BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Policy #: 076
Latest Review Date: August 2022
Category: Medical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after February 14, 2021:

For extracorporeal shock wave treatment (ESWT) related to CPT code 0101T and 0102T, refer to LCD L38775 and Article A58367.

For ESWT related to CPT code 28890, refer to guidance below:

Blue Advantage will treat **ESWT,** using either a high- or low-dose protocol or radial ESWT as a **non-covered** benefit and as **investigational** when used to treat conditions involving the plantar fascia, including but not limited to plantar fasciitis and heel spur syndrome.

Effective for dates of service March 24, 2020, through February 13, 2021:

Blue Advantage will treat **ESWT**, using either a high- or low-dose protocol or radial ESWT as a **non-covered** benefit and as **investigational** when used to treat musculoskeletal conditions, including but not limited to: plantar fasciitis, tendinopathies including tendinitis of the shoulder, tendinitis of the elbow (lateral epicondylitis), Achilles tendinitis, and patellar tendinitis, spasticity; stress fractures, delayed union and non-union of fractures, and avascular necrosis of the femoral head.

Blue Advantage will treat **ESWT** as a **non-covered** benefit and as **investigational** when used to treat chronic pelvic pain syndrome (CPPS) resulting from abacterial chronic prostatitis.

Effective for dates of service February 26, 2018, through March 23, 2020, refer to LCDs L34555 & L36954

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **ESWT** when used to treat plantar fasciitis or other musculoskeletal conditions as a **non-covered** benefit and as **investigational when using either a high- or low-dose protocol or radial ESWT**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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, (e.g., 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.

Chronic Musculoskeletal Conditions
Chronic musculoskeletal conditions (e.g., 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 a common associated finding, although it is unproven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

Tendinitis and Tendinopathies
Common tendinitis and tendinopathy syndromes are summarized in the table below. Many tendinitis and tendinopathy syndromes are related to overuse injury.

Tendinitis and Tendinopathy Syndromes

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Lateral epicondylitis ("tennis elbow")	Lateral elbow (insertion of wrist extensors)	Tenderness over lateral epicondyle and proximal wrist extensor muscle mass; pain with resisted wrist extension with elbow in full extension; pain with passive terminal wrist flexion with elbow in full extension	• Rest • Activity modification • NSAIDs • Physical therapy • Orthotic devices	Corticosteroid injections; joint débridement (open or laparoscopic)
Shoulder tendinopathy	Rotator cuff muscle tendons, most commonly supraspinatus	Pain with overhead activity	• Rest • Ice • NSAIDs • Physical therapy	Corticosteroid injections

Disorder	Location	Symptoms	Conservative Therapy	Other Therapies
Achilles tendinopathy	Achilles tendon	Pain or stiffness 2-6 cm above the posterior calcaneus	• Avoidance of aggravating activities • Ice when symptomatic • NSAIDs • Heel lift	Surgical repair for tendon rupture
Patellar tendinopathy ("jumper's knee")	Proximal tendon at lower pole of patella	Pain over anterior knee and patellar tendon; may progress to tendon calcification and/or tear	• Ice • Supportive taping • Patellar tendon straps • NSAIDs	

NSAIDs: nonsteroidal anti-inflammatory drugs

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

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

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

Other Musculoskeletal and Neurologic Conditions
Other musculoskeletal conditions include medial tibial stress syndrome, osteonecrosis (avascular necrosis) of the femoral head, coccydynia, and painful stump neuromas. Neurologic conditions include spasticity, which refers to a motor disorder characterized by increased velocity-

dependent stretch reflexes. It is a characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

Chronic Pelvic Pain
Prostatitis is one of the most frequent urological diagnoses, resulting in more than two million physician visits in the United States annually. Most men have the abacterial form of chronic prostatitis, or chronic pelvic pain syndrome (CPPS). Symptoms of CPPS are urinary and erectile dysfunction, pain focused in the prostate region, as well as perineal, inguinal, scrotal and suprapubic pain.

