Extracorporeal Shock Wave Therapy Indications (Musculoskeletal and Soft Tissue)

Policy Number: 2016M0045B  Effective Date: May 1, 2016

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INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual® Guidelines, to assist us in administering health benefits. The InterQual® Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
**POLICY DESCRIPTION:**

This policy describes the use of extracorporeal shock wave therapy (ESWT) as a noninvasive treatment for individuals with epicondylitis, chronic calcific rotator cuff tendonitis, and/or chronic plantar fasciitis.

Lateral epicondylitis, sometimes called tennis elbow, is a painful condition caused by a variety of sports activities and occupations that involve overuse of the tendons that join the forearm muscles on the outside of the elbow. Rotator cuff tendonitis is an inflammation of a group of muscles in the shoulder together with an inflammation of the lubrication mechanism. Plantar fasciitis refers to inflammation of tissue on the sole of the foot (the plantar fascia), and is a common cause of sharp pain in the heel thought to develop as a result of repetitive strain on the ligament.

There are a number of conservative treatments for these conditions, including avoidance of activities with high impact, taping, casting, ice, heel cups or pads, physical therapy, exercise programs, night splints, bracing, nonsteroidal anti-inflammatory drugs (NSAIDs), orthoses, shoe modifications, and steroid injections. None of these treatments is universally effective although patients generally respond to nonoperative treatment and time.

ESWT is a noninvasive treatment for patients with these conditions that have not responded to any of the above conservative therapies. ESWT involves delivery of shock waves to the painful region with the goal of reducing pain, increasing function, and promoting healing of the affected soft tissue.

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**COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:**

Extracorporeal shock wave therapy (ESWT), whether High-Energy (HE) or Low-Energy (LE), is considered **EXPERIMENTAL AND/OR INVESTIGATIONAL and NOT MEDICALLY NECESSARY** for the following indications (not an all-inclusive list) because there is insufficient evidence of effectiveness of ESWT for these indications in the medical literature:

- Chronic plantar fasciitis
- Chronic lateral epicondylitis
- Chronic calcific rotator cuff tendonitis
- Achilles tendonitis (tendinopathy)
- Calcaneal spur
- Delayed or nonunion of fractures
- Erectile dysfunction
- Hammer toe
- Low back pain
- Osteonecrosis of the femoral head
- Patellar tendinopathy
- Peyronie's disease
- Stress fractures
- Tenosynovitis of the foot or ankle
- Tibialis tendinitis
Clinical & Quality Management

MEDICAL POLICY

Clinical Considerations:

- Wound healing (including burn wounds)
- Other musculoskeletal indications.

**Clinical Considerations:**

- Alternatives to extracorporeal shock wave therapy (ESWT) include, but may not be limited to, the following:
  - Home exercises
  - Immobilization
  - Night splints
  - Orthotics
  - Padding and/or taping of the heel
  - Prescription drug therapy
  - Physical therapy and Occupational Therapy

- Contraindications:
  - Contraindications for ESWT include:
    - Previous proximal plantar fascia surgery
    - Neurological or vascular insufficiencies
    - Nerve entrapment syndrome
    - History of plantar fascia rupture
    - Medications that may prolong or interfere with blood clotting
    - History of bleeding problems

ESWT should also be used with caution or avoided in patients with diabetes, open growth plates, tumors, osteoporosis, rheumatoid arthritis, infection, a pacemaker, a cardiac stent, and in pregnant patients.

- Possible Complications: Adverse events were more common among patients treated with full-dose extracorporeal shock wave therapy (ESWT) than those allocated to placebo, but all adverse events reported in the reviewed studies were transient. These consisted primarily of redness of the skin at the treatment site, increased pain or discomfort during or just after treatment, swelling, and bruising. Less common adverse events, some of which may not be related to treatment, included nausea, dizziness, hair loss, hematoma, paresthesia, petechia, back pain, edema, spasm, and sleep disturbances. Some studies that used nerve block anesthesia reported transient neurological symptoms.

