

VHA Office of Integrated Veteran Care
Clinical Determination and Indication
Extracorporeal Shock Wave Therapy for Musculoskeletal Conditions

CDI Number: 00016

Original Effective Date: November 1, 2024

Last Review Date: November 1, 2024

I. Disclaimer

This document is currently in draft and is intended to be used as a reference for non-VA providers and not intended to replace clinical judgment when determining care pathways. These guidelines do not guarantee benefits or constitute medical advice.

II. Clinical Determinations and Indications

a. Indications for Extracorporeal Shock Wave Therapy

High-energy extracorporeal shock wave therapy (ESWT) is generally considered **investigational and experimental**; however, it is U.S. Food and Drug Administration (FDA)-approved for the treatment of chronic plantar fasciitis and lateral epicondylitis of the elbow.

i. Indications for Treatment of Chronic Plantar Fasciitis

High-energy ESWT may be considered medically necessary for chronic plantar fasciitis when **ALL** the following conditions are met:

- A diagnosis of chronic plantar fasciitis for at least six months
- Veteran has progressed through and failed six months of appropriate conservative therapy for chronic plantar fasciitis
 - Must have tried multiple, cohesive, and comprehensive conservative therapies
 - E.g., Prosthetics (off the shelf inserts or night splint), pharmaceuticals (topical and/or oral NSAIDs), supportive shoe gear, physical therapy, and/or stretching and icing three times a day
- Used in conjunction with standard treatment for chronic plantar fasciitis

ii. Indications for Treatment of Chronic Lateral Epicondylitis of the Elbow

High-energy ESWT may be considered **medically necessary** for chronic lateral epicondylitis of the elbow when **ALL** the following conditions are met:

- A diagnosis of chronic lateral epicondylitis
- Veteran has experienced elbow pain for 6 months
- Veteran has progressed through and failed to respond to at least two of following appropriate conventional methods for treating elbow pain:
 - At least 4 weeks of physical/occupational therapy
 - At least 4 weeks course of NSAIDs
 - Local steroid injections

b. Limitations/Exclusions

The following procedures are unproven for the treatment of chronic plantar fasciitis due to insufficient evidence of efficacy and safety.

- Low-energy ESWT

Conditions/indications for which high-energy ESWT is **not medically necessary** include, but are not limited to, the following:

- Calcific tendinopathy of the shoulder
- Achilles tendinopathy
- Iliotibial band (ITB) syndrome
- Medial elbow tendinopathies (medial epicondylitis)
- Greater trochanteric pain syndrome
- Patellar tendinopathy
- Fractures and delayed union/non-unions of the bone
- Osteonecrosis of the femoral head

For all conditions/indications not listed in section II.a. of this document, high-energy ESWT is considered **not medically necessary** due to insufficient evidence of efficacy and safety.

c. Description of Treatment

Extracorporeal shock wave therapy is a non-invasive procedure that uses acoustic shock waves to help treat pain and stimulate healing (for example, osteogenic, neovascularization, protein synthesis, cell proliferation, calcium destruction) of the affected area. There are three energy categories for ESWT; low, medium, and high based on the amount of energy used. There are two kinds of shock waves; focal (higher intensity; electrohydraulic,

piezoelectric, or electromagnetic with a negative phase; effects reach deeper) and radial (lower intensity, pneumatic without a negative phase, effects more superficial).

Extracorporeal shock wave therapy's therapeutic mechanism in musculoskeletal conditions is not completely known; however, some theories include:

- The shock waves disrupt fibrous tissue and promote revascularization
- The shock waves break up calcified deposits, loosen structures, and promote calcium resorption, resulting in decreased pain and improved function

III. Background and Supporting Information

The following information is for reference purposes only in accordance with the medical benefits package outlined in 38 C.F.R. § 17.38 (b). Each subsection supports VA's determinations for medical necessity and alignment with generally accepted standards of medical practice.

a. Background Information

Plantar fasciitis, defined as inflammation of the plantar fascia in the foot, is the most common condition causing heel pain and occurs in approximately 10% of the U.S. population. Plantar fasciitis may be caused by a number of factors, including the structure of the foot, heel cord (calf) and hamstring tightness, the type of shoes worn, use and overuse of the feet, conditioning, exercise technique, and the type of surface being walked on. This condition is usually diagnosed by a physical examination and review of medical history.

Traditional treatment options often include stretching and physical therapy, icing and non-steroidal anti-inflammatory medications, and a combination of activity modification and orthotics.

b. Research, Clinical Trials, and Evidence Summaries

Clinical studies have found ESWT to be an effective treatment for some musculoskeletal conditions, such as chronic plantar fasciitis and chronic lateral epicondylitis of the elbow. This therapy has been found to be beneficial in patients when used in conjunction with other physical therapies.

Extracorporeal shockwave therapy has proven to be a cost-effective treatment for plantar fasciitis while demonstrating long-term success.

