BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 2.01.40 Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Effective Policy Date: October 1, 2023

Original Policy Date: December 2011

Related Policies:

1.01.05 - Low Intensity Pulsed Ultrasound Fracture Healing Device
7.01.07 - Electrical Bone Growth Stimulation of the Appendicular Skeleton

Extracorporeal Shock Wave Treatment for Plantar Fasciitis and Other Musculoskeletal Conditions

Description

Extracorporeal shock wave therapy (ESWT) is a noninvasive method used to treat pain with shock or sound waves directed from outside the body onto the area to be treated (eg, the heel in the case of plantar fasciitis). Shock waves are generated at high- or low-energy intensity, and treatment protocols can include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

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 U.S. Food and Drug Administration (FDA) approval was first granted in 2002 for focused ESWT devices and in 2007 for RSW devices.

OBJECTIVE

The objective of this evidence review is to examine whether the use of extracorporeal shock wave treatment for plantar fasciitis, lateral epicondylitis, tendinopathy (shoulder, Achilles, and patellar), medial tibial stress syndrome, osteonecrosis of the femoral head, acute fracture nonunion or delayed union, or spasticity improves the net health outcome.

POLICY STATEMENT

Extracorporeal shock wave therapy using either a high- or low-dose protocol or radial extracorporeal shock wave therapy is considered **not medically necessary** as a treatment of musculoskeletal conditions, including but not limited to plantar fasciitis; tendinopathies including tendinitis of the shoulder, Achilles tendinitis, tendinitis of the elbow (lateral epicondylitis), and patellar tendinitis; stress fractures; avascular necrosis of the femoral head; delayed union and nonunion of fractures; and spasticity.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

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

FDA REGULATORY STATUS

Selected ESWT devices that have been approved or cleared by FDA are included in Table 1.

Table 1. Food and Drug Administration-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/mm^2). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which lower dose shock waves are 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.

RATIONALE

Summary of Evidence

For treatment of plantar fasciitis using extracorporeal shock wave therapy (ESWT), numerous randomized controlled trials (RCTs) were identified, including several well-designed, double-blind 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 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 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 1 month and 16 months on measures of pain and function. The most

recent RCT found that activity-related pain was lower with ESWT at 6 weeks compared to ultrasound therapy, but there was no difference in pain at rest. 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 showed 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 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 systematic reviews, relatively small RCTs with methodologic limitations (eg, heterogeneous outcomes and treatment protocols), and 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Foot and Ankle Surgeons

In 2010, Thomas et al revised guidelines on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons.[93,] 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 Foot and Ankle Surgeons clinical consensus statement, Schneider et al stated that ESWT is a safe and effective treatment for plantar fasciitis.[94,]

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.

- 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".[95,96,]
- 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".[97,]

- 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".[98,]
- A guidance issued in 2022 stated that evidence on the efficacy of ESWT for calcific tendinopathy of the shoulder is inadequate. Despite a lack of safety concerns, the ESWT should only be used in the context of research.[99,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. 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): 606-20. PMID 23552334
2. 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): 3645-52. PMID 23813184
3. 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. PMID 23832373
4. 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): 1585-93. PMID 24662810
5. 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. 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 local corticosteroid 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: a meta-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 wave therapy in the treatment of chronic plantar fasciitis: a randomized, controlled multicenter study. J Bone Joint Surg Am. May 06 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 of chronic recalcitrant plantar fasciitis: results of a confirmatory randomized placebo-controlled multicenter study. Am J Sports 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 fascial release. 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 in the 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 therapy and 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 Corticosteroid Injection 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 the Treatment of Plantar Fasciitis: A Comparative, Prospective, Case Series Study. Cureus. Jan 2023; 15(1): e33593. PMID 36779116
18. 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. PMID 29327602

