Corporate Medical Policy

Extracorporeal Shock Wave Treatment for Musculoskeletal Conditions and Wound Healing

File Name: extracorporeal_shock_wave_treatment_for_musculoskeletal_conditions
Origination: 1/2001
Last Review: 6/2023

Description of Procedure or Service

Extracorporeal shockwave treatment (ESWT), also known as orthotripsy, 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. Chronic musculoskeletal conditions, such as 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 these calcific deposits by shock waves may loosen adjacent structures and promote resorption of calcium, thereby decreasing pain and improving function.

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 in healing. Finally, shock waves have been shown to stimulate osteogenesis and promote callous formation in animals, which is the rationale for trials of ESWT in delayed union or non-union 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.

Currently, six focused ESWT devices for orthopedic use are approved for marketing by the U.S. Food and Drug Administration (FDA):

- OssaTron® device (HealthTronics, Marietta, GA), an electrohydraulic delivery system was approved by the FDA on July 20, 2000, for patients with chronic proximal plantar fasciitis—i.e., pain persisting more than 6 months and not responding to conservative management. It is also FDA approved for treatment of lateral epicondylitis (tennis elbow).
- Epos™ Ultra (Dornier, Germering, Germany), an electromagnetic delivery system, was approved by the FDA on January 15, 2002, for plantar fasciitis.
- SONOCUR® Basic (Seimans, Erlangen, Germany) also uses an electromagnetic delivery system and was approved by the FDA for use in chronic lateral epicondylitis (symptoms unresponsive to conservative therapy for more than 6 months) on July 19, 2002.

- Orthospec™ Orthopedic ESWT (Medispec Ltd, Germantown, MD), an electrohydraulic spark-gap device, and the Orbasone™ Pain Relief System (Orthometrix, White Plains, NY), a high-energy sonic wave system, received approval in 2005 for treatment of chronic proximal plantar fasciitis in patients 18 years of age or older.
- Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG, Switzerland), an electromagnetic delivery system received approval in 2016 for treatment of chronic proximal plantar fasciitis in patients 18 years of age and older with a history of failed alternative conservative therapies for longer than 6 months.

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high energy shock waves (1300mJ/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 is 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 May 2007, Dolorclast® (EMS Electro Medical Systems, Nyon, Switzerland), 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.

Sanuwave Health, Inc. (Alpharetta, GA), has developed a device using shock wave therapy to treat diabetic foot ulcers. The dermaPACE® system was granted De Novo approval by FDA in December 2017 as “an extracorporeal shock wave device for treatment of chronic wounds. The device is indicated “to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers…”.

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 may persist, 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 a common associated finding, although it has never been proven that heel spurs cause the pain and asymptomatic heel spurs can be found in up to 10% of the population. 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.

Tendinitis and Tendinopathies

ESWT has been investigated for a variety of tendinitis/tendinopathy syndromes. Some of the more common tendinitis syndromes are summarized below. Many tendinitis/tendinopathy syndromes are related to overuse injury. Conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications.

- Lateral epicondylitis (elbow tendinitis/"tennis elbow"). Symptoms include tenderness over the lateral epicondyle and proximal wrist extensor muscle mass, pain with resisted wrist extension with the elbow in full extension, and pain with passive terminal wrist flexion with the elbow in full extension. Conservative therapy consists of rest, activity modification, nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, and orthotic devices. Other therapies may include corticosteroid injections, and open or laparascopic joint debridement.
- Shoulder tendinopathy. Symptoms include pain with overhead activity. Conservative therapy consists of rest, ice, NSAIDs, and physical therapy. Corticosteroid injections may be used.
- Achilles tendinopathy. Symptoms include pain or stiffness 2 to 6 centimeters above the posterior calcaneus. Conservative therapy consists of avoidance of aggravating activities, ice when symptomatic, NSAIDs, and heel lift. Surgical repair for tendon rupture may be used.
- Patellar tendinopathy. Symptoms include pain over the anterior knee and patellar tendon; may progress to tendon calcification and/or tear. Conservative therapy consists of ice, supportive taping, patellar tendon straps, and NSAIDs.

Related Policies
Ultrasound Accelerated Fracture Healing Device
Electrical Bone Growth Stimulation
Bone Morphogenetic Protein

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

Policy

Extracorporeal shockwave treatment for musculoskeletal conditions and wound healing is considered investigational. BCBSNC does not cover investigational services.