**BACKGROUND:**

**Plantar fasciitis (PF):** PT refers to inflammation of the connective tissue on the sole of the foot (the plantar fascia), which may occur as a result of overuse of the plantar fascia. Plantar fasciitis is a common cause of heel pain, and affects approximately 10% of the United States population over the course of a lifetime. Plantar fasciitis is thought to develop as a result of repetitive strain on the ligament. High arches, flat feet, overweight, and lifestyles involving long periods of standing and walking may be risk factors. The condition is more likely in middle-aged individuals and in women. It is often referred to as “heel spurs” because in
50% to 60% of patients, osseous spurs, or exostosis, can develop on the calcaneus as a result of stretching of the periosteum. Plantar fasciitis may have several different clinical presentations but generally causes sharp pain in the heel that is more severe first thing in the morning or after an extended period of rest, and decreases gradually with walking. Although pain may occur along the entire course of the plantar fascia, it is usually limited to the inferior medial aspect of the calcaneus, at the medial process of the calcaneal tubercle. There is generally no history of trauma. Although plantar fasciitis occurs in both men and women, it is more common in women.

Plantar fasciitis often gradually resolves in most patients within 12 months of onset. Approximately 10% of patients experience persistent, disabling symptoms. The goals of therapy are to alleviate pain and restore function. There are a number of conservative treatments for plantar fasciitis, including avoidance of activities with high impact on the heel, taping, casting, ice, heel cups or pads, physical therapy, exercise programs, night splints, nonsteroidal anti-inflammatory drugs (NSAIDs), orthoses, shoe modifications, and steroid injections. None of these treatments is universally effective, and some patients suffer from chronic pain, despite aggressive and consistent medical treatment. Repeated injections of analgesics and cortisone are painful and may lead to several complications, including rupture of the plantar fascia. Surgical therapy is sometimes performed in patients who fail to respond to a lengthy period of conservative treatment, and involves a plantar fasciotomy, in which the plantar fascia is partially transected. However, surgery does not always relieve the pain, may cause weakening of the arch, and results in a prolonged recovery time.

**Lateral epicondylitis (LE):** LE sometimes called tennis elbow or rowing elbow, is characterized by pain at the lateral epicondyle that radiates into the forearm with tenderness over the tendon origins slightly distal and anterior to the midpoint of the lateral epicondyle. It is a condition commonly associated with a variety of sports activities and occupations that involve overuse of the muscle groups that attach at the lateral epicondyle (extensor carpi radialis brevis and longus and supinator longus and brevis). Although the condition is common in tennis players, it is usually work-related in most patients.

There are a number of conservative treatments for lateral epicondylitis, including rest, counterforce bracing that helps to reduce mechanical stress to the affected elbow, physical therapy, nonsteroidal anti-inflammatory drugs (NSAIDs), and steroid injections. None of these treatments is universally effective, although patients generally respond to nonoperative treatment and time. Patients who do not respond to these nonoperative treatments for 6 to 12 months are often advised to undergo surgery to release the tendons over the affected epicondyle, remove the area of tendinosis and any bone spurs that may be present on the epicondyle, and reattach the common extensor origin if it is violated.

**Rotator cuff (RC) tendonitis:** RC tendonitis typically results from repetitive activities that involve use of the arm in an overhead position, e.g., swimming, paper hanging, painting, or may be caused by minor trauma or degenerative changes. Symptoms include pain and restricted range of motion (ROM) and are usually self-limiting. Tendonitis is sometimes associated with calcium deposits within the supraspinatus. The calcium deposits can be present without causing symptoms. Shoulder tendonitis, like tendonitis of other joints, is treated initially using conservative measures, such as physical therapy, stretching and strengthening exercises, analgesics, and cortisone injections. In addition to these symptom-directed efforts, calcium deposits, if present, may be removed with needling and lavage. Surgical options include acromioplasty and for calcific tendonitis, curettage of the calcium deposit.