CPPS is thought to be manifested as a myofascial pain syndrome with an abnormal tone of the periprostatic musculature with neurological components.

Analgesics, anti-inflammatory agents, antibiotics, α-receptor blockers and 5α-reductase inhibitors are used alone and in various combinations without sufficient clarification of the evidence and effectiveness of each of these treatments. Therefore, clinicians have increasingly begun to look for non-drug treatment options. Physiotherapy, "trigger-point" massage and electromagnetic treatment have been tried.

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

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

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

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

There are 2 types of ESWT: focused and radial. Focused ESWT sends medium- to high-energy shockwaves of single pressure pulses lasting microseconds, directed on a specific target using ultrasound or radiographic guidance. Radial ESWT (RSW) transmits low- to medium-energy

shockwaves radially over a larger surface area. The Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

KEY POINTS:

The most recent literature update covered the period through May 2, 2022. Following is a summary of key studies to date.

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. 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-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. 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 the effects of the technology on health outcomes.

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 H-FSW, L-FSW, and RSW. It reported that the most effective treatment for pain reduction was UGN, 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 UGN, 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 the effects of the technology on health outcomes.

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 non-operative 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 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 impacted 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. 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 the effects of the technology on health outcomes.

For individuals who have nonunion or delayed union who receive ESWT, the evidence includes several relatively small RCTs with methodologic limitations (e.g., 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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.80 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) state that ESWT is a safe and effective treatment for plantar fasciitis.

National Institute for Health and Care Excellence
The National Institute for Health and Care 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."

U.S. Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Extracorporeal Shock Wave, Extracorporeal Shock Wave Therapy, Extracorporeal Shock Wave Treatment, ESW, ESWT, OssaTron, Orthospec™ Orbasone™, SONOCOR, Epos™ Ultra, Extracorporeal pulse activation therapy, EPAT, D-Actor 100

APPROVED BY GOVERNING BODIES:
Selected ESWT devices have been approved by FDA are included in the table below.

FDA-Approved Extracorporeal Shock Wave Therapy Devices

Device Name	Approval Date	Delivery System Type	Indication
OssaTron® device (HealthTronics)	2000	Electrohydraulic delivery system	• Chronic proximal plantar fasciitis, ie, pain persisting >6 mo and unresponsive to conservative management • Lateral epicondylitis
Epos™ Ultra (Dornier)	2002	Electromagnetic delivery system	Plantar fasciitis
Sonocur® Basic (Siemens)	2002	Electromagnetic delivery system	Chronic lateral epicondylitis (unresponsive to conservative therapy for >6 mo)
Orthospec™ Orthopedic ESWT (Medispec)	2005	Electrohydraulic spark-gap system	Chronic proximal plantar fasciitis in patients ≥18 y
Orbasone™ Pain Relief System (Orthometrix)	2005	High-energy sonic wave system	Chronic proximal plantar fasciitis in patients ≥18 y
Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG)	2016	Electromagnetic delivery system	Chronic proximal plantar fasciitis in patients ≥18 y with history of failed alternative conservative therapies >6 mo

Both high-dose and low-dose protocols have been investigated. A high-dose protocol consists of a single treatment of high-energy shock waves (1300 mJ/mm²). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced one week to one 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 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

28890	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia
0101T	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T	Extracorporeal shock wave, high energy, performed by a physician requiring anesthesia other than local, involving lateral humeral epicondyle
20999	Unlisted procedure, musculoskeletal system, general

REFERENCES:

