MEDICAL POLICY – 2.01.40

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

BCBSA Ref. Policy: 2.01.40

Effective Date: June 10, 2020
Last Revised: June 9, 2020
Replaces: 2.01.109

RELATED MEDICAL POLICIES:
1.01.05 Low Intensity Pulsed Ultrasound Fracture Healing Device

Introduction

Extracorporeal is a term that means outside of the body. Extracorporeal shockwave therapy uses shock waves to try to treat conditions affecting bone and tissues. There are two forms of this treatment, low-energy and high-energy. It’s believed that the shock waves create small amounts of damage to the tissues being treated. The body then responds by creating new blood vessels and sending more nutrients to the area. This natural healing response is thought to affect the condition being treated. The low-energy treatments might need no or only mild anesthesia. The high-energy shock wave treatments often require general anesthesia or a block to stop the pain in a particular area. The effectiveness of this treatment is in question. More medical studies are needed to determine if shock wave therapy is effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria
Extracorporeal shock wave therapy (ESWT) is considered investigational as a treatment of musculoskeletal conditions, including but not limited to:

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

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
</tr>
<tr>
<td>0101T</td>
<td>Extracorporeal shock wave therapy; involving musculoskeletal system, not otherwise specified; high energy</td>
</tr>
<tr>
<td>0102T</td>
<td>Extracorporeal shock wave therapy; high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle</td>
</tr>
<tr>
<td>20999</td>
<td>Unlisted procedure, musculoskeletal system, general</td>
</tr>
<tr>
<td>28890</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia</td>
</tr>
</tbody>
</table>

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

**Note:** High-energy ESWT requires the use of anesthesia and is performed in a hospital or ambulatory surgery center. Low-energy ESWT is usually used in the office without anesthesia.
Benefit Application

Extracorporeal shock wave treatment for plantar fasciitis may be performed by podiatrists, orthopedic surgeons, and primary care physicians.

Evidence Review

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 one treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

Background

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 unclear, although repetitive injury is suspected. Heel spurs are often an associated finding, although it is unproven that heel spurs actually 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**

<table>
<thead>
<tr>
<th>Disorder</th>
<th>Location</th>
<th>Symptoms</th>
<th>Conservative Therapy</th>
<th>Other Therapies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lateral epicondylitis</td>
<td>Lateral elbow (insertion of</td>
<td>Tenderness over lateral epicondyle and proximal wrist extensor muscle</td>
<td>• Rest • Activity modification • NSAIDs • Physical therapy • Orthotic devices</td>
<td>Corticosteroid injections; joint débridement (open or laparoscopic)</td>
</tr>
<tr>
<td>(elbow tendinitis/</td>
<td>wrist extensors)</td>
<td>mass; pain with resisted wrist extension with the elbow in full extension;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>“tennis elbow”)</td>
<td></td>
<td>pain with passive terminal wrist flexion with the elbow in full extension</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shoulder tendinopathy</td>
<td>Rotator cuff muscle tendons,</td>
<td>Pain with overhead activity</td>
<td>• Rest • Ice • NSAIDs • Physical therapy</td>
<td>Corticosteroid injections</td>
</tr>
<tr>
<td></td>
<td>most commonly supraspinatus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Achilles tendinopathy</td>
<td>Achilles tendon</td>
<td>Pain or stiffness 2-6 cm above the posterior calcaneus</td>
<td>• Avoidance of aggravating activities • Ice when symptomatic • NSAIDs • Heel lift</td>
<td>Surgical repair for tendon rupture</td>
</tr>
<tr>
<td>Patellar tendinopathy</td>
<td>Proximal tendon at lower pole</td>
<td>Pain over anterior knee and patellar tendon; may progress to tendon</td>
<td>• Ice • Supportive taping • Patellar tendon straps • NSAIDs</td>
<td></td>
</tr>
<tr>
<td>(“jumper’s knee”)</td>
<td>of the patella</td>
<td>calcification and/or tear</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 three 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 policy:

- At least three 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 non-weight bearing.