Al-Siyabi et al. (2022) completed a systematic review and meta-analysis to compare the outcomes of ESWT versus ultrasound therapy for the treatment of plantar fasciitis. Seven studies, including randomized controlled trials and observational studies, resulted in a total of 369 patients. The results of this meta-analysis suggest that ESWT is a superior option over ultrasound

therapy for the treatment of patients with plantar fasciitis. Outcomes showed ESWT was proven to improve the pain activity and intensity, primary efficacy success rate, activity limitations, and patient satisfaction. Additionally, ESWT does not worsen morning pain, functional impairment, American Orthopaedic Foot and Ankle Society (AOFAS) scale score, or plantar fascial thickness compared to ultrasound therapy.

De la Corte-Rodríguez et al. (2023) performed a narrative review of current literature from PubMed, the Cochrane Database, EMBASE, CINAHL, and PEDro containing “ESWT for musculoskeletal pain (MSK).” A total of 3,517 studies were initially identified of which 93 were included in the final review. The reviewers aimed to provide updated information on the function of ESWT in the treatment of different pathologies that cause MSK pain. The purpose was to review possible new mechanisms of action, update the level of evidence for known indications, and assess possible new indications that have emerged in recent years. The current literature indicates ESWT is a safe and effective treatment for numerous MSK pathologies when conservative treatment has failed. Minimal adverse effects were reported. Extracorporeal shock wave therapy can be used alone or in conjunction with other physical therapies such as eccentric strengthening exercises or static stretching, which can enhance its therapeutic effect.

Tognolo et al. (2022) studied plantar fasciitis in an open label randomized control clinical trial. Thirty patients were included in this limited study. It was noted that ESWT was used on the plantar fascia as well as several myofascial points of the entire effected limb. It was hypothesized that plantar fasciitis was a result of an altered force along the entire body system and needed correction in multiple areas to alleviate pain. During the study, patients who received ESWT were found to have an overall reduction in pain. This limited study showed favorable results in recovery time and pain reduction through ESWT treatment and may indicate ESWT is more effective when used for “re-equilibrium of the body.”

Schroeder et al. (2021) outlined management guidelines and recommendations for use of ESWT in sports medicine injuries. The team highlights that although lateral epicondylitis is an FDA-approved indication for ESWT, current studies show mixed treatment efficacy. A meta-analysis of five RCTs comparing ESWT to ultrasound therapy showed statistically significant improvement in short-term pain and grip strength. The recommendation from this guideline is treatment of lateral epicondylitis may be indicated in cases in which other therapies have been unsuccessful. ESWT has been found to significantly improve short term pain (at 1, 3, and 6 months) and grip strength (at 3 months) but not in function (1-3 months) compared to ultrasound. ESWT can be painful during treatment of lateral epicondylitis and may not always be

tolerated. It is recommended to adjust the energy level to keep the patient's pain level tolerable and to consider starting at a lower energy level with gradual increase in dosage.

c. U.S. Food & Drug Administration (FDA) Information

VA generally only approves use of medical devices that have received at least FDA clearance for 510(k) Premarket Notification. The FDA has determined these Class II devices are substantially equivalent (SE) to legally marketed predicate devices and may be marketed in the U.S.

To search for devices that have received FDA 510(k) clearance or Premarket Approval (PMA), please visit the [FDA Devices database](#).

d. Medicare Coverage Determinations

Available Medicare coverage determinations are listed below as a resource. VA and Medicare are governed by separate laws and regulations; thus, VA coverage determinations may be different.

Local coverage determinations from Palmetto GBA considers ESWT not reasonable or necessary for the treatment of musculoskeletal conditions.

NCD Number	Name	Effective Date
None	N/A	N/A

LCD Number	Contractor	Original/Revision Effective Date
L38775	Palmetto GBA	09/12/2024

- NCD: National Coverage Determination
- LCD: Local Coverage Determination

e. TRICARE Policy Manual

Available TRICARE coverage determinations are listed below as a resource. VA and TRICARE are governed by separate laws and regulations; thus, VA coverage determinations may be different.

[TRICARE Policy Manual 6010.60-M, Chapter 4, Section 6.1](#)

- **4.8:** High Energy Extracorporeal Shock Wave Therapy (HE ESWT) for the treatment of plantar fasciitis is covered when all of the following conditions are met:
 - Patients have chronic plantar fasciitis of at least six months duration

- Patients have undergone and failed six months of appropriate conservative therapy
- HE ESWT is defined as Energy Flux Density (EFD) greater than 0.12 millijoules per square millimeter (mJ/mm²)
- **5.8:** Low Energy (LE) or radial ESWT for the treatment of plantar fasciitis is unproven. Any form of ESWT for the treatment of lateral epicondylitis is unproven

IV. Definitions

Term	Definition
Avascular	A condition in which there is a decreased or loss of blood flow to tissue
Eccentric strengthening exercises	Exercises that focus on movements, or phases of a movement, that lengthen the muscles
Osteonecrosis	A condition in which a lack of blood supply causes the bone to be deprived of nutrients and decay

V. References

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U.S. Food & Drug Administration Devices @ FDA Database. (n.d.). Retrieved February 14, 2023, from <https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm>

VI. CDI History/Revision Information

- Explanation of changes to the CDI

Revision Type	Date of Revision	Update(s) Made to CDI
	MM/DD/YYYY	
	MM/DD/YYYY	