Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal/Orthopedic Indications

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DEFINITION

Extracorporeal shock wave therapy (ESWT) describes noninvasive pulses of high-pressure shock waves applied directly to specific areas of the body. For injuries and pain, the purpose of ESWT is to reduce pain and promote healing. Also, ESWT can be used to break up calcium deposits and has been proposed as a noninvasive option for patients who have failed conventional medical therapy.¹

ESWT involves the delivery of either high-energy (HE ESWT) or low-energy (LE ESWT) shock waves, and may also be called radial ESWT or (RSWT). HE ESWT (with energy flux density [EFD]>0.12 millijoules per square millimeter [mJ/mm²]) may provide a moderate degree of pain relief in select patients. However, LE ESWT (EFD ≤ 0.12mJ/mm²) produced only inconsistent relief.²

While the mechanism of action that allows ESWT to undermine the pain process remains unknown, one theory involves the possibility of ESWT increasing blood flow and decreasing inflammation in the affected area thus reducing pain. The second theory is that ESWT damages cell membranes involved in the transmission of pain signals.³

Conventional/conservative medical therapy mentioned in this or any other section of this Coverage Guideline may include one or more of the following:

- Activity modification
- Anti-inflammatory medications
- Applications of heat or cold
- Braces, heel cups or other over-the-counter orthotics
- Physical therapy
- Rest
• Steroid injections.

**COVERAGE CRITERIA**

ESWT for plantar fasciitis is not currently considered medically necessary or is considered experimental / investigational for all members including but not limited to the following:

- High Energy Extracorporeal Shock Wave Therapy (HE ESWT) for members with chronic plantar fasciitis of at least six-months duration who have failed appropriate conservative therapy.
- Low Energy Extracorporeal Shock Wave Therapy (LE ESWT) for members with chronic plantar fasciitis of at least 6-months duration who have failed appropriate conservative therapy (See Definition section).
- Radial pneumatic ESWT in members chronic plantar fasciitis of at least 6-months duration who have failed appropriate conservative therapy.
- ESWT in members who have specific contraindications to ESWT, such as pregnancy and/or bleeding tendencies
- ESWT in members with plantar fasciitis of less than six-months duration.

ESWT is not currently considered medically necessary or is considered experimental / investigational for any indication/condition including but not limited to:

- Achilles tendonitis
- Chronic lateral epicondylitis (tennis elbow)
- Chronic medial epicondylitis (golfer’s elbow)
- Chronic tendinitis of the shoulder
- Peyronie’s disease
- Nonhealing wounds

**MEDICAL BACKGROUND**

Extracorporeal shock wave therapy (ESWT) has been proposed as a treatment option for chronic pain conditions as well as calcifications that have failed to respond to conservative treatment. Among the proposed indications for ESWT are chronic medial epicondylitis, chronic lateral epicondylitis, chronic tendonitis of the shoulder, Peyronie’s disease, and wound healing. ESWT is performed as an outpatient procedure, usually requiring anywhere from one to five treatments depending on the energy level administered.

Preliminary evidence supported the use of ESWT in a variety of clinical settings, however, subsequent evidence has resulted in the procedure being considered unproven for all indications. The current body of evidence-based, peer-reviewed literature has not demonstrated the safety and efficacy of ESWT over standard treatment and/or a placebo for any indication.
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Plantar fasciitis was among the most promising indication for ESWT, particularly high energy (HE ESWT) for patients who had failed to improve following six months of conventional/conservative management.

Surgical treatments are usually recommended for plantar fasciitis following a failure to respond to conventional/conservative management. ESWT was once proposed as an alternative to surgical treatment for plantar fasciitis. An updated Hayes technology report published on October 20, 2015 rated high energy (HE) ESWT for the treatment of plantar fasciitis as “B”. Given the Food and Drug Administration (FDA) guidelines for ESWT that define chronic plantar fasciitis as symptom duration of 6 months or more, the majority of published studies evaluated the use of ESWT in patients with chronic plantar fasciitis. However, the Hayes rating cautions the use of ESWT, stating that “open questions remain as to how HE ESWT compares with surgical treatment, and optimal treatment parameters are not yet established.” A recent report published by UpToDate states that ESWT should not be used in routine care for the treatment of plantar fasciitis due to conflicting results in the evidence-based, peer-reviewed literature.