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 three 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 one year in some cases.

For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications (see Table 1).
**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 the 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 two 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. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

**Summary of Evidence**

For treatment of plantar fasciitis using ESWT, numerous RCTs were identified, including several well-designed double-blinded RCTs, that evaluated ESWT for the treatment of plantar fasciitis. Seven systematic reviews and meta-analyses have been conducted, covering a total of 27 studies. Pooled results were inconsistent. Some meta-analysis 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 three months, but it is not evident that the longer-term disease natural history is altered with ESWT. Currently, it is not possible to conclude definitively that ESWT improves outcomes for patients with plantar fasciitis.
For individuals who have lateral epicondylitis who receive ESWT, the evidence includes small RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Overall, although some RCTs have demonstrated benefits in pain and functional outcomes associated with ESWT, the limited amount of high-quality RCT evidence precludes conclusions about the efficacy of ESWT for lateral epicondylitis. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have shoulder tendinopathy who receive ESWT, the evidence includes 2 network meta-analyses as well as several systematic reviews and meta-analyses of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The 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 ESWT (H-FSW), low-energy ESWT, and radial ESWT (RSW). This analysis reported 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, then H-FSW. Many of the RCTs were judged to be of poor quality. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Achilles tendinopathy who receive ESWT, the evidence includes systematic reviews of RCTs, an RCT published after the systematic review, and nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. In the most recent systematic review, a pooled analysis reported 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 studies (eg, patient populations, 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have patellar tendinopathy who receive ESWT, the evidence includes systematic reviews of small studies, an RCT published after the systematic review, and a nonrandomized study. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The studies reported inconsistent results. Many had methodologic deficiencies such as small numbers, short follow-up periods, and heterogeneous treatment protocols. Results from a nonrandomized study suggested that the location of the patellar tendinopathy might impact the response to ESWT (patients with
retropatellar fat extension did not respond to RSW compared with patients with tendon involvement). The evidence is insufficient to determine the effects of the technology on health outcomes.

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 reported no difference in self-reported pain between study groups. The cohort study reported improvements with ESWT, although selection bias impacts the strength of the conclusions. The available evidence is limited and inconsistent; it does not permit conclusions about the benefits of ESWT for medial tibial stress syndrome. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteonecrosis of the femoral head who receive ESWT, the evidence includes 2 systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While many of the studies have suggested that ESWT might be effective in improving motor function and reducing pain, particularly in patients with early-stage osteonecrosis, the studies were judged of low quality based on lack of blinding, lack of comparators, small ample sizes, short follow-up, and variations in treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes a systematic review of a RCT and several case series, as well as 2 RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Reviewers concluded that the evidence was inconsistent and of poor quality. Data pooling was not possible due to the heterogeneity of outcome definitions and treatment protocols. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. As a treatment for spasticity, several small studies have demonstrated ESWT provides short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (eg, pain, function) are lacking. Differences in treatment parameters among studies, including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia, limit generalizations about the evidence base. The evidence is insufficient to determine the effects of the technology on health outcomes.
Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02424084</td>
<td>Effects of Extracorporeal Shock Wave Therapy in Bone Microcirculation</td>
<td>80</td>
<td>Dec 2017 (ongoing)</td>
</tr>
<tr>
<td>NCT02757664</td>
<td>Shock Wave Therapy, Associated to Eccentric Strengthening Versus Isolated Eccentric Strengthening for Treating Insertional Achilles Tendinopathy: Double Blinded Randomized Clinical Trial</td>
<td>93</td>
<td>Sep 2018</td>
</tr>
<tr>
<td>NCT02668510</td>
<td>A Randomized Controlled Trial Comparing Extracorporeal Shock Wave Therapy with Platelet Rich Plasma versus Extracorporeal Shock Wave Therapy in a High Demand Cohort with Resistant Plantar Fasciitis</td>
<td>30</td>
<td>Dec 2018</td>
</tr>
<tr>
<td>NCT02546128</td>
<td>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</td>
<td>300</td>
<td>Jun 2020</td>
</tr>
<tr>
<td>NCT03472989</td>
<td>The Effectiveness of Radial Extracorporeal Shockwave Therapy (rESWT), Sham-ESWT, Standardized Exercise Program or Usual Care for Patients With Plantar Fasciopathy. Study Protocol for a Double-blind, Randomized Sham-Controlled Trial</td>
<td>200</td>
<td>Feb 2021</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02613455</td>
<td>Prospective Randomized Trial Comparing Corticosteroid Injection to High Energy Extracorporeal Shock Wave Therapy for Lateral Epicondylitis</td>
<td>80</td>
<td>Dec 2016 (unknown)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Practice Guidelines and Position Statements

