions of the bone involved in the non-union are separated by less than one cm.
- B. Risk of delayed or nonunion of any fresh, closed fractures due to the following conditions or comorbidities (list may not be all inclusive):
  - 1. Alcoholism:
  - 2. Chemotherapy;
  - 3. Diabetes;
  - 4. Obesity;
  - 5. Osteoporosis;
  - 6. Renal disease;
  - 7. Tobacco use:
  - 8. Steroid use.
- **IV.** It is the policy of Louisiana Healthcare Connections that *ultrasonic osteogenesis stimulators* are **not medically necessary** for the following indications:
  - A. Used with other noninvasive osteogenic stimulators;
  - B. Avascular necrosis of the femoral head;
  - C. Stress fractures;
  - D. Fractures in which the gap exceeds one cm;
  - E. Fresh fractures in locations other than distal radius, tibial diaphysis, 5th metatarsal (Jones fracture only) or scaphoid;
  - F. Fresh tibial diaphyseal or tibial and fibular fractures treated with closed reduction and intramedullary nailing and no risk factors for poor or prolonged healing;
  - G. Preoperative use for fractures that require surgical intervention, or internal or external fixation (i.e., use of ultrasonic bone growth stimulators for fractures in the preoperative period would not be medically necessary);
  - H. Tibial stress fractures.
- V. It is the policy of Lousiana Healthcare Connections that osteogenic devices are not medically necessary for nonunion fractures of the skull, vertebrae, or those that are tumorrelated.

#### **Background**

Of the estimated 7.9 million fractures that occur annually in the United States, approximately five to 10 percent will demonstrate signs of delayed or impaired healing.<sup>3</sup> The healing of a bone fracture is a complex process that can be influenced by many factors. Standard management of fractures include stabilization of the fracture site with internal or external fixation devices, compression devices, and/or casting. In some cases, insufficient blood supply, inadequate immobilization at the fracture site, too much space between ends of the fracture, infection, bonetissue loss, poor nutrition, osteoporosis, or metabolic dysfunctions can interfere with normal



healing and result in delayed union or nonunion of the fracture. Diagnosis of fracture nonunion is based on clinical findings of motion, pain, and tenderness at the fracture site and on findings from radiography, fluoroscopy, intraosseous venography, or bone scintigraphy. Treatment of nonunion generally consists of further or enhanced stabilization of the fracture site and the induction of osteogenesis. Stabilization is achieved with a cast or with internal or external fixation devices in order to realign and closely approximate fracture fragments, and bone grafts may be used to induce osteogenesis. Other methods available are those that are designed to stimulate bone growth, such as electrical or low-intensity pulsed ultrasound (LIPUS) therapy.<sup>4,5</sup>

#### Ultrasonic (US) Osteogenic Stimulation

In LIPUS technology, mechanical energy is transmitted into the body as high-frequency acoustic pressure waves that apply micromechanical stresses and strain to the bone and surrounding tissues. While the exact mechanisms are unclear, LIPUS causes biochemical changes at the cellular level that promote and accelerate bone formation, and thus, fracture healing. LIPUS therapy is used in conjunction with the stabilization of fresh fractures or as secondary therapy for nonunions that remain unhealed after surgery and other therapies. The patient uses the LIPUS device, which is prescribed by a physician, at home for 20 minutes once daily until healing occurs. <sup>5,6,7</sup>

LIPUS therapy safely and effectively enhances the fracture healing process at the cellular, radiological, and clinical level. At-home use of the LIPUS device accelerates fracture healing when used in conjunction with closed reduction and cast immobilization for the treatment of selected patients with fresh fractures of the tibia or radius that are treated within seven days post fracture. There is insufficient evidence to conclude that LIPUS therapy is useful for any other type of fresh fracture. Figure 1.5 LIPUS improved quality of life when compared to placebo for treatment of fresh fractures, in addition to providing a shorter period of immobilization, a more expedient return to normal activities, avoidance of the need for additional treatments, and reduced healthcare and related costs. These positive effects are most pronounced in patients with a higher risk of delayed healing or nonunion, such as smokers, older patients, or those with certain comorbidities. 5,6

