

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 CAP Review: 7/2019
Next CAP Review: 6/2020
Last Review: 7/2019

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). The 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). The Epos™ Ultra (Dornier, Germering, Germany), an electromagnetic delivery system, was approved by the FDA on January 15, 2002, for plantar fasciitis. The 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. In 2005, the Orthospec™ Orthopedic ESWT

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(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 for treatment of chronic proximal plantar fasciitis in patients 18 years of age or older. In 2016, the Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG, Switzerland), an electromagnetic delivery system received approval 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 device 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 recently evaluated in a company-sponsored double-blinded, randomized Phase III, Investigational Device Exemption (IDE) clinical trial. DermaPACE® was compared with Sham-control (non-active treatment), combined with current standard of care for the treatment of diabetic foot ulcers (NCT00536744).

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

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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 laparoscopic 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. 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;

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- delayed union and non-union 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 individuals who have plantar fasciitis who receive ESWT, the evidence includes three recent systematic reviews, each analyzing 9 randomized controlled trials (RCTs), for a total of 21 RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. While several of the same trials were included in multiple meta-analyses, pooled results were inconsistent. One 2017 meta-analysis reported that ESWT was beneficial in reducing pain, while another reported nonsignificant findings in pain reduction. The most recent trial (2018) compared ESWT to corticosteroid injections (CSIs) and found that high-energy ESWT is more effective than CSI and low-energy ESWT is not. Reasons for the differing results include lack of uniformity in the definitions of outcomes, and heterogeneity in ESWT protocols (focused vs radial, high-energy vs low-energy, number and duration of shocks per treatment, the number of treatments, and different comparators). The evidence is insufficient to determine the effects of the technology on health outcomes.

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 two 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 three 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 are considered 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 the authors warned that

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results were inconsistent across the RCTs and that there was heterogeneity across studies in 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. 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 not included in the systematic reviews, 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 retropatella 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 three 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 low quality based on lack of blinding, lack of comparators, small sample sizes, and short follow-up. Treatment protocols also differed between studies. 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 two RCTs published after the systematic review. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The review 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 short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (e.g., 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.

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.

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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.

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.

Nonunions:

The FDA labeling simply suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the time frame of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months. The following patient selection criteria are suggested, consistent with those proposed for electrical stimulation as a treatment of nonunions:

- At least 3 months have passed since the date of the fracture, AND
- Serial radiographs have confirmed that no progressive signs of healing have occurred, AND
- The fracture gap is 1cm or less, AND
- The patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

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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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

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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, 0020T deleted 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

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- 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)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational

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purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.