In a double blind randomized controlled study of 25 patients with chronic plantar fasciitis, no difference in outcomes was reported for ESWT as compared to a sham procedure. In a prospective, randomized, controlled, observer-blinded study of 132 patients comparing ESWT and corticosteroid injection (CSI), CSI was found to be consistently more effective. In a 2013 meta-analysis including only prospective randomized controlled trials, seven studies were evaluated with 369 patients included in the placebo arm and 294 in the ESWT arm. However, this analysis included results from studies in which different types of ESWT were used including high and low energy as well as RSWT, and the treatment programs also lacked uniformity. The authors also noted that given the pain associated with ESWT, maintaining the blind would be difficult between the two arms. Although the ESWT group did report better than or at least comparable outcomes in pain reduction and improvements functional status as compared to the sham group, follow up periods were short, leaving many questions regarding the long-term safety and efficacy of ESWT. Another 2013 meta-analyses evaluated 11 randomized controlled trials comparing results from patients undergoing both LE ESWT and HE ESWT to sham procedures. Although these authors noted that moderate and high intensity ESWT were more effective in improving functional outcomes, they also cautioned the results given because a variety of dose intensities were studied and follow up time periods were not uniform. This study noted that further research is necessary to determine the appropriate intensity and frequency of ESWT. ESWT has been used for various orthopedic conditions in European countries since the late 1980s. However, weak published evidence has prevented the widespread use for these indications in the US. Chronic lateral epicondylitis, otherwise known as tennis elbow, is an example of an indication for which ESWT was proposed. There is no consensus on the optimal treatment for chronic lateral epicondylitis. Surgical treatments include percutaneous release of the extensor tendons, excision of pathologic tissue and arthroscopic debridement. Emerging studies demonstrate the possibility of using ESWT to treat Achilles tendonitis. A 2009 study compared the use of ESWT to physical therapy at 4 months follow up, in which ESWT outperformed in all outcome measures. At 13 to 24 months follow up, ESWT demonstrated a success rate of 76%. These encouraging findings are few and far between, which prompted the recommendation in 2012 for more studies regarding the role of ESWT as a possible treatment option for Achilles tendonitis. A review of currently available peer-reviewed literature yielded no significant new data exploring the role of ESWT for Achilles tendonitis. A 2009 updated Hayes technology report first published in 2005 rated ESWT for lateral
epicondylitis as C and D. No meaningful evidence has been published in peer-reviewed literature following the last Hayes report. A 2013 review of both lateral epicondylitis and medial epicondylitis, otherwise known as golfer’s elbow, found conflicting evidence for the effectiveness of ESWT versus placebo, percutaneous tenotomy and physical therapy on short-term, mid-term and long-term follow-up.\textsuperscript{24}

Chronic tendonitis of the shoulder was last evaluated by Hayes in 2009, which was the last update to the initial 2005 report. The ratings for ESWT for shoulder indications were C and D.\textsuperscript{25} Little has been published since that time. A 2011 review found that the majority of studies seem to originate from the same European countries and research groups. The review also found that the inferior quality of these studies and short follow up periods made it difficult to comment on the safety and efficacy of ESWT for this indication.\textsuperscript{26}

A 2015 report from Hayes evaluated ESWT for use in nonhealing wounds. This report noted that only a small body of literature was available, including 11 studies, in which conflicting results were published.\textsuperscript{27} Following this report, several studies have evaluated ESWT for various types of wounds, muscle injury, and nerve injury. A 2016 prospective, single-blind, placebo-controlled study of 40 patients with burn scar pain who had failed to improve despite standard therapy did show improvements in the ESWT arm over the sham study arm according to patient reported pain scores.\textsuperscript{28}