LIPUS therapy also promotes fracture healing in patients with nonunions with a fracture age of greater than nine months and in those with delayed unions with a fracture age of three to nine months in whom healing has ceased or is not progressing.<sup>7,9</sup> While there are some differences in healing rates among types of bones, the overall healing rates in patients with previously unhealed and poorly healing fractures were 85 to 100%, respectively. LIPUS therapy promotes healing in complicated cases, such as those with metal implants or with fractures greater than three years old.<sup>10</sup>

#### Electrical Osteogenic Stimulation

The clinical use of electrical stimulation for inducing osteogenesis at bone fracture and bone fusion sites began in the early 1970s. While the precise mechanism by which electrical energy may promote bone healing is not known, it is known that electrical potentials are produced in bone that is actively involved in the formation of new bone. Electrical bone growth stimulators fall into one of three categories: invasive, semi-invasive, or noninvasive. Invasive and semi-invasive devices, also called implantable electrical stimulators, utilize direct current that is



delivered directly to the fracture site via implanted electrodes. Noninvasive systems utilize treatment coils situated externally around the fracture and an external power supply. Noninvasive bone growth stimulators deliver electrical current to the fracture site via capacitive coupling (CC), pulsed electromagnetic field (PEMF), or combined electromagnetic field (CEMF) technology. 1,2,11

Available evidence from an FDA literary review confirms expected benefits of PEMF and CEMF devices; however, variation in methodology, such as differences in devices used, anatomic location, treatment waveform and frequency, and patient population, likely account for the effectiveness range of 32.8% to 97.4%. Noninvasive electrical bone growth stimulation, particularly when delivered via PEMF, can stimulate healing of long bone fracture nonunion. A single arm prospective study findings demonstrated a 77.3% fusion rate in the tibia via PEMF. Additional randomized control studies resulted in an 83.6% fusion rate in the treatment group compared to a 68.6% fusion rate in the control group. However, due to lack of sufficient data, no definitive conclusions can be drawn regarding the efficacy of noninvasive electrical stimulation for nonunions of appendicular bones other than long bones. 11 There is limited evidence to support the effectiveness of electromagnetic bone stimulation to treat atypical or stress fractures that would otherwise require surgery. 4 There is also some evidence to support the efficacy of noninvasive electrical stimulation as an adjunct to surgery for spinal fusion, however, the evidence is less consistent. One retrospective study of spinal fusion rates via PEMF showed a 73.2% fusion rate in the cervical spine at 6 months. <sup>1,11</sup> A preliminary observational study designed to investigate the role of CC to treat vertebral edema in acute vertebral compression fractures demonstrated improvement in symptoms, faster fracture healing and complete resolution of the vertebral edema. 12 A critical analysis of eleven studies using CC notes high level of evidence for its effectiveness for treating nonunion fractures. Although electrical stimulation demonstrates promise in promoting bone healing, better-designed clinical studies are needed for optimal application in clinical practice. 13 A recent small study of 29 patients with confirmed nonunion fractures evaluated union rates and times following CEMF treatment. Findings demonstrated an overall success rate of 84% with an average union time of 6.62 months. Additional studies need to be conducted to confirm efficacy conclusively. <sup>14</sup> In one of the first studies to compare PEMF and CEMF treatment following spinal fusion in a group of 60 patients, CEMF was superior to PEMF, even though, the addition of the bone growth stimulators did not improve fusion outcomes.<sup>15</sup>

Implantable electrical bone growth stimulators are FDA-approved for the treatment of nonunion of long bone fractures and as an adjunct to spinal fusion in patients at high-risk of pseudarthrosis due to previously failed spinal fusion at the same site or who require multilevel fusion.<sup>2</sup>

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources



of professional coding guidance prior to the submission of claims for reimbursement of covered services.

