Medical Coverage Policy | Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

EFFECTIVE DATE: 10|01|2015
POLICY LAST UPDATED: 06|21|2023

OVERVIEW

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

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

Extracorporeal shock wave therapy, using either a high- or low-dose protocol or radial ESWT, is not covered as a treatment of 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 nonunion of fractures; and avascular necrosis of the femoral head, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products

Extracorporeal shock wave therapy, using either a high- or low-dose protocol or radial ESWT, is considered not medically necessary as a treatment of 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 nonunion of fractures; and avascular necrosis of the femoral head, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

Chronic musculoskeletal conditions

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

Plantar Fasciitis
Plantar fasciitis is a very 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.

Tendinitis and Tendinopathies
Common tendinitis and tendinopathy syndromes are:

- Lateral epicondylitis ("tennis elbow")
- Shoulder tendinopathy
- Achilles tendinopathy
- Patellar tendinopathy ("jumper's knee")

Fracture Nonunion and Delayed Union
The following criteria are used to define fracture nonunion:

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

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 one characteristic of upper motor neuron dysfunction, which may be due to a variety of pathologies.

Treatment
Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal-anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases. For tendinitis and tendinopathy syndromes, conservative treatment often involves rest, activity modifications, physical therapy, and anti-inflammatory medications.

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 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 nonunion of bone fractures.

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

Currently, 6 focused ESWT devices have been approved by FDA through the premarket approval process for orthopedic use:

- OssaTron® device (HealthTronics) - Approval date: 2000. Delivery system: Electrohydraulic. Indications: chronic proximal plantar fasciitis, i.e., pain persisting >6 months and not responding to conservative management; lateral epicondylitis
- Epos™ Ultra (Dornier) - Approval date: 2002. Delivery system: Electromagnetic. Indications: plantar fasciitis.
- Sonocur® Basic (Siemens) - Approval date: 2002. Delivery system: Electromagnetic. Indications: chronic lateral epicondylitis (unresponsive to conservative therapy for >6 months)
- Orthospec™ Orthopedic ESWT (Medispec) - Approval date: 2005. Delivery system: Electrohydraulic spark-gap. Indications: Chronic proximal plantar fasciitis in patients ≥18 years of age.
- Orbasone™ Pain Relief System (Orthometrix) - Approval date: 2005. Delivery system: High-energy sonic wave. Indications: Chronic proximal plantar fasciitis in patients ≥18 years of age.
- Duolith® SD1 Shock Wave Therapy Device (Storz Medical AG) - Approval date: 2016. Delivery system: Electromagnetic. Indications: Chronic proximal plantar fasciitis in patients ≥18 years of age 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 (1300mJ/mm-2). 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 devices 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.

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome for individuals who have the following:

- plantar fasciitis
- lateral epicondylitis
- shoulder tendinopathy
- Achilles tendinopathy
- patellar tendinopathy

- medial tibial stress syndrome
- osteonecrosis of the femoral head
- nonunion or delayed union
- spasticity

CODING

Medicare Advantage Plans and Commercial Products

The following CPT codes are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

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 therapy; involving musculoskeletal system, not otherwise specified (Revised text 1/01/2022)

0102T Extracorporeal shock wave therapy; performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle (Revised text 1/01/2022)

There is no specific CPT code for low-energy or radial ESWT. The unlisted CPT code for general musculoskeletal procedure (20999) should be used.

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations
Unlisted Procedures

PUBLISHED

Provider Update, August 2023
Provider Update, October 2022
Provider Update, January 2022
Provider Update, February 2021
Provider Update, January 2020

REFERENCES

1. Dizon JN, Gonzalez-Suarez C, Zamora MT, et al. Effectiveness of extracorporeal shock wave therapy in chronic plantarfasciitis: a meta-analysis. Am J Phys Med Rehabil. Jul 2013; 92(7): 606-20. PMID 23552334
2. Aqil A, Siddiqui MR, Solan M, et al. Extracorporeal shock wave therapy is effective in treating chronic plantar fasciitis: ameta-analysis of RCTs. Clin Orthop Relat Res. Nov 2013; 471(11): 3645-52. PMID 23813184
3. Zhiyun L, Tao J, Zengwu S. Meta-analysis of high-energy extracorporeal shock wave therapy in recalcitrant plantarfasciitis. Swiss Med Wkly. 2013; 143: w13825. PMID 23832373
4. Yin MC, Ye J, Yao M, et al. Is extracorporeal shock wave therapy clinical efficacy for relief of chronic, recalcitrant plantarfasciitis? A systematic review and meta-analysis of randomized placebo or active-treatment controlled trials. Arch Phys Med Rehabil. Aug 2014; 95(8): 1585-93. PMID 24662810
5. Lou J, Wang S, Liu S, et al. Effectiveness of Extracorporeal Shock Wave Therapy Without Local Anesthesia in PatientsWith Recalcitrant Plantar Fasciitis: A Meta-Analysis of Randomized Controlled Trials. Am J Phys Med Rehabil. Aug 2017;96(8): 529-534. PMID 27977431
6. 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. PMID 28403111
7. Li S, Wang K, Sun H, et al. Clinical effects of extracorporeal shock-wave therapy and ultrasound-guided localcorticosteroid injections for plantar fasciitis in adults: A meta-analysis of randomized controlled trials. Medicine (Baltimore).Dec 2018; 97(50): e13687. PMID 30558080
8. Xiong Y, Wu Q, Mi B, et al. Comparison of efficacy of shock-wave therapy versus corticosteroids in plantar fasciitis: ameta-analysis of randomized controlled trials. Arch Orthop Trauma Surg. Apr 2019; 139(4): 529-536. PMID 30426211