Benefits Application

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

When Extracorporeal Shock Wave Treatments are covered

Not Applicable

When Extracorporeal Shock Wave Treatments are not covered

Extracorporeal shock wave therapy (ESWT), using either a high- or low-dose protocol or radial ESWT, is considered investigational, as a treatment of the following clinical conditions, including but not limited to:

- plantar fasciitis;

- tendinopathies: including tendinitis of the shoulder, tendinitis of the elbow (epicondylitis), Achilles tendinitis, and patellar tendinitis;

- stress fractures;
- delayed union and non-union of fractures;
- avascular necrosis of the femoral head;
- wound healing;
- spasticity

Policy Guidelines

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

For treatment of plantar fasciitis using ESWT, numerous randomized controlled trials (RCTs) were identified, including several well-designed double-blinded 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. 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 versus radial, low- versus 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, which did not consistently show outcome improvements beyond those seen in control groups. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. 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 available trials have been considered poor quality. 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 one month and sixteen months on measures of pain and function. 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 trials have reported inconsistent results and were heterogeneous in treatment protocols and lengths of follow-up. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. 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 reported 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 three systematic reviews of small, mostly nonrandomized studies. Relevant outcomes are 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 several relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), along with 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. Several studies have demonstrated improvements in spasticity measures after ESWT, but most studies have small sample sizes and single center designs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. 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.

Efficacy and safety of radial ESWT in the treatment of spasticity in patients with cerebral palsy has been examined in a small RCT from Europe in 2011. Additional study with a larger number of subjects is needed to permit conclusions regarding the efficacy of this technology on spasticity.

There is inconclusive medical and scientific evidence in peer-reviewed medical literature that extracorporeal shock wave therapy for diabetic foot ulcers has a beneficial effect on health outcomes.

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

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

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: *0101T, 0102T, 0512T, 0513T, 20999, 28890*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Specialty Matched Consultant Advisory Panel 6/2022

Medical Director Review 6/2023

Specialty Matched Consultant Advisory Panel 6/2023

Policy Implementation/Update Information

01/01	New policy issued.
07/01	**Policy re-titled. Name changed from Extracorporeal Shock Wave Lithotripsy for Orthopedic Problems to Lithotripsy, Extracorporeal, for Orthopedic Problems.**
8/01	Specialty Matched Consultant Advisory Panel. No changes.
1/02	Changed policy to cover Extracorporeal shock wave lithotripsy for plantar fasciitis according to criteria stated in policy. Remains investigational for all other musculoskeletal problems.
5/02	Revised to include "chronic proximal" plantar fasciitis for clarification. Typos corrected. Format changes.

9/02 Medical director review. Revised section under when it is covered to clarify criteria. Added numbers 4. and 5. a. - c. Typos corrected.

11/02 Policy revised under when it is covered and when it is not covered to include criteria for chronic lateral epicondylitis. Criteria numbers 4. and 5. a. - c. were moved under the Policy Guidelines section. Format changes. System coding changes.

2/03 Policy revised under the Description section to include low and high energy shock waves. Policy Guidelines revised to include low and high energy shock wave therapy. Codes G0279 and G0280 added to Billing/Coding section.

2/03 Terms added to the Medical Term Definitions.

5/03 Specialty Matched Consultant Advisory Panel review. No criteria changes.

4/04 Benefits Application and Billing/Coding sections updated for consistency.

6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to policy statement. Code descriptions removed. SUR6323 added as key word. References added.

7/07/2005 Codes 0101T and 0102T added to Billing/Coding section.

8/18/2005 Coverage criteria section of the policy revised as following: 1. (no change) 2. Changed " There has been a lack of response over at least 6 weeks..." to "There has been a documented lack of response over at least 6 weeks..."; "a. rest" changed to "a. rest (defined as use of a cast boot or cessation of painful activities for plantar fasciitis); "b. physical therapy" changed to "b. a formal physical therapy program, which can include either compliance with a home exercise program taught in the physician's office (in which case the specifics of the program as well as specific references to compliance must be documented in the record; merely referring to "stretching" is not sufficient) OR supervised physical therapy in a physical therapy facility documented by appropriate records"; "c. anti-inflammatory medication" changed to "c. anti-inflammatory medication (name of medication, dose and frequency must be specified)"; d. (no change) e. (no change) 3. (no change). Additional notation made in this section, "Please note: information supplied in cover letters does not replace the need to provide copies of office records to document compliance with the criteria above." Notification given 8/18/2005. Policy effective date 10/20/2005.

1/05/06 CPT Codes G0279, G0280, 0020Tdeleted and CPT Code 28890 added to Billing/Coding section.