NOTE: Coverage is subject to each requested code's inclusion on the corresponding LDH fee schedule. Non-covered codes are denoted (\*) and are reviewed for Medical Necessity for members under 21 years of age on a per case basis.

CPT®* Codes	Description
20974*	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS ®* Codes	Description
A4559*	Coupling gel or paste, for use with ultrasound device, per oz.
E0747	Osteogenesis stimulator; electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator; electrical, noninvasive, spinal applications
E0749*	Osteogenesis stimulator; electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

Reviews, Revisions, and Approvals		Approval Date	Effective Date
Converted Corporate to local policy		4/10/22	
Annual review completed. Added "electrical" to I. and II.		1/14/23	
Replaced "smoking habit" with "tobacco use" in criteria I.E.7.,			
II.E.7., and III.B.7. Removed criteria point III.6.c. "The patient			
has failed more than one surgery and other medical therapies			
(e.g. immobilization and non-weight bearing status)".			
Background updated and minor rewording with no clinical			
significance. References reviewed and updated. Specialist			
reviewed.			
Annual review completed. Background and references		11/27/23	
reviewed and updated. Note for non-covered codes added.			
Annual review. Updated Criteria I.A.3. to state, "appropriate		10/23/24	11/22/24
fracture care and immobilization." Updated language in			
Criteria I.A.4. from radiographs to imaging. Updated Criteria			
II.A.3. to state, "appropriate fracture care and immobilization."			
Updated language in Criteria II.A.4. from radiographs to			
imaging. Updated language in Criteria III.A.6.a. from			
radiographs to imaging. Background updated with no impact			
on criteria. References reviewed and updated. Reviewed by			
external specialist.			



#### References

- 1. Evidence analysis research brief. Noninvasive electrical bone growth stimulation for cervical spinal fusion. Hayes. <a href="https://www.hayesinc.com">www.hayesinc.com</a>. Published June 12, 2023. Accessed June 26, 2024.
- 2. National coverage determination: osteogenic stimulators (150.2). Centers for Medicare and Medicaid Services Web site. <a href="http://www.cms.hhs.gov/mcd/search.asp">http://www.cms.hhs.gov/mcd/search.asp</a>. Published April 27, 2005. Accessed June 21, 2024.
- 3. Buza JA 3rd, Einhorn T. Bone healing in 2016. *Clin Cases Miner Bone Metab*. 2016;13(2):101 to 105. doi:10.11138/ccmbm/2016.13.2.101 Buza JA 3rd, Einhorn T. Bone healing in 2016. *Clin Cases Miner Bone Metab*. 2016;13(2):101-105. doi:10.11138/ccmbm/2016.13.2.101
- 4. American Academy of Orthopaedic Surgeons. Nonunions. <a href="https://orthoinfo.aaos.org/en/diseases--conditions/nonunions/">https://orthoinfo.aaos.org/en/diseases--conditions/nonunions/</a>. Published March 2014. Accessed June 25, 2024.
- 5. Evidence analysis research brief. Ultrasound bone growth stimulation for foot and ankle nonunion or delayed union fractures. Hayes. <a href="www.hayesinc.com">www.hayesinc.com</a>. Published February 04, 2022. Accessed June 21, 2024.
- 6. National Institute for Health and Care Excellence (NICE). Low-intensity pulsed ultrasound to promote healing of fresh fractures at low risk of non-healing. Interventional procedures guidance [IPG621]. <a href="https://www.nice.org.uk/guidance/ipg621/evidence/overview-pdf-4908164509">https://www.nice.org.uk/guidance/ipg621/evidence/overview-pdf-4908164509</a>. Published July 31, 2018. Accessed June 24, 2024.
- 7. Rashid MS, Tourné Y, Teoh KH. The use of low intensity pulsed ultrasound in the foot and ankle. *EFORT Open Rev.* 2021;6(4):217 to 224. Published 2021 Apr 1. doi:10.1302/2058-5241.6.200045 Rashid MS, Tourné Y, Teoh KH. The use of low intensity pulsed ultrasound in the foot and ankle. *EFORT Open Rev.* 2021;6(4):217-224. Published 2021 Apr 1. doi:10.1302/2058-5241.6.200045
- 8. Low intensity ultrasound treatment for acceleration of bone fracture healing Exogen<sup>™</sup> bone growth stimulator. Exogen. MSAC application 1030.