19. Pisirici P, Cil ET, Coskunsu DK, et al. Extracorporeal Shockwave Therapy Versus Graston Instrument-Assisted Soft-Tissue Mobilization in Chronic Plantar Heel Pain: A Randomized Controlled Trial. J Am Podiatr Med Assoc. 2022; 112(6). PMID 36125974
20. 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. PMID 33410228
21. Buchbinder R, Green SE, Youd JM, et al. Shock wave therapy for lateral elbow pain. Cochrane Database Syst Rev. Oct 19 2005; 2005(4): CD003524. PMID 16235324
22. 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): 957-65. 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 in Lateral 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 elbow tendinopathy: systematic review and meta-analysis. Clin Rehabil. Oct 2021; 35(10): 1383-1398. PMID 33813913
26. Liu WC, Chen CT, Lu CC, et al. Extracorporeal Shock Wave Therapy Shows Superiority Over Injections for Pain Relief and Grip Strength Recovery in Lateral Epicondylitis: A Systematic Review and Network Meta-analysis. Arthroscopy. Jun 2022; 38(6): 2018-2034.e12. PMID 35093494
27. Yao G, Chen J, Duan Y, et al. Efficacy of Extracorporeal Shock Wave Therapy for Lateral Epicondylitis: A Systematic Review and Meta-Analysis. Biomed Res Int. 2020; 2020: 2064781. PMID 32309425
28. 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. J Orthop Surg Res. Aug 06 2019; 14(1): 248. PMID 31387611
29. Xiong Y, Xue H, Zhou W, et al. Shock-wave therapy versus corticosteroid injection on lateral epicondylitis: a meta-analysis of randomized controlled trials. Phys Sportsmed. Sep 2019; 47(3): 284-289. PMID 30951399
30. 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). PMID 35323612
31. 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. Niger J Clin Pract. May 2020; 23(5): 704-710. PMID 32367880
32. 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. PMID 27323324
33. 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. Jul 2016; 95(7): 495-506. PMID 26544854
34. Lizis P. Analgesic effect of extracorporeal shock wave therapy versus ultrasound therapy in chronic tennis elbow. J Phys Ther Sci. Aug 2015; 27(8): 2563-7. PMID 26357440
35. Gndz R, Malas F, 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): 807-12. PMID 22278162
36. 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): 2038-46. PMID 18792997
37. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Extracorporeal shock wave treatment for musculoskeletal indications TEC Assessments. 2003;Volume 18:Tab 5.
38. Pettrone FA, McCall BR. Extracorporeal shock wave therapy without local anesthesia for chronic lateral epicondylitis. J Bone Joint Surg Am. Jun 2005; 87(6): 1297-304. PMID 15930540
39. Angileri HS, Gohal C, Comeau-Gauthier M, et al. Chronic Calcific Tendonitis of the Rotator Cuff: A Systematic Review and Meta-analysis of Randomized Controlled Trials Comparing Operative and Non-operative Interventions. J Shoulder Elbow Surg. Apr 18 2023. PMID 37080421
40. Wu YC, Tsai WC, Tu YK, et al. Comparative Effectiveness of Nonoperative Treatments for Chronic Calcific Tendinitis of the Shoulder: A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials. Arch Phys Med Rehabil. Aug 2017; 98(8): 1678-1692.e6. PMID 28400182
41. 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. PMID 27554465
42. 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. PMID 23499780
43. Yu H, Ct 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): 306-18. PMID 25394425
44. 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): 2816-25. PMID 24872197
45. 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): 542-9. PMID 24733195
46. 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): 419-33. PMID 21396877