1. Abdelkader NA, Helmy MNK, Fayaz NA, et al. Short- and Intermediate-Term Results of Extracorporeal Shockwave Therapy for Noninsertional Achilles Tendinopathy. Foot Ankle Int. Jan 15 2021: 1071100720982613.
2. Al-Abbad H, Simon JV. The effectiveness of extracorporeal shock wave therapy on chronic achilles tendinopathy: a systematic review. Foot Ankle Int. Jan 2013; 34(1):33-41.
3. Ahadi T, Hosseinverdi S, Raissi G, et al. Comparison of Extracorporeal Shockwave Therapy and Blind Steroid Injection in Patients With Coccydynia: A Randomized Clinical Trial. Am J Phys Med Rehabil. May 01 2022; 101(5): 417-422.
4. Aldajah S, Alashram AR, Annino G, et al. Analgesic Effect of Extracorporeal Shock-Wave Therapy in Individuals with Lateral Epicondylitis: A Randomized Controlled Trial. J Funct Morphol Kinesiol. Mar 18 2022; 7(1).
5. Alves EM, Angrisani AT, Santiago MB. The use of extracorporeal shock waves in the treatment of osteonecrosis of the femoral head: a systematic review. Clin Rheumatol. Nov 2009; 28(11):1247-1251.

6. Aqil A, Siddiqui MR, Solan M et al. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: a meta-analysis of RCTs. Clin Orthop Relat Res. Nov 2013; 471(11):3645-3652.
7. Arirachakaran A, Boonard M, Yamaphai S, et al. Extracorporeal shock wave therapy, ultrasound-guided percutaneous lavage, corticosteroid injection and combined treatment for the treatment of rotator cuff calcific tendinopathy: a network meta-analysis of RCTs. Eur J Orthop Surg Traumatol. Apr 2017; 27(3):381-390.
8. Bahar-Ozdemir Y, Atan T. Effects of adjuvant low-dye Kinesio taping, adjuvant sham taping, or extracorporeal shockwave therapy alone in plantar fasciitis: A randomised double-blind controlled trial. Int J Clin Pract. May 2021; 75(5): e13993.
9. Bannuru RR, Flavin NE, Vaysbrot E, et al. High-energy extracorporeal shock-wave therapy for treating chronic calcific tendinitis of the shoulder: a systematic review. Ann Intern Med. Apr 15 2014; 160(8):542-549.
10. Barnes M. Letter to the editor. "Low-energy extracorporeal shock wave therapy as a treatment for medial tibial stress syndrome". Am J Sports Med. Nov 2010; 38(11):NP1; author reply NP1-2.
11. Buchbinder R, Green S, Youd J et al. Shock wave therapy for lateral elbow pain. Cochrane Database Syst Rev 2005; 4:CD003524.
12. Cabanas-Valdes R, Serra-Llobet P, Rodriguez-Rubio PR, et al. The effectiveness of extracorporeal shock wave therapy for improving upper limb spasticity and functionality in stroke patients: a systematic review and meta-analysis.. Sep 2020; 34(9): 1141-1156.
13. Cacchio A, Giordano L, Colafarina O et al. Extracorporeal shock-wave therapy compared with surgery for hypertrophic long-bone nonunions. J Bone Joint Surg Am. Nov 2009; 91(11):2589-2597.
14. Capan N, Esmaeilzadeh S, Oral A, et al. Radial extracorporeal shock wave therapy is not more effective than placebo in the management of lateral epicondylitis: a double-blind, randomized, placebo-controlled trial. Am J Phys Med Rehabil. Jul2016; 95(7): 495-506.
15. Cinar E, Saxena S, Uygur F. Combination therapy versus exercise and orthotic support in the management of pain in plantar fasciitis: a randomized controlled trial. Foot Ankle Int. Apr 2018; 39(4):406-414.
16. Costa ML, Shepstone L, Donell ST et al. Shock wave therapy for chronic Achilles tendon pain: a randomized placebo-controlled trial. Clin Orthop Relat Res. Nov 2005; 440:199-204.
17. Dingemanse R, Randsdorp M, Koes BW, et al. Evidence for the effectiveness of electrophysical modalities for treatment of medial and lateral epicondylitis: a systematic review. Br J Sports Med. Jun 2014; 48(12):957-965.
18. Dizon JN, Gonzalez-Suarez C, Zamora MT et al. Effectiveness of extracorporeal shock wave therapy in chronic plantar fasciitis: a meta-analysis. Am J Phys Med Rehabil. Jul 2013; 92(7):606-620.
19. Eslamian F, Shakouri SK, Jahanjoo F, et al. Extra corporeal shock wave therapy versus local corticosteroid injection in the treatment of chronic plantar fasciitis, a single blinded randomized clinical trial. Pain Med. Sep 2016; 17(9):1722-1731.