9. Gollwitzer H, Saxena A, DiDomenico LA, et al. Clinically relevant effectiveness of focused extracorporeal shock wavetherapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study. J Bone Joint Surg Am. May06 2015; 97(9): 701-8. PMID 25948515
10. Gerdesmeyer L, Frey C, Vester J, et al. Radial extracorporeal shock wave therapy is safe and effective in the treatment ofchronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. Am JSports Med. Nov 2008; 36(11): 2100-9. PMID 18832341
11. Food and Drug Administration. Summary of safety and effectiveness data: OrthospecTM Orthopedic ESWT. 2005;https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040026b.pdf. Accessed April 21, 2023.
12. Food and Drug Administration. Summary of safety and effectiveness: Orbasone Pain Relief System. 2005;https://www.accessdata.fda.gov/cdrh_docs/pdf4/P040039b.pdf. Accessed April 19, 2023.
13.Radwan YA, Mansour AM, Badawy WS. Resistant plantar fasciopathy: shock wave versus endoscopic plantar fascialrelease. Int Orthop. Oct 2012; 36(10): 2147-56. PMID 22782376
14. Eslamian F, Shakouri SK, Jahanjoo F, et al. Extra Corporeal Shock Wave Therapy Versus Local Corticosteroid Injection inthe Treatment of Chronic Plantar Fasciitis, a Single Blinded Randomized Clinical Trial. Pain Med. Sep 2016; 17(9): 1722-31. PMID 27282594
15. Lai TW, Ma HL, Lee MS, et al. Ultrasonography and clinical outcome comparison of extracorporeal shock wave therapyand corticosteroid injections for chronic plantar fasciitis: A randomized controlled trial. J Musculoskelet Neuronal Interact.Mar 01 2018; 18(1): 47-54. PMID 29504578
16. Xu D, Jiang W, Huang D, et al. Comparison Between Extracorporeal Shock Wave Therapy and Local CorticosteroidInjection for Plantar Fasciitis. Foot Ankle Int. Feb 2020; 41(2): 200-205. PMID 31744313
17. Rai S, Rajauria S, Khandelwal N, et al. Intralesional Steroid Injection Versus Extracorporeal Shockwave Therapy in theTreatment of Plantar Fasciitis: A Comparative, Prospective, Case Series Study. Cureus. Jan 2023; 15(1): e33593. PMID36779116
18. Cinar E, Saxena S, Uygur F. Combination Therapy Versus Exercise and Orthotic Support in the Management of Pain inPlantar Fasciitis: A Randomized Controlled Trial. Foot Ankle Int. Apr 2018; 39(4): 406-414. PMID 29327602
19. Pisirici P, Cil ET, Coskunsu DK, et al. Extracorporeal Shockwave Therapy Versus Graston Instrument-Assisted Soft-TissueMobilization in Chronic Plantar Heel Pain: A Randomized Controlled Trial. J Am Podiatr Med Assoc. 2022; 112(6). PMID36125974
20. Bahar-Ozdemir Y, Atan T. Effects of adjuvant low-dye Kinesio taping, adjuvant sham taping, or extracorporeal shockwavetherapy alone in plantar fasciitis: A randomised double-blind controlled trial. Int J Clin Pract. May 2021; 75(5): e13993.PMID 33410228
21. Buchbinder R, Green SE, Youd JM, et al. Shock wave therapy for lateral elbow pain. Cochrane Database Syst Rev. Oct19 2005; 2005(4): CD003524. PMID 16235324
22. Dingemanse R, Randsdorp M, Koes BW, et al. Evidence for the effectiveness of electrophysical modalities for treatment ofmedial and lateral epicondylitis: a systematic review. Br J Sports Med. Jun 2014; 48(12): 957-65. PMID 23335238
23. 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. Medicine (Baltimore). Jul 24 2020; 99(30): e21189. PMID 32791694
24. Yoon SY, Kim YW, Shin IS, et al. Does the Type of Extracorporeal Shock Therapy Influence Treatment Effectiveness inLateral Epicondylitis? A Systematic Review and Meta-analysis. Clin Orthop Relat Res. Oct 2020; 478(10): 2324-2339.PMID 32332245
25. Karanasios S, Tsamasiotis GK, Michopoulos K, et al. Clinical effectiveness of shockwave therapy in lateral elbowtendinopathy: systematic review and meta-analysis. Clin Rehabil. Oct 2021; 35(10): 1383-1398. PMID 33813913

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