  <a href="http://www.msac.gov.au/internet/msac/publishing.nsf/Content/74AD57FC3C7B2372CA25801000123B50/\$File/1030-Exogen-bone-growth-stimulator-Assessment-Report.pdf">http://www.msac.gov.au/internet/msac/publishing.nsf/Content/74AD57FC3C7B2372CA25801000123B50/\$File/1030-Exogen-bone-growth-stimulator-Assessment-Report.pdf</a>.

  Published November 2001. Accessed June 26, 2024.
- 9. Zura R, Della Rocca GJ, Mehta S, et al. Treatment of chronic (>1 year) fracture nonunion: heal rate in a cohort of 767 patients treated with low-intensity pulsed ultrasound (LIPUS). *Injury*, 2015;46(10):2036 to 2041. doi:10.1016/j.injury.2015.05.042
- 10. National Institute for Health and Care Excellence (NICE). Exogen ultrasound bone healing system for long bone fractures with non-union or delayed healing. Medical technologies guidance [MTG12] <a href="https://www.nice.org.uk/guidance/mtg12">https://www.nice.org.uk/guidance/mtg12</a>. Published January 09, 2013 (updated October 08, 2019). Accessed June 26, 2024.
- 11. U.S. Federal Drug Administration (FDA). Orthopaedic and rehabilitation devices panel Sept. 8-9, 2020: bone growth stimulators executive summary. Summary of: The Orthopaedic and Rehabilitation Devices Panel meeting on the reclassification of non-invasive bone growth. <a href="https://www.fda.gov/media/141850/download">https://www.fda.gov/media/141850/download</a>. Published September 8, 2020. Accessed June 24, 2024.
- 12. Piazzolla A, Solarino G, Bizzoca D, et al. Capacitive coupling electric fields in the treatment of vertebral compression fractures. *J Biol Regul Homeost Agents*. 2015;29(3):637 to 646.