20. Food and Drug Administration. Summary of safety and effectiveness: HealthTronicsTM OssaTron 2000;https://www.accessdata.fda.gov/cdrh_docs/pdf/P990086b.pdf.
21. Food and Drug Administration. Summary of safety and effectiveness data: OrthospecTM Orthopedic ESWT. 2005;https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040026b.pdf.
22. Food and Drug Administration. Summary of safety and effectiveness: Orbasone Pain Relief System. 2005;https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040039b.pdf.
23. Food and Drug Administration. Summary of safety and effectiveness: SONOCUR Basic. 2002;https://www.accessdata.fda.gov/cdrh_docs/pdf/P010039b.pdf.
24. Furia JP, Rompe JD, Maffulli N, et al. Radial extracorporeal shock wave therapy is effective and safe in chronic distal biceps tendinopathy. Clin J Sport Med. Sep 2017; 27(5):430-437.
25. Gerdesmeyer L, Frey C, Vester J et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. Am J Sports Med. Nov 2008; 36(11):2100-2109.
26. Gollwitzer H, Diehl P, von Korff A et al. Extracorporeal shock wave therapy for chronic painful heel syndrome: a prospective, double blind, randomized trial assessing the efficacy of a new electromagnetic shock wave device. J Foot Ankle Surg. Sep-Oct 2007; 46(5):348-357.
27. Gollwitzer H, Saxena A, DiDomenico LA, et al. Clinically relevant effectiveness of focused extracorporeal shock wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study. J Bone Joint Surg Am. May 6 2015; 97(9):701-708.
28. Greve JM, Grecco MV, Santos-Silva PR. Comparison of radial shockwaves and conventional physiotherapy for treating plantar fasciitis. Clinics (Sao Paulo) 2009; 64(2):97-103.
29. Guler T, Yildirim P. Comparison of the efficacy of kinesiotaping and extracorporeal shock wave therapy in patients with newly diagnosed lateral epicondylitis: A prospective randomized trial.. May 2020; 23(5): 704-710.
30. Gunduz R, Malas FU, Borman P et al. Physical therapy, corticosteroid injection, and extracorporeal shock wave treatment in lateral epicondylitis. Clinical and ultrasonographical comparison. Clin Rheumatol. May 2012; 31(5):807-812.
31. Haake M, Konig IR, Decker T et al. Extracorporeal shock wave therapy for lateral epicondylitis: a randomized multicenter trial. J Bone Joint Surg Am. Nov 2002; 84-A (11):1982-1991.
32. Hao Y, Guo H, Xu Z, et al. Meta-analysis of the potential role of extracorporeal shockwave therapy in osteonecrosis of the femoral head. J Orthop Surg Res. 2018 Jul 3;13(1):166.
33. Huisstede BM, Gebremariam L, van der Sande R et al. Evidence for effectiveness of Extracorporal Shock-Wave Therapy (ESWT) to treat calcific and non-calcific rotator cuff tendinosis--a systematic review. Man Ther. Oct 2011; 16(5):419-433.
34. Ibrahim MI, Donatelli RA, Hellman M, et al. Long-term results of radial extracorporeal shock wave treatment for chronic plantar fasciopathy: A prospective, randomized,

placebo-controlled trial with two years follow-up. J Orthop Res. Jul 2017; 35(7):1532-1538.