American College of Foot and Ankle Surgeons

Thomas et al (2010) 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 Food and Ankle Surgeons clinical consensus statement, Schneider et al (2018) stat that ESWT is a safe and effective treatment for plantar fasciitis.

National Institute for Health and Care Excellence

The National Institute for Clinical Excellence has published guidance on ESWT for a number of applications.

- A guidance issued in 2003 stated that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder "appears adequate to support the use of the procedure."
- 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.”

Canadian Agency for Drugs and Technologies in Health

A 2007 summary by the Canadian Agency for Drugs and Technologies in Health (CADTH) noted that results from randomized trials of ESWT for plantar fasciitis have been conflicting. The report noted that the “lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests uncertainty about its effectiveness. The evidence reviewed ... does not support the use of this technology for this condition.”
Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis noted conflicting results from randomized trials (RCTs), with half showing no benefit over placebo for any outcome measures. The report noted that “the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE [chronic lateral epicondylitis].”

A third 2007 summary by CADTH concluded that, “the current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence.”

A 2016 update from CADTH addressed the use of shockwave therapy for pain associated with upper-extremity orthopedic disorders. Based on results from 7 systematic reviews (with overlapping randomized controlled trials), the Agency concluded the following (see Table 3).

### Table 3. Conclusions on the Use of ESWT for Upper-Extremity Pain

<table>
<thead>
<tr>
<th>Condition</th>
<th>Evidence</th>
<th>Comparator</th>
<th>Conclusions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Shoulder</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calcific tendonitis</td>
<td>Systematic reviews</td>
<td>Placebo</td>
<td>Effective in reducing pain</td>
</tr>
<tr>
<td>Noncalcific tendonitis</td>
<td>Systematic reviews</td>
<td>Placebo or other treatments</td>
<td>No significant benefit</td>
</tr>
<tr>
<td>Tendonitis</td>
<td>Single RCTs</td>
<td>Exercise or radiotherapy</td>
<td>No significant benefit</td>
</tr>
<tr>
<td>Tendonitis</td>
<td>1 RCT</td>
<td>Transcutaneous electric nerve stimulation</td>
<td>Effective in reducing pain</td>
</tr>
<tr>
<td><strong>Elbow</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lateral epicondylitis</td>
<td>Systematic reviews</td>
<td>Placebo</td>
<td>Inconclusive</td>
</tr>
<tr>
<td>Lateral epicondylitis</td>
<td>Single RCTs</td>
<td>Physical therapy or percutaneous tenotomy</td>
<td>No significant benefit</td>
</tr>
<tr>
<td>Lateral epicondylitis</td>
<td>Single RCTs</td>
<td>Corticosteroid injections</td>
<td>Inconclusive</td>
</tr>
</tbody>
</table>

ESWT: extracorporeal shockwave treatment; RCT: randomized controlled trial

**Medicare National Coverage**

There is no national coverage determination.
Regulatory Status

Currently, six focused ESWT devices have been approved by the FDA through the premarket approval process for orthopedic use (see Table 4). FDA product code: NBN.

