

## **Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions**

**Policy # 00039**

Original Effective Date: 08/27/2001

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*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers extracorporeal shockwave therapy (ESWT), using either a high-dose or low-dose protocol or radial extracorporeal shockwave therapy (rESWT), as a treatment of musculoskeletal conditions to be **investigational\***, including but not limited to:

- Plantar fasciitis;
- Tendinopathies including tendinitis of the shoulder;
- Tendinitis of the elbow (lateral epicondylitis, tennis elbow);
- Achilles tendinitis;
- Patellar tendinitis;
- Spasticity;
- Stress fractures;
- Delayed union and non-union of fractures;
- Avascular necrosis of the femoral head.

### **Background/Overview**

#### **Chronic Musculoskeletal Conditions**

Chronic musculoskeletal conditions (eg, tendinitis) can be associated with a substantial degree of scarring and calcium deposition. Calcium deposits may restrict motion and encroach on other structures, such as nerves and blood vessels, causing pain and decreased function. One hypothesis is that disruption of calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function.

#### **Plantar Fasciitis**

Plantar fasciitis is a common ailment characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients, the pain persists, interrupting activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is

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unclear, although repetitive injury is suspected. Heel spurs are a common associated finding, although it is unproven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

### Tendinitis and Tendinopathies

Common tendinitis and tendinopathy syndromes are summarized in Table 1. Many tendinitis and tendinopathy syndromes are related to overuse injury.

**Table 1. Tendinitis and Tendinopathy Syndromes**

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Lateral epicondylitis ("tennis elbow")	Lateral elbow (insertion of wrist extensors)	Tenderness over lateral epicondyle and proximal wrist extensor muscle mass; pain with resisted wrist extension with elbow in full extension; pain with passive terminal wrist flexion with elbow in full extension	<ul style="list-style-type: none"> <li>• Rest</li> <li>• Activity modification</li> <li>• NSAIDs</li> <li>• Physical therapy</li> <li>• Orthotic devices</li> </ul>	Corticosteroid injections; joint debridement (open or laparoscopic)
Shoulder tendinopathy	Rotator cuff muscle tendons, most commonly supraspinatus	Pain with overhead activity	<ul style="list-style-type: none"> <li>• Rest</li> <li>• Ice</li> <li>• NSAIDs</li> <li>• Physical therapy</li> </ul>	Corticosteroid injections
Achilles tendinopathy	Achilles tendon	Pain or stiffness 2 to 6 cm above the posterior calcaneus	<ul style="list-style-type: none"> <li>• Avoidance of aggravating activities</li> <li>• Ice when symptomatic</li> <li>• NSAIDs</li> <li>• Heel lift</li> </ul>	Surgical repair for tendon rupture
Patellar tendinopathy ("jumper's knee")	Proximal tendon at lower pole of patella	Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear	<ul style="list-style-type: none"> <li>• Ice</li> <li>• Supportive taping</li> <li>• Patellar tendon straps</li> </ul>	•

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Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
			<ul style="list-style-type: none"><li>• NSAIDs</li></ul>	

NSAIDs: nonsteroidal anti-inflammatory drugs.

### Fracture Nonunion and Delayed Union

The definition of a fracture nonunion remains controversial, particularly the duration necessary to define nonunion. One proposed definition is a failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months after the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing). The following criteria to define nonunion were used to inform this review:

- at least 3 months since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1 cm or less; and
- the patient can be adequately immobilized and is of an age likely to comply with nonweight-bearing limitation.

The delayed union can be defined as a decelerating healing process, as determined by serial radiographs, 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. (In contrast, nonunion serial radiographs show no evidence of healing.)

### Other Musculoskeletal and Neurologic Conditions

Other musculoskeletal conditions include medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas. Neurologic conditions include spasticity, which refers to a motor disorder characterized by increased velocity-dependent stretch reflexes. It is a characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

### Treatment

Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal-anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications (Table 1).

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### **Extracorporeal Shock Wave Therapy**

Also known as orthotripsy, extracorporeal shock wave therapy (ESWT) has been available since the early 1980s for the treatment of renal stones and has been widely investigated for the treatment of biliary stones. ESWT uses externally applied shock waves to create a transient pressure disturbance, which disrupts solid structures, breaking them into smaller fragments, thus allowing spontaneous passage and/or removal of stones. The mechanism by which ESWT might have an effect on musculoskeletal conditions is not well-defined.