35. Ibrahim MI, et al. Chronic plantar fasciitis treated with two sessions of radial extracorporeal shock wave therapy. Foot & Ankle International. May 2010; 31(5): 391-397.
36. Ioppolo F, Tattoli M, Di Sante L et al. Clinical improvement and resorption of calcifications in calcific tendinitis of the shoulder after shock wave therapy at 6 months' follow-up: a systematic review and meta-analysis. Arch Phys Med Rehabil. Sep 2013; 94(9):1699-706.
37. Jia G, Ma J, Wang S, et al. Long-term Effects of Extracorporeal Shock Wave Therapy on Poststroke Spasticity: A Meta-analysis of Randomized Controlled Trials.. Mar 2020; 29(3): 104591.
38. Jung YJ, Park WY, Jeon JH, et al. Outcomes of ultrasound-guided extracorporeal shock wave therapy for painful stump neuroma. Ann Rehabil Med. Aug 2014; 38(4):523-533.
39. Karanasios S, Tsamasiotis GK, Michopoulos K, et al. Clinical effectiveness of shockwave therapy in lateral elbow tendinopathy:systematic review and meta-analysis. Clin Rehabil. Apr 04 2021: 2692155211006860.
40. Kim EK, Kwak KI. Effect of extracorporeal shock wave therapy on the shoulder joint functional status of patients with calcific tendinitis. J Phys Ther Sci. Sep 2016; 28(9):2522-2524.
41. Kim HJ, Park JW, Nam K. Effect of extracorporeal shockwave therapy on muscle spasticity in patients with cerebral palsy: metaanalysis and systematic review.. Dec 2019; 55(6): 761-771.
42. Kim YS, Lee HJ, Kim YV, et al. Which method is more effective in treatment of calcific tendinitis in the shoulder? Prospective randomized comparison between ultrasound-guided needling and extracorporeal shock wave therapy. J Shoulder Elbow Surg. Nov 2014; 23(11):1640-1646.
43. Kvalvaag E, Roe C, Engebretsen KB, et al. One year results of a randomized controlled trial on radial Extracorporeal Shock Wave Treatment, with predictors of pain, disability and return to work in patients with subacromial pain syndrome. Eur J Phys Rehabil Med. Jun 27 2017.
44. Lai TW, Ma HL, Lee MS, et al. Ultrasonography and clinical outcome comparison of extracorporeal shock wave therapy and corticosteroid injections for chronic plantar fasciitis: A randomized controlled trial. J Musculoskelet Neuronal Interact. Mar 1 2018; 18(1):47-54.
45. Lee JY, Kim SN, Lee IS, et al. Effects of Extracorporeal Shock Wave Therapy on Spasticity in Patients after Brain Injury: A Meta-analysis. J Phys Ther Sci. Oct 2014; 26(10):1641-1647.
46. Lee JY, Yoon K, Yi Y, et al. Long-term outcome and factors affecting prognosis of extracorporeal shockwave therapy for chronic refractory Achilles tendinopathy. Ann Rehabil Med. Feb 2017; 41(1):42-50.
47. Li S, Wang K, Sun H, et al. Clinical effects of extracorporeal shock-wave therapy and ultrasound-guided local corticosteroid injections for plantar fasciitis in adults: A meta-

analysis of randomized controlled trials. Medicine (Baltimore). 2018 Dec;97(50):e13687.