47. ElGendy MH, Mazen MM, Saied AM, et al. Extracorporeal Shock Wave Therapy vs. Corticosteroid Local Injection in Shoulder Impingement Syndrome : A Three-Arm Randomized Controlled Trial. Am J Phys Med Rehabil. Jun 01 2023; 102(6): 533-540. PMID 36730000
48. Lee HW, Kim JY, Park CW, et al. Comparison of Extracorporeal Shock Wave Therapy and Ultrasound-Guided Shoulder Injection Therapy in Patients with Supraspinatus Tendinitis. Clin Orthop Surg. Dec 2022; 14(4): 585-592. PMID 36518938
49. 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 2018; 54(3): 341-350. PMID 28655271
50. Kvalvaag E, Brox JI, Engebretsen KB, et al. Effectiveness of Radial Extracorporeal Shock Wave Therapy (rESWT) When Combined With Supervised Exercises in Patients With Subacromial Shoulder Pain: A Double-Masked, Randomized, Sham-Controlled Trial. Am J Sports Med. Sep 2017; 45(11): 2547-2554. PMID 28586628
51. 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. PMID 27799684
52. 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): 1640-6. PMID 25219475
53. Schofer MD, Hinrichs F, Peterlein CD, et al. High- versus low-energy extracorporeal shock wave therapy of rotator cuff tendinopathy: a prospective, randomised, controlled study. Acta Orthop Belg. Aug 2009; 75(4): 452-8. PMID 19774810
54. 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): 727-35. PMID 22425375
55. 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. Mar 2015; 43(3): 752-61. PMID 24817008
56. 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. PMID 23386759
57. 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. PMID 16239807
58. 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): 249-56. PMID 18484252
59. Stania M, Juras G, Marszałek W, et al. Analysis of pain intensity and postural control for assessing the efficacy of shock wave therapy and sonotherapy in Achilles tendinopathy - A randomized controlled trial. Clin Biomech (Bristol, Avon). Jan 2023; 101: 105830. PMID 36469960
60. Abdelkader NA, Helmy MNK, Fayaz NA, et al. Short- and Intermediate-Term Results of Extracorporeal Shockwave Therapy for Noninsertional Achilles Tendinopathy. Foot Ankle Int. Jun 2021; 42(6): 788-797. PMID 33451253
61. Pinitkwamdee S, Laohajaroensombat S, Orapin J, et al. Effectiveness of Extracorporeal Shockwave Therapy in the Treatment of Chronic Insertional Achilles Tendinopathy. Foot Ankle Int. Apr 2020; 41(4): 403-410. PMID 31924120
62. 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. PMID 27639439
63. Stania M, Krl T, Marszałek W, et al. Treatment of Jumper's Knee with Extracorporeal Shockwave Therapy: A Systematic Review and Meta-Analysis. J Hum Kinet. Oct 2022; 84: 124-134. PMID 36457482
64. 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. Aug 02 2018; 19(1): 278. PMID 30068324
65. 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): 163-8. PMID 18718975
66. 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. PMID 27347857
67. Smith J, Sellon JL. Comparing PRP injections with ESWT for athletes with chronic patellar tendinopathy. Clin J Sport Med. Jan 2014; 24(1): 88-9. PMID 24366015
68. 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. PMID 27640922
69. 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): 125-32. PMID 19776340
70. 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. PMID 20971968
71. 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. Jul 03 2018; 13(1): 166. PMID 29970103
72. 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. PMID 28121934
73. 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): 1247-51. PMID 19609482
74. 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). PMID 35407583
75. Zelle BA, Gollwitzer H, Zlowodzki M, et al. Extracorporeal shock wave therapy: current evidence. J Orthop Trauma. Mar 2010; 24 Suppl 1: S66-70. PMID 20182240