Other mechanisms are also thought to be involved in ESWT. Physical stimuli are known to activate endogenous pain control systems, and activation by shock waves may "reset" the endogenous pain receptors. Damage to endothelial tissue from ESWT may result in increased vessel wall permeability, causing increased diffusion of cytokines, which may, in turn, promote healing. Microtrauma induced by ESWT may promote angiogenesis and thus aid healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the basis for trials of ESWT in delayed union or nonunion of bone fractures.

There are 2 types of ESWT: focused and radial. Focused ESWT sends medium- to high-energy shockwaves of single pressure pulses lasting microseconds, directed on a specific target using ultrasound or radiographic guidance. Radial ESWT (RSW) transmits low- to medium-energy shockwaves radially over a larger surface area. The U.S. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

## **FDA or Other Governmental Regulatory Approval**

### **U.S. Food and Drug Administration (FDA)**

Selected ESWT devices that have been approved or cleared by FDA are included in Table 2.

**Table 2. Food and Drug Administration-approved Extracorporeal Shock Wave Therapy Devices**

<b>Device Name</b>	<b>Approval Date</b>	<b>Delivery System Type</b>	<b>Indication</b>
OssaTron <sup>®†</sup> device (HealthTronics)	2000	Electrohydraulic delivery system	<ul style="list-style-type: none"><li>• Chronic proximal plantar fasciitis, ie, pain persisting &gt;6 mo and unresponsive to conservative management</li><li>• Lateral epicondylitis</li></ul>
Epos <sup>™†</sup> Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis

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Sonocur <sup>®</sup> Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec <sup>™</sup> Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone <sup>™</sup> Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith <sup>®</sup> SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies >6 mo

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300 mJ/mm<sup>2</sup>). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are applied. This protocol does not require anesthesia. The FDA labeled indication for the OssaTron and Epos Ultra devices specifically describes a high-dose protocol, while the labeled indication for the Sonocur device describes a low-dose protocol.

In 2007, Dolorclast<sup>®</sup> (EMS Electro Medical Systems), a radial ESWT, was approved by FDA through the premarket approval process. Radial ESWT is generated ballistically by accelerating a bullet to hit an applicator, which transforms the kinetic energy into radially expanding shock waves. Radial ESWT is described as an alternative to focused ESWT and is said to address larger treatment areas, thus providing potential advantages in superficial applications like tendinopathies. The FDA approved indication is for the treatment of patients 18 years and older with chronic proximal plantar fasciitis and a history of unsuccessful conservative therapy.

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

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### **Description**

Extracorporeal shock wave therapy (ESWT) is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated (eg, the heel in the case of plantar fasciitis). Shock waves are generated at high- or low-energy intensity, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

### **Summary of Evidence**

For treatment of plantar fasciitis using extracorporeal shock wave therapy (ESWT), numerous randomized controlled trials (RCTs) were identified, including several well-designed, double-blind RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Several systematic reviews and meta-analyses have been conducted, covering numerous studies, including studies that compared ESWT with corticosteroid injections. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Pooled results were inconsistent. Some meta-analyses reported that ESWT reduced pain, while others reported nonsignificant pain reduction. Reasons for the differing results included lack of uniformity in the definitions of outcomes and heterogeneity in ESWT protocols (focused vs. radial, low-vs. high-intensity/energy, number and duration of shocks per treatment, number of treatments, and differing comparators). Some studies reported significant benefits in pain and functional improvement at 3 months, but it is not evident that the longer-term disease natural history is altered with ESWT. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have lateral epicondylitis who receive ESWT, the most direct evidence on the use of ESWT to treat lateral epicondylitis comes from multiple small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCTs did not consistently show outcome improvements beyond those seen in control groups. The highest quality trials tend to show no benefit, and systematic reviews have generally concluded that the evidence does not support a treatment benefit over placebo or no treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have shoulder tendinopathy who receive ESWT, a number of small RCTs, summarized in several systematic reviews and meta-analyses, comprise the evidence. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Network meta-analyses focused on 3 outcomes: pain reduction, functional assessment, and change in calcific deposits. One network meta-analysis separated trials using high-energy focused shock wave (H-FSW), low-energy focused shock wave, and radial shock wave (RSW). It reported that the most effective treatment for pain reduction was ultrasound-guided needling, followed by RSW and H-FSW. The only treatment showing a benefit in functional outcomes was H-FSW. For the largest change in calcific deposits, the most effective treatment was ultrasound-guided needling followed by RSW and H-FSW. Although some trials have reported a benefit for pain and functional outcomes, particularly for high-energy ESWT for calcific tendinopathy, many