48. Li G, Yuan W, Liu G, et al. Effects of radial extracorporeal shockwave therapy on spasticity of upper-limb agonist/antagonist muscles in patients affected by stroke: a randomized, single-blind clinical trial.. Feb 27 2020; 49(2): 246-252.
49. Liao CD, Xie GM, Tsauo JY, et al. Efficacy of extracorporeal shock wave therapy for knee tendinopathies and other soft tissue disorders: a meta-analysis of randomized controlled trials. BMC Musculoskelet Disord. 2018 Aug 2;19(1):278.
50. Liu S, Zhai L, Shi Z et al. Radial extracorporeal pressure pulse therapy for the primary long bicipital tenosynovitis a prospective randomized controlled study. Ultrasound Med Biol. May 2012; 38(5):727- 735.
51. Lizis P. Analgesic effect of extracorporeal shock wave therapy versus ultrasound therapy in chronic tennis elbow. J Phys Ther Sci. Aug 2015; 27(8):2563-2567.
52. Lou J, Wang S, Liu S, et al. Effectiveness of extracorporeal shock wave therapy without local anesthesia in patients with recalcitrant plantar fasciitis: a meta-analysis of randomized controlled trials. Am J Phys Med Rehabil. Aug 2017; 96(8):529-534.
53. Lynen N, De Vroey T, Spiegel I, et al. Comparison of peritendinous hyaluronan injections versus extracorporeal shock wave therapy in the treatment of painful Achilles' tendinopathy: a randomized clinical efficacy and safety study. Arch Phys Med Rehabil. Jan 2017; 98(1):64-71.
54. Mani-Babu S, Morrissey D, Waugh C, et al. The Effectiveness of Extracorporeal Shock Wave Therapy in Lower Limb Tendinopathy: A Systematic Review. Am J Sports Med. May 9 2014.
55. Marwan Y, Husain W, Alhajii W, et al. Extracorporeal shock wave therapy relieved pain in patients with coccydynia: a report of two cases. Spine J. Jan 2014; 14(1):e1-4.
56. Mihai EE, Dumitru L, Mihai IV, et al. Long-Term Efficacy of Extracorporeal Shock Wave Therapy on Lower Limb Post-Stroke Spasticity:A Systematic Review and Meta-Analysis of Randomized Controlled Trials. J Clin Med. Dec 29 2020; 10(1).
57. National Institute for Health and Clinical Excellence (NICE). Extracorporeal shockwave therapy for refractory tennis elbow: guidance. 2009. www.nice.org.uk/nicemedia/live/12124/45249/45249.pdf.
58. National Institute for Health and Clinical Excellence (NICE). Extracorporeal shockwave therapy for refractory Achilles tendonopathy: guidance. 2009. www.nice.org.uk/nicemedia/live/12123/45245/45245.pdf.
59. National Institute for Health and Clinical Excellence (NICE). Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome. 2011. www.nice.org.uk/nicemedia/live/12975/52604/52604.pdf.
60. National Institute of Health and Clinical Excellence (NICE). Extracorporeal shockwave lithotripsy for calcific tendonitis (tendonopathy) of the shoulder: guidance. 2003. https://www.nice.org.uk/nicemedia/live/11093/30992/30992.pdf.
61. National Institute of Health and Clinical Excellence (NICE). Extracorporeal shockwave therapy for refractory plantar fasciitis: guidance. 2009. www.nice.org.uk/nicemedia/live/11187/45188/45188.pdf.