- 13. Griffin M, Bayat A. Electrical stimulation in bone healing: critical analysis by evaluating levels of evidence. *Eplasty*. 2011;11:e34.
- 14. Sibanda V, Anazor F, Relwani J, Dhinsa BS. Outcomes of the Treatment of Fracture Non-union Using Combined Magnetic Field Bone Growth Stimulation: Experiences From a UK Trauma Unit. *Cureus*. 2022;14(5):e25100. Published 2022 May 18. doi:10.7759/cureus.25100
- 15. Cheaney B 2nd, El Hashemi M, Obayashi J, Than KD. Combined magnetic field results in higher fusion rates than pulsed electromagnetic field bone stimulation after thoracolumbar fusion surgery. *J Clin Neurosci*. 2020;74:115 to 119. doi:10.1016/j.jocn.2020.02.012
- 16. Beutler A, Titus S. General principles of definitive fracture management. UpToDate. <a href="https://www.uptodate.com">www.uptodate.com</a>. Updated April 18, 2023. Accessed June 25, 2024.
- 17. Banken R. Low-intensity ultrasound (Exogen) for the treatment of fractures. AETMIS 03-05. Montreal, QC: Agence d'Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS); 2004.
- 18. Searle HK, Lewis SR, Coyle C, Welch M, Griffin XL. Ultrasound and shockwave therapy for acute fractures in adults. *Cochrane Database Syst Rev.* 2023;3(3):CD008579. Published 2023 Mar 3. doi:10.1002/14651858.CD008579.pub4
- 19. Rutten S, van den Bekerom MPJ, Sierevelt IN, Nolte PA. Enhancement of Bone-Healing by Low-Intensity Pulsed Ultrasound: A Systematic Review. *JBJS Rev.* 2016;4(3):e6. doi:10.2106/JBJS.RVW.O.00027
- 20. Ricardo M. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. *Int Orthop*. 2006;30(2):123 to 127. doi: 10.1007/s00264-005-0034-2
- 21. Rue JP, Armstrong DW 3rd, Frassica FJ, Deafenbaugh M, Wilckens JH. The effect of pulsed ultrasound in the treatment of tibial stress fractures. *Orthopedics*. 2004;27(11):1192 to 1195. doi:10.3928/0147-7447-20041101-18
- 22. Aleem IS, Aleem I, Evaniew N, et al. Efficacy of Electrical Stimulators for Bone Healing: A Meta-Analysis of Randomized Sham-Controlled Trials. *Sci Rep.* 2016;6:31724. Published 2016 Aug 19. doi:10.1038/srep31724
- 23. Gan JC, Glazer PA. Electrical stimulation therapies for spinal fusions: current concepts. *Eur Spine J.* 2006;15(9):1301-1311. doi:10.1007/s00586-006-0087-y
- 24. Kuzyk PR, Schemitsch EH. The science of electrical stimulation therapy for fracture healing. *Indian J Orthop*. 2009;43(2):127 to 131. doi: 10.4103/0019-5413.50846
- 25. Evidence analysis research brief. Ultrasound bone growth stimulation for nonspinal arthrodesis. Hayes. <a href="www.hayesinc.com">www.hayesinc.com</a>. Published January 07, 2022. Accessed June 26, 2024.
- 26. Khalifeh JM, Zohny Z, MacEwan M, et al. Electrical stimulation and bone healing: a review of current technology and clinical applications. *IEEE Rev Biomed Eng.* 2018;11:217 to 232. doi:10.1109/RBME.2018.2799189
- 27. 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 Syst Rev*. 2011;(4):CD008471. Published 2011 Apr 13. doi:10.1002/14651858.CD008471.pub2
- 28. Palanisamy P, Alam M, Li S, Chow SKH, Zheng YP. Low-Intensity Pulsed Ultrasound Stimulation for Bone Fractures Healing: A Review. *J Ultrasound Med.* 2022;41(3):547-563. doi:10.1002/jum.15738
- 29. Murakami R, Sanada T, Inagawa M, et al. Can low-intensity pulsed ultrasound (LIPUS) accelerate bone healing after intramedullary screw fixation for proximal fifth metatarsal



- stress fractures? A retrospective study. *BMC Musculoskelet Disord*. 2021;22(1):725. Published 2021 Aug 23. doi:10.1186/s12891-021-04611-z
- 30. Bawale R, Segmeister M, Sinha S, Shariff S, Singh B. Experience of an isolated use of low-intensity pulsed ultrasound therapy on fracture healing in established non-unions: a prospective case series. *J Ultrasound*. 2021;24(3):249-252. doi:10.1007/s40477-020-00464-9
- 31. Khawar H, Craxford S, Ollivere B. Radial head fractures. *Br J Hosp Med (Lond)*. 2020;81(4):1-6. doi:10.12968/hmed.2019.0404
- 32. deVet T, Jhirad A, Pravato L, Wohl GR. Bone Bioelectricity and Bone-Cell Response to Electrical Stimulation: A Review. *Crit Rev Biomed Eng.* 2021;49(1):1-19. doi:10.1615/CritRevBiomedEng.2021035327

#### **Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.



Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

This clinical policy is the property of LHCC. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

©2023 Louisiana Healthcare Connections. All rights reserved. All materials are exclusively owned by Louisiana Healthcare Connections and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Louisiana Healthcare Connections. You may not alter or remove any trademark, copyright or other notice contained herein. Louisiana Healthcare Connections is a registered trademark exclusively owned by Louisiana Healthcare Connections.