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available trials have been considered poor quality. For non-calcific tendinopathy, 1 meta-analysis found that ESWT exhibited a small improvement in shoulder pain compared to sham ESWT at short-term follow-up ( $\leq 3$  months). However, ESWT was not superior to sham ESWT in improving function at short- or long-term follow up ( $\geq 12$  months), and ESWT was not superior to other treatments. More high-quality trials are needed to determine whether ESWT improves outcomes for shoulder tendinopathy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs and RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In the most recent systematic review, a pooled analysis found that ESWT reduced both short- and long-term pain compared with nonoperative treatments, although reviewers warned that results were inconsistent across the RCTs and that there was heterogeneity across patient populations and treatment protocols. An RCT published after the systematic review compared ESWT with hyaluronan injections and reported improvements in both treatment groups, although the improvements were significantly higher in the injection group. Another RCT found no difference in pain scores between low-energy ESWT and sham controls at week 24, but ESWT may provide short therapeutic effects at weeks 4 to 12. Another RCT found scores were statistically and clinically improved with ESWT compared with sham control at 1 month and 16 months on measures of pain and function. The most recent RCT found that activity-related pain was lower with ESWT at 6 weeks compared to ultrasound therapy, but there was no difference in pain at rest. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews and RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Systematic reviews and trials have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have medial tibial stress syndrome who receive ESWT, the evidence includes a small RCT and a small nonrandomized cohort study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The RCT showed no difference in self-reported pain measurements between study groups. The nonrandomized trial reported improvements with ESWT, but selection bias limited the strength of the conclusions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are

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symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Many of the studies were low quality and lacked comparators. While most studies reported favorable outcomes with ESWT, limitations such as heterogeneity in the treatment protocols, patient populations, and lengths of follow-up make conclusions on the efficacy of ESWT for osteonecrosis uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes systematic reviews, relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available evidence does not permit conclusions on the efficacy of ESWT in fracture nonunion, delayed union, or acute long bone fractures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews, primarily in patients with stroke and cerebral palsy. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several studies have demonstrated improvements in spasticity measures after ESWT, but most studies have small sample sizes and single center designs. More well-designed controlled trials in larger populations are needed to determine whether ESWT leads to clinically meaningful improvements in pain and/or functional outcomes for spasticity. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **Supplemental Information**

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American College of Foot and Ankle Surgeons**

In 2010, Thomas et al revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons. The guidelines identified extracorporeal shock wave therapy (ESWT) as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guidelines recommended ESWT as a reasonable alternative to surgery. In an update to the American College of Foot and Ankle Surgeons clinical consensus statement, Schneider et al stated that ESWT is a safe and effective treatment for plantar fasciitis.



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### National Institute for Health and Care Excellence

The NICE has published guidance on ESWT for a number of applications.

- The 2 guidance documents issued in 2009 stated that current evidence on the efficacy of ESWT for refractory tennis elbow and plantar fasciitis "is inconsistent".
- A guidance issued in 2011 stated that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome "is limited in quality and quantity".
- A guidance issued in 2016 stated that current evidence on the efficacy of ESWT for Achilles tendinopathy "is inconsistent and limited in quality and quantity".
- A guidance issued in 2022 stated that evidence on the efficacy of ESWT for calcific tendinopathy of the shoulder is inadequate. Despite a lack of safety concerns, the ESWT should only be used in the context of research.

### U.S. Preventive Services Task Force Recommendations

Not applicable.

### Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

### Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT06128616	Efficacy of Extracorporeal Shock Wave Therapy in Children With Cerebral Palsy	40	Sept 2024
NCT05883020	Effect of Radial Shockwave on Calf Muscle Spasticity in Patients With Cerebral Palsy	50	March 2024
NCT06076239	Effect of Extracorporeal Shock Wave Therapy in Impingement Syndrome (ESWT)	32	June 2022
NCT06329154	Clinical Study On Extracorporeal Shock Wave Therapy For Rotator Cuff Injuries	58	Feb 2025
NCT06128616	Efficacy of Extracorporeal Shock Wave Therapy in Children With Cerebral Palsy	40	Sept 2024