Table 4: FDA-Approved Extracorporeal Shock Wave Therapy Devices

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Approval Date</th>
<th>Delivery System Type</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>OssaTron® device (HealthTronis)</td>
<td>2000</td>
<td>Electrohydraulic delivery system</td>
<td>Chronic proximal plantar fasciitis, ie, pain persisting &gt;6 mo and not responding to conservative management</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Lateral epicondylitis</td>
</tr>
<tr>
<td>Epos™ Ultra (Dornier)</td>
<td>2002</td>
<td>Electromagnetic delivery system</td>
<td>Plantar fasciitis</td>
</tr>
<tr>
<td>SONOCUR® Basic (Siemens)</td>
<td>2002</td>
<td>Electromagnetic delivery system</td>
<td>Chronic lateral epicondylitis (unresponsive to conservative therapy for &gt;6 mo)</td>
</tr>
<tr>
<td>Orthospec™ Orthopedic ESWT (Medispec)</td>
<td>2005</td>
<td>Electrohydraulic spark-gap system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y</td>
</tr>
<tr>
<td>Orbasone™ Pai Pain Relief System (Orthometrix)</td>
<td>2005</td>
<td>High-energy sonic wave system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y</td>
</tr>
<tr>
<td>Duolith® SDI Shock Wave Therapy Device (Storz Medical AG)</td>
<td>2016</td>
<td>Electromagnetic delivery system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y with a history of failed alternative conservative therapies &gt;6 mo</td>
</tr>
</tbody>
</table>

FDA: Food and Drug Administration

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/mm²). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which a lower dose of shock waves are applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron® and Epos™ Ultra device specifically describes a high-dose protocol, while the labeled indication for the Sonocur® device describes a low-dose protocol.

In 2007, Dolorclast® (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. FDA product code: NBN.