76. Wang CJ, Liu HC, Fu TH. The effects of extracorporeal shockwave on acute high-energy long bone fractures of the lower extremity. Arch Orthop Trauma Surg. Feb 2007; 127(2): 137-42. PMID 17053946
77. 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): 2589-97. PMID 19884432
78. 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. PMID 27746499
79. 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). PMID 33383655
80. Cabanas-Valds 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. Clin Rehabil. Sep 2020; 34(9): 1141-1156. PMID 32513019
81. 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. J Stroke Cerebrovasc Dis. Mar 2020; 29(3): 104591. PMID 31899073
82. Kim HJ, Park JW, Nam K. Effect of extracorporeal shockwave therapy on muscle spasticity in patients with cerebral palsy: meta-analysis and systematic review. Eur J Phys Rehabil Med. Dec 2019; 55(6): 761-771. PMID 31615195
83. 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): 1641-7. PMID 25364134
84. Brunelli S, Gentileschi N, Span B, et al. Effect of Early Radial Shock Wave Treatment on Spasticity in Subacute Stroke Patients: A Pilot Study. Biomed Res Int. 2022; 2022: 8064548. PMID 35909493
85. Vidal X, Mart-Fàbregas J, Canet O, et al. Efficacy of radial extracorporeal shock wave therapy compared with botulinum toxin type A injection in treatment of lower extremity spasticity in subjects with cerebral palsy: A randomized, controlled, cross-over study. J Rehabil Med. Jun 30 2020; 52(6): jrm00076. PMID 32556354
86. 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. Age Ageing. Feb 27 2020; 49(2): 246-252. PMID 31846499
87. Wu YT, Yu HK, Chen LR, et al. Extracorporeal Shock Waves Versus Botulinum Toxin Type A in the Treatment of Poststroke Upper Limb Spasticity: A Randomized Noninferiority Trial. Arch Phys Med Rehabil. Nov 2018; 99(11): 2143-2150. PMID 30392753
88. 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. 2011; 29(4): 413-9. PMID 22207070
89. 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. PMID 24094989
90. 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. PMID 34091468
91. 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): 523-33. PMID 25229031
92. 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. PMID 27893487
93. 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. 2010; 49(3 Suppl): S1-19. PMID 20439021
94. 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. 2018; 57(2): 370-381. PMID 29284574
95. National Institute for Health and Care Excellence (NICE). Extracorporeal shockwave therapy for refractory tennis elbow [IPG313]. 2009; https://www.nice.org.uk/guidance/ipg313. Accessed April 17, 2023.
96. National Institute for Health and Care Excellence (NICE). Extracorporeal shockwave therapy for refractory plantar fasciitis: guidance [IPG311]. 2009; https://www.nice.org.uk/guidance/ipg311. Accessed April 18, 2023.
97. National Institute for Health and Care Excellence (NICE). Extracorporeal shockwave therapy for refractory greater trochanteric pain syndrome [IPG376]. 2011; https://www.nice.org.uk/guidance/ipg376. Accessed April 19, 2023.
98. National Institute for Health and Care Excellence (NICE). Extracorporeal shockwave therapy for Achilles tendinopathy [IPG571]. 2016; https://www.nice.org.uk/guidance/ipg571. Accessed April 20, 2023.
99. National Institute for Health and Care Excellence. Extracorporeal shockwave therapy for calcific tendinopathy in the shoulder. Published November 2022. https://www.nice.org.uk/guidance/ipg742. Accessed April 21, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	ESWT is not medically necessary
June 2013	Replace policy	Policy updated with literature review, references 11, 19, 20, 21, 24, 25 and 36 added; some references removed. No change to policy statements. Related policies added.
June 2014	Replace policy	Policy updated with literature review, references 5-7, 24-25, 30 and 34 added. No change to policy statement.
June 2015	Replace policy	Policy updated with literature review; References 8, 15, 17, 28, 31, 34, 40, 45, 47-48, and 54-55 added. Editorial changes made for clarity to policy statements; intent of policy statements unchanged
December 2016	Replace policy	Policy updated with literature review through May 2, 2016; references 9, 27-28, and 30 added. Policy statements unchanged.
September 2018	Replace policy	Policy updated with literature review through April 30, 2018; references 5-6, 18, 20-22, 27, 34-35, 37, 41-43, 45-46, 51-53, 56-58, 61, 64, 68 and 79. Policy statement unchanged.
September 2019	Replace policy	Policy updated with literature review through April 3, 2019; references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through September 2, 2020; references added. Policy statement unchanged.
September 2021	Replace policy	Policy updated with literature review through April 21, 2021; references added. Policy statement unchanged.
September 2022	Replace policy	Policy updated with literature review through May 2, 2022; references added. Policy statement unchanged.
September 2023	Replace policy	Policy updated with literature review through April 21, 2023; references added. Policy statement unchanged.