**REGULATORY INFORMATION**

As of December 8, 2009 the FDA had approved the following ESWT devices:

- The Ossatron\textsuperscript{®} lithotripter, an electrohydraulic device approved for treatment of plantar fasciitis and lateral epicondylitis
- The Epos\textsuperscript{™} Ultra, an electromagnetic device approved for treatment of chronic plantar fasciitis
- The SONOCUR\textsuperscript{®} Basic, an electromagnetic device approved for treatment of chronic lateral epicondylitis

By December 2, 2013, four more devices had been approved:\textsuperscript{29}

- The EMS Swiss Dolorcast
- The Orbasone Pain Relief system
- The Orthospec ESWT System, and,
- The Dornier Epos Ultra

No legislative mandates were found for coverage of ESWT in Kentucky or Indiana.\textsuperscript{30}

**Baptist Health Plan Coverage Guidelines** are created to provide members and providers with peer-reviewed, current medical information.

State and federal laws/mandates and contract language have priority over Coverage Guidelines and must be taken into consideration before eligibility for coverage is determined.

Baptist Health Plan Coverage Guidelines may or may not mirror Centers for Medicare & Medicaid Services benefits or coverage offered by any other health insurance company.
For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern. In addition, coverage for Medicare Advantage members may differ. This is a result of applicable coverage statements by the Center for Medicare and Medicaid Services (CMS). The National Coverage Determinations, Local Coverage Determinations, and Local Medical Review Policies may be found at the CMS website, [http://www.cms.gov](http://www.cms.gov). Please note that for all plans, the member’s health plan benefits that are in effect on the rendered date of service must be used in coverage determinations.

## COVERAGE DETAIL

CODES INCLUDE BUT MAY NOT BE LIMITED TO THE FOLLOWING

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<th>Category III CPT® Codes</th>
<th>Description</th>
<th>Coverage Information</th>
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<td>0019T</td>
<td>Extracorporeal shock wave therapy; involving musculoskeletal system, not otherwise specified, low energy</td>
<td>Is medically necessary when criteria are met</td>
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<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified; high energy</td>
<td>Is medically necessary when criteria are met</td>
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<td>0102T</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational</td>
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<th>CPT® Codes</th>
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<tr>
<td>28890</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, or other qualified health care professional, requiring anesthesia other than local, including ultrasound guidance involving the plantar fascia</td>
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<th>ICD.10® Procedure Codes</th>
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<td>Shock Wave Therapy, Musculoskeletal, Single</td>
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<td>ICD.10© Codes</td>
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<td>M25.511-M25.529, M25.571-M25.579</td>
<td>Pain in joint of shoulder region [subacromial impingement syndrome]</td>
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<td>Stress fracture</td>
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<td>Calcification and ossification of muscle, unspecified</td>
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<td>Other synovitis and tenosynovitis, ankle and foot</td>
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<td>Plantar fascial fibromatosis</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational</td>
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<td>M75.00 – M75.02</td>
<td>Adhesive capsulitis of shoulder</td>
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<td>M75.100-M75.22, M75.40-M75.95</td>
<td>Rotator cuff syndrome of shoulder and allied disorders</td>
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<td>M75.30-M75.32</td>
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<td>M77.10 – M77.12</td>
<td>Lateral epicondylitis</td>
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<td>Calcaneal spur</td>
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<td>N48.6</td>
<td>Peyronie’s disease</td>
<td>Is not currently considered medically necessary or is considered experimental / investigational</td>
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**REFERENCES**

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Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal/Orthopedic Indications
12/08/16; 09/11/14; 12/08/09; 11/09/06; 06/01/05


SEARCH TERMS

Chronic lateral epicondylitis
Chronic plantar fasciitis
Chronic tendonitis of the shoulder
Heel pain
High Energy Extracorporeal Shock Wave Therapy (HE ESWT)
Low Energy Extracorporeal Shock Wave Therapy (LE ESWT)
Peyronie’s disease.
Radial ESWT (RSWT)