7/2/07 Item 1 in the When Lithotripsy is Covered section revised to read: The history in the record must be of sufficient detail to establish chronicity of symptoms for at least 6 months. (This consists of persistent symptoms over a 6 month period of time with no more than 4 weeks of symptom-free time after prior interventions.) References updated. Specialty Matched Consultant Advisory Panel review 5/18/07. (adn)

7/6/09 Specialty Matched Consultant Advisory Panel review 5/21/09. No change to policy statement.(adn)

For Policy Renamed: Extracorporeal Shock Wave Treatment for Musculoskeletal Conditions

9/28/09 Policy name changed from Lithotripsy, Extracorporeal, for Orthopedic Problems to Extracorporeal Shock Wave Treatment for Musculoskeletal Conditions. Description section extensively revised. Policy statement changed to read: BCBSNC will not provide coverage for extracorporeal shockwave treatment for musculoskeletal conditions. It is considered investigational and BCBSNC does not cover investigational services. Information in the When Covered section was deleted and replaced with the statement: "not applicable." Information in the When Not Covered section was deleted and replaced with the following: "Extracorporeal shock wave therapy (ESWT), using either a high- or lo-dose protocol or radial ESWT, is considered investigational, as a treatment of musculoskeletal conditions, including but limited to: plantar fasciitis; tendinopathies, including tendinitis of the shoulder and tendinitis of the elbow (epicondylitis, tennis elbow); stress fractures; delayed union and non-union fractures; avascular necrosis of the femoral head." Notification given 9/28/09. Effective date 1/01/10. (adn)

08/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Medical Policy number removed. References updated. (mco)

4/26/11 Description section updated. References updated. Policy Guidelines updated. No change to policy statement. (mco)

8/16/11 Specialty Matched Consultant Advisory Panel review 7/2011. No changes to policy statements. (mco)

For Policy Re-titled: Extracorporeal Shock Wave Treatment for Musculoskeletal Conditions and Wound Healing

12/30/11 Policy re-titled to “Extracorporeal Shock Wave Treatment for Musculoskeletal Conditions and Wound Healing.” “Description” section updated to include information on dermaPACE®, new ESWT for treatment of diabetic foot ulcers. “When not Covered” section updated to include wound healing as an investigational clinical condition. 0299T and 0300T added to “Billing/Coding” section. New codes to be effective 1/1/2012. “Policy Guidelines” section updated. References update. Medical Director review 12/2011. (mco)

5/1/12 “When not Covered” section updated to include treatment of spasticity. Policy Guidelines updated. References updated. Medical Director review 4/2012. (mco)

8/7/12 Specialty Matched Consultant Advisory Panel review 7/2012. No changes to Policy Statement. (mco)

4/1/13 References updated. Policy Guidelines updated. No changes to Policy Statement. (mco)

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

4/1/14 References updated. Policy Guidelines updated. No changes to Policy Statements. (mco)

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

4/28/15 Reference added. Description section and Policy Guidelines section updated. Achilles tendinitis and patellar tendinitis added to list of tendinopathies in the When Not Covered section. No change to Policy statement. (sk)

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

7/26/16 Specialty Matched Consultant Advisory Panel review 6/29/2016. Reference added. Policy Guidelines updated. (sk)

12/30/16 Code 0019T deleted from Billing/Coding section. Code 20999 added to Billing/Coding section. (sk)

7/28/17 Specialty Matched Consultant Advisory Panel review 6/28/2017. (sk)

9/15/17 Reference added. Policy Guidelines updated. (sk)

7/13/18 Specialty Matched Consultant Advisory Panel review 6/27/2018. (sk)

10/12/18 Reference added. (sk)

12/14/18 Codes 0512T and 0513T added to Billing/Coding section for effective date 1/1/2019. (sk)

8/27/19 Expired codes 0299T and 0300T removed from Billing/Coding section. Specialty Matched Consultant Advisory Panel review 7/30/2019. Reference added. Policy Guidelines updated. (sk)

6/30/20 Reference added. Description section updated. Specialty Matched Consultant Advisory Panel review 6/17/2020. (sk)

8/10/21 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 6/16/2021. (sk)

7/26/22 Specialty Matched Consultant Advisory Panel review 6/29/2022. (sk)

8/01/23 Minimal formatting changes to the Description section. Update definition of nonunion in the Policy Guidelines. Specialty Matched Consultant Advisory Panel review 6/2023. Medical Director Review 6/2023. References updated. (ldh)