62. Newman P, Waddington G, Adams R. Shockwave treatment for medial tibial stress syndrome: A randomized double blind sham-controlled pilot trial. J Sci Med Sport. Mar 2017; 20(3):220-224.
63. Pettrone FA, McCall BR. Extracorporeal shock wave therapy without local anesthesia for chronic lateral epicondylitis. J Bone Joint Surg Am. Jun 2005; 87(6):1297-1304.
64. Pinitkwamdee S, Laohajaroensombat S, Orapin J, et al. Effectiveness of Extracorporeal Shockwave Therapy in the Treatment of Chronic Insertional Achilles Tendinopathy.. Apr 2020; 41(4): 403-410.
65. Radwan YA, Mansour AM, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascial release. Int Orthop. Oct 2012; 36(10):2147-2156.
66. Rasmussen S, Christensen M, Mathiesen I et al. Shockwave therapy for chronic Achilles tendinopathy: a double-blind, randomized clinical trial of efficacy. Acta Orthop. Apr 2008; 79(2):249-256.
67. Rompe JD, Cacchio A, Furia JP et al. Low-energy extracorporeal shock wave therapy as a treatment for medial tibial stress syndrome. Am J Sports Med. Jan 2010; 38(1):125-132.
68. Rompe JD, Decking J, Schoellner C et al. Repetitive low-energy shock wave treatment for chronic lateral epicondylitis in tennis players. Am J Sports Med. Apr-May 2004; 32(3):734-743.
69. Schneider HP, Baca JM, Carpenter BB, et al. American College of Foot and Ankle Surgeons Clinical Consensus Statement : Diagnosis and Treatment of Adult Acquired Infracalcaneal Heel Pain. J Foot Ankle Surg. Mar-Apr 2018 ;57(2) ;370-381.
70. Schofer MD, Hinrichs F, Peterlein CD et al. High-versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy; a prospective, randomized, controlled study. Acta Orthop Beig. Aug 2009; 75(4):452-458.
71. Smith J, Sellon JL. Comparing PRP injections with ESWT for athletes with chronic patellar tendinopathy. Clin J Sport Med. Jan 2014; 24(1):88-89.
72. Sansone V, Ravier D, Pascale V, et al. Extracorporeal Shockwave Therapy in the Treatment of Nonunion in Long Bones: A Systematic Review and Meta-Analysis. J Clin Med. Apr 01 2022; 11(7).
73. Staples MP, Forbes A, Ptasznik R et al. A randomized controlled trial of extracorporeal shock wave therapy for lateral epicondylitis (tennis elbow). J Rheumatol. Oct 2008; 35(10):2038-2046.
74. Sun J, Gao F, Wang Y, et al. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: A meta-analysis of RCTs. Medicine (Baltimore). Apr 2017; 96(15):e6621.
75. Thijs KM, Zwerver J, Backx FJ, et al. Effectiveness of shockwave treatment combined with eccentric training for patellar tendinopathy: a double-blinded randomized study. Clin J Sport Med. Mar 2017; 27(2):89-96.
76. Thomas JL, Christensen JC, Kravitz SR et al. The diagnosis and treatment of heel pain: a clinical practice guideline-revision 2010. J Foot Ankle Surg. May-Jun 2010; 49(3 Suppl):S1-19.