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NCT04316026	Effectiveness of Shock Wave Therapy to Treat Upper Limb Spasticity in Hemiparetic Patients	48	Jun 2024
NCT02546128	LEICSTES=LEICeSter Tendon Extracorporeal Shock Wave Studies Assessing the Benefits of the Addition of Extracorporeal Shock Wave Treatment to a Home-Rehabilitation Programme for Patients with Tendinopathy	720	Dec 2024
NCT04332471	Treatment of Plantar Fasciitis With Radial Shockwave Therapy vs. Focused Shockwave Therapy: a Randomized Controlled Trial	114	Mar 2025
NCT05689593	Comparison of the Efficiency of Low Intensity Extracorporeal Shock Wave Therapy and Low Intensity Laser Therapy in Adhesive Capsulitis Treatment: a Randomized Controlled Study	60	Aug 2023
NCT05405140	Multiphasic Neuroplasticity Based Training Protocol With Shock Wave Therapy For Post Stroke Spasticity	32	Oct 2023
NCT05771220	The Effect of Extracorporeal Shockwave Therapy on Adhesive Capsulitis Shoulder: A Randomized Controlled Trial	40	Jul 2023
<i>Unpublished</i>			
NCT03472989	The Effectiveness of Radial Extracorporeal Shockwave Therapy (rESWT), Sham- rESWT, Standardized Exercise Program or Usual Care for Patients With Plantar Fasciopathy. Study Protocol for a Double-blind, Randomized Sham-Controlled Trial	200	Feb 2023
NCT05423366	Comparative Effects of Large Focused and Controlled Unfocused (Radial) Extracorporeal Shock Wave Therapies in the Treatment of Patellar Tendinopathy	75	Dec 2022
NCT05702606	Radial Extracorporeal Shock Wave Therapy for Management of Spasticity in Patients With Cerebral Palsy	73	Oct 2022

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NCT05360316	The Effect of Extracorporeal Shock Wave Therapy Applied to the Plantar Region in Individuals With Hemiplegia on Mobility, Plantar Pressure Distribution and Sensory	60	May 2021
NCT03779919	The Therapeutic Effect of the Extracorporeal Shock Wave Therapy on Shoulder Calcific Tendinitis	90	May 2020
NCT03399968	Extracorporeal Shockwave Therapy (ESWT) in Patients Suffering From Complete Paraplegia at the Thoracic Level	25	May 2020
NCT02424084	Effects of Extracorporeal Shock Wave Therapy in Bone Microcirculation	80	Feb 2023

NCT: national clinical trial.

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### **Policy History**

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|------------|---|
| 08/16/2001 | Medical Policy Committee review   |
| 08/27/2001 | Managed Care Advisory Council approval  |
| 03/21/2002 | Medical Policy Committee review. Coverage eligibility changed to reflect current literature.  |
| 03/25/2002 | Managed Care Advisory Council approval  |
| 02/03/2004 | Medical Director Review   |
| 02/17/2004 | Medical Policy Committee review. Format revision. Coverage eligibility change to reflect the investigational status of the technology identified in current literature.           |
| 02/23/2004 | Managed Care Advisory Council approval. Claims Processing effective date based on revised policy will be 4/1/04.  |
| 02/01/2006 | Medical Director review   |
| 02/15/2006 | Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged. |
| 02/23/2006 | Quality Care Advisory Council approval  |
| 02/13/2008 | Medical Director review   |
| 02/20/2008 | Medical Policy Committee approval. No change to coverage eligibility.   |
| 02/04/2009 | Medical Director review   |
| 02/19/2009 | Medical Policy Committee approval. No change to coverage eligibility.   |
| 02/04/2010 | Medical Director review   |
| 02/17/2010 | Medical Policy Committee approval. Title changed to Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions.                               |
| 02/03/2011 | Medical Policy Committee review   |
| 02/16/2011 | Medical Policy Implementation Committee approval. No change to coverage statement.  |
| 02/02/2012 | Medical Policy Committee review   |
| 02/15/2012 | Medical Policy Implementation Committee approval. No change to coverage statement.  |

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01/03/2013	Medical Policy Committee review
01/09/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/04/2013	Coding revised
01/09/2014	Medical Policy Committee review
01/15/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2015	Medical Policy Committee review
03/20/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
03/04/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Added additional indications into coverage statement. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes and CPT coding update
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/01/2018	Medical Policy Committee review
03/21/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2019	Coding update
03/07/2019	Medical Policy Committee review
03/20/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/10/2019	Coding update
03/05/2020	Medical Policy Committee review
03/11/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
09/10/2020	Coding update
03/04/2021	Medical Policy Committee review
03/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/02/2023	Medical Policy Committee review
03/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/07/2024	Medical Policy Committee review

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03/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

03/06/2025 Medical Policy Committee review

03/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 03/2026

### **Coding**

*The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0101T, 0102T, 20999, 28890
HCPCS	No codes
ICD-10 Diagnosis	All related Diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.