References


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>06/19/01</td>
<td>Add to Medicine Section - New Policy</td>
</tr>
<tr>
<td>01/08/02</td>
<td>Replace policy - Patient criteria updated to include patient criteria, Policy statement changed to &quot;may be considered medically necessary.&quot; Name changed to include &quot;and Other Musculoskeletal Conditions&quot;. Policy replaces CP.MP.BC.2.01.40.</td>
</tr>
<tr>
<td>03/12/02</td>
<td>Replace policy - Policy updated with TEC assessments. Policy replaces CP.MP.BC.2.01.109.</td>
</tr>
<tr>
<td>08/12/03</td>
<td>Replace Policy - Policy replaces CP.MP.BC.2.01.40. No change to policy statement.</td>
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<tr>
<td>02/10/04</td>
<td>Replace Policy - Policy replaces CP.MP.PR.2.01.109. Policy updated with additional references for treatment of plantar fasciitis; policy statement is changed to investigational. Effective July 15, 2004 due to notification process.</td>
</tr>
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<td>01/11/05</td>
<td>Replace Policy - Policy updated with October 2004 TEC Assessments; endonitis of the elbow added to investigational status in the policy statement.</td>
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<tr>
<td>07/12/05</td>
<td>Replace Policy - Policy updated with CPT codes effective 7/1/05.</td>
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<td>02/06/06</td>
<td>Codes updated - No other changes.</td>
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<tr>
<td>03/14/06</td>
<td>Replace Policy - Policy updated with additional references and information on newly approved ESWT devices; no change to policy statement.</td>
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<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>03/19/07</td>
<td>Cross Reference Update - No other changes.</td>
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<tr>
<td>10/9/07</td>
<td>Replace Policy - Policy updated with literature search through April 2007; no change in policy statement. References added.</td>
</tr>
<tr>
<td>02/10/09</td>
<td>Replace Policy - Policy updated with literature search. Policy statement updated to include radial ESWT to the investigational criteria. References added.</td>
</tr>
<tr>
<td>11/10/09</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Replace policy - Policy updated with literature search; no change to the policy statement. References added.</td>
</tr>
<tr>
<td>05/10/11</td>
<td>Replace Policy - Policy updated with literature search; reference numbers 37-44 added; references 13,14,16,17 and 45-48 updated. No change in policy statement. ICD-10 codes added.</td>
</tr>
<tr>
<td>04/25/12</td>
<td>Replace policy. Policy updated with literature search through December 2011; references 25 and 36 added and references reordered; some references removed. No change in policy statement.</td>
</tr>
<tr>
<td>08/27/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>04/16/13</td>
<td>Replace policy. Policy updated with literature review, references 11, 19, 20, 21, 24 added. No change to policy statements.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
<td>05/05/14</td>
<td>Annual Review. Policy updated with literature review through January 20, 2014. Moved details of high/low intensity therapy from the Regulatory section to the Description section. References 5-7, 24-25, 30, 34 added; others renumbered/removed. Policy statements unchanged. ICD-9 and ICD-10 diagnosis and procedure codes removed; they are not utilized in policy adjudication.</td>
</tr>
<tr>
<td>04/24/15</td>
<td>Annual Review. Policy updated with literature review through January 12, 2015. References 8, 15, 17, 28, 31, 34, 40, 45, 47-48, and 54-55 added. Editorial changes made for clarity to policy statements; intent of policy statements unchanged.</td>
</tr>
<tr>
<td>09/01/16</td>
<td>Annual Review, approved August 9, 2016. Policy updated with literature review through May 2, 2016; references 9, 28-29, and 31 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT code 0019T as it was terminated 1/1/17, replaced with CPT 20999.</td>
</tr>
<tr>
<td>09/01/19</td>
<td>Annual Review, approved August 6, 2019. Policy updated with literature review through April 2019; references added. Policy statement unchanged.</td>
</tr>
<tr>
<td>04/01/20</td>
<td>Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.</td>
</tr>
<tr>
<td>06/10/20</td>
<td>Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2020 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
Discrimination is Against the Law

Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with: Civil Rights Coordinator - Complaints and Appeals PO Box 91102, Seattle, WA 98111 Toll free 855-332-4535, Fax 425-918-5952. TTY 800-842-5357 Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.


Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
- يحتوي هذا الإشعار معلومات هامة. قد يحتوي هذا الإشعار معلومات مهمة يخص طبلك أو مكوناته الحالية التي تيدد الحصول عليها من خلال طلبك.Premera Blue Cross. هذه المعلومات التي تيدد الحصول عليها من خلال طلبك. 

中文 (Chinese):
- 本通知有重要的讯息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或服務的重要訊息。本通知內可能有重要日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 800-842-5357).

Italiano (Italian):
- Questo avviso contiene informazioni importanti. Questo avviso può contenere informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross. Potrebbe essere necessario un tuo intervento entro una scadenza determinata per consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.

Chiama 800-722-1471 (TTY: 800-842-5357).

Russian (Russian): Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

Spanish (Spanish): Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tener una medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).


Thai (Thai): ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้มีข้อมูลสำคัญเกี่ยวกับการขอความช่วยเหลือระยะสั้นของ Premera Blue Cross และข้อมูลในประกาศนี้มีความสำคัญในการกำหนดเวลาซึ่งจะทำให้สามารถสัญญาขาดสิทธิ์การช่วยเหลือที่มีการจัดให้ คุณมีสิทธิ์ที่จะได้รับความช่วยเหลือภายในระยะเวลาที่ไม่มีการจัดให้ โปรดติดต่อ Premera Blue Cross (ไทย: 800-722-1471) หรือ (English: 800-842-5357).

UKRAINIAN (Ukrainian): Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує Імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дозвоніться за номером телефону 800-722-1471 (TTY: 800-842-5357).