77. van Leeuwen MT, Zwerver J, van den Akker-Scheek I. Extracorporeal shockwave therapy for patellar tendinopathy; a review of the literature. Br J Sports Med. Mar 2009; 43(3):163- 168.
78. Verstraelen FU, In den Kleef NJ, Jansen L, et al. High-energy versus low-energy extracorporeal shock wave therapy for calcifying tendinitis of the shoulder: which is superior? A meta-analysis. Clin Orthop Relat Res. Sep 2014; 472(9):2816-2825.
79. Vidal X, Morral A, Costa L et al. Radial extracorporeal shock wave therapy (rESWT) in the treatment of spasticity in cerebral palsy: a randomized, placebo-controlled clinical trial. NeuroRehabilitation. Jan 1 2011; 29(4):413-419.
80. Vidal X, Marti-Fabregas J, Canet O, et al. Efficacy of radial extracorporeal shock wave therapy compared with botulinum toxin type Ainjection in treatment of lower extremity spasticity in subjects with cerebral palsy: A randomized, controlled, cross-over study. J RehabilMed. 2020;52(6):jrm00076.
81. Wu YC, Tsai WC, Tu YK, et al. Comparative effectiveness of non-operative treatments for chronic calcific tendinitis of the shoulder: A systematic review and network meta-analysis of randomized-controlled trials. Arch Phys Med Rehabil. Apr 08 2017.
82. Wu Z, Yao W, Chen S, et al. Outcome of extracorporeal shock wave therapy for insertional Achilles tendinopathy with and without Haglund's deformity. Biomed Res Int. Nov 2016;2016:6315846.
83. Xiong Y, Xue H, Zhou W, et al. Shock-wave therapy versus corticosteroid injection on lateral epicondylitis: a meta-analysis of randomized controlled trials.. Sep 2019; 47(3): 284-289.
84. Xiong Y, Wu Q, Mi B, et al. Comparison of efficacy of shock-wave therapy versus corticosteroids in plantar fasciitis: a meta-analysis of randomized controlled trials.. Apr 2019; 139(4): 529-536.
85. Xu D, Jiang W, Huang D, et al. Comparison Between Extracorporeal Shock Wave Therapy and Local Corticosteroid Injection for Plantar Fasciitis.. Feb 2020; 41(2): 200-205.
86. Yan C, Xiong Y, Chen L, et al. A comparative study of the efficacy of ultrasonics and extracorporeal shock wave in the treatment of tennis elbow: a meta-analysis of randomized controlled trials.. Aug 06 2019; 14(1): 248.
87. Yang TH, Huang YC, Lau YC, et al. Efficacy of radial extracorporeal shock wave therapy on lateral epicondylosis, and changes in the common extensor tendon stiffness with pretherapy and posttherapy in real-time sonoelastography: a randomized controlled study. Am J Phys Med Rehabil. Feb 2017; 96(2):93-100.
88. Yao G, Chen J, Duan Y, et al. Efficacy of Extracorporeal Shock Wave Therapy for Lateral Epicondylitis: A Systematic Review and Meta-Analysis. 2020: 2064781.
89. Yin MC, Ye J, Yao M, et al. Is extracorporeal shock wave therapy clinical efficacy for relief of chronic, recalcitrant plantar fasciitis? A systematic review and meta-analysis of randomized placebo or active-treatment controlled trials. Arch Phys Med Rehabil. Aug 2014; 95(8):1585-1593.

90. Yoon SY, Kim YW, Shin IS, et al. Does the Type of Extracorporeal Shock Therapy Influence Treatment Effectiveness in Lateral Epicondylitis? A Systematic Review and Meta-analysis.. Oct 2020; 478(10): 2324-2339.
91. Yu H, Cote P, Shearer HM, et al. Effectiveness of passive physical modalities for shoulder pain: systematic review by the Ontario protocol for traffic injury management collaboration. Phys Ther. Mar 2015; 95(3):306-318.
92. Zelle BA, Gollwitzer H, Zlowodzki M et al. Extracorporeal shock wave therapy: current evidence. J Orthop Trauma. Mar 2010; 24 Suppl 1:S66-70.
93. Zhai L, Ma XL, Jiang C, et al. Human autologous mesenchymal stem cells with extracorporeal shock wave therapy for nonunion of long bones. Indian J Orthop. Sep 2016; 50(5):543-550.
94. Zhang Q, Liu L, Sun W, et al. Extracorporeal shockwave therapy in osteonecrosis of femoral head: A systematic review of now available clinical evidences. Medicine (Baltimore). Jan 2017; 96(4):e5897.
95. Zheng C, Zeng D, Chen J, et al. Effectiveness of extracorporeal shock wave therapy in patients with tennis elbow: A meta-analysis of randomized controlled trials.. Jul 24 2020; 99(30): e21189.
96. Zhiyun L, Tao J, Zengwu S. Meta-analysis of high-energy extracorporeal shock wave therapy in recalcitrant plantar fasciitis. Swiss Med Wkly. 2013; 143:w13825.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, December 2006
Medical Policy Group, July 2007
Medical Policy Group, January 2009
Available for comment January 9-February 23, 2009
Medical Policy Group, March 2010
Medical Policy Group, January 2011
Medical Policy Group, February 2011
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Medical Policy Group, February 2012
Medical Policy Group, February 2013
Medical Policy Group, February 2014
Medical Policy Group, February 2015
Medical Policy Group, July 2016
Medical Policy Group, December 2016
Medical Policy Group, July 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated effective March 24, 2020.
Medical Policy Group, August 2021
Medical Policy Group, August 2022

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.