**Extracorporeal shock wave therapy (ESWT):** ESWT is a noninvasive treatment introduced as an alternative to surgery for patients with chronic pain associated with musculoskeletal problems that has not responded
to other conservative therapies for at least 6 months. ESWT involves delivery of shock waves to the painful region with the goal of reducing pain, increasing function, and promoting healing of the affected soft tissue. The mechanism of therapeutic effect for ESWT has not been established, although it has been proposed that shock waves may have a direct mechanical effect through the rapid buildup of positive pressure and/or a more indirect effect through the implosion of bubbles in the interstitial fluid. It has been hypothesized that these forces may reduce transmission of pain signals from sensory nerves in the fascia, cause calcium deposits to disintegrate, cause a transient inflammatory response, and/or stimulate tissue healing.

ESWT devices are similar to the lithotripters used for breaking up kidney stones. They produce low- or high-energy pulses arising from 3-dimensional acoustic energy, called shock waves, which can be focused and then propagated through water within body tissues. When focused on a boundary between tissues of differing densities, the shock wave is altered and an emission of energy occurs. Such a boundary occurs where the plantar fascia attaches to the calcaneus.

The most common ESWT devices utilize electrohydraulic (similar to a spark plug mechanism) or electromagnetic technology to create the pressure differentials that produce shock waves in a liquid medium. Devices that generate shock waves piezo-electrically (electrically induced contraction and expansion of crystals on the inside of a sphere surrounded by water) are less common. At least 1 device generates shock waves pneumatically rather than electrically; air pressure causes a projectile to hit the end of the applicator at high speed. Pneumatic devices deliver radial shock waves to a wider area at a relatively low energy level. The original generators were electrohydraulic (EH), but shock waves generated by this mechanism are difficult to focus. Piezoelectric (PE) generation achieves the most accurate focus but usually generates only high peak pressures, whereas a range of peak pressures can be chosen with EH and electromagnetic (EM) generators. An image-based localization system—typically fluoroscopy or ultrasound (US)—focuses on the target region, and the shock wave is simultaneously focused, by virtue of the ESWT generator design, with the goal of optimizing therapeutic benefit and minimizing damage to other tissues. Imaging units may be integrated with the lithotripter or operated separately. Alternatively, localization of the point of maximal tenderness may be directed using patient feedback. The therapy head is coupled to the patient’s body via a water cushion and/or water-based conductive gel, which conducts the shock waves. The pulses are generated from 70 to 120 times per minute. ESWT is noninvasive and is performed as an outpatient procedure. If anesthesia is used, it is typically local, often a nerve block. General anesthesia is often unnecessary because the shock waves can be gradually increased so that analgesia is enhanced through hyperstimulation. Therapy usually consists of 1 to 3 sessions, during which 1000 to 3000 pulses of low- or high-energy shock waves are administered to the pain site.

REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**

   There are multiple extracorporeal shock wave therapy systems that have received FDA approval for treatment of musculoskeletal indications. These devices include, but are not limited to:

   - OssaTron® Device (HealthTronics): This is an electrohydraulic, high-energy device, approved for treatment of plantar fasciitis and lateral epicondylitis that have failed conservative treatment after six months. Approved by the FDA on October 12, 2000. The OssaTron was later approved (March


- Orthospec™ (Medispec): Electrohydraulic device which utilize the spark gap method to create a shock wave. Approved for the treatment of chronic plantar fasciitis on April 1, 2005. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/P040026b.pdf.


- The EMS Swiss Dolorclast® (Electro Medical Systems): This device was granted premarket approval (PMA) by the FDA on May 8, 2007. Indications for use of this device are chronic proximal plantar fasciitis, in patients age 18 and older, with symptoms for six months or more, and a history of unsuccessful conservative therapy. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf5/P050004A.pdf.

- Additional Products: Minilith SL1, Orthowave® and Piezoson® 300, Reflectron® Evotron®, dermaPACE®, ActiVitor-Derma®

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):

National and Local Coverage Determination.

Category III CPT® Codes (LCD: L33392).

Medicare Does Not Cover Services for Extracorporeal Shock Wave Therapy.

A recent review of Medicare Part B claims has seen an increase in claims for extracorporeal shock wave therapy (ESWT) services. These codes are not considered medically necessary and will be denied.

It is important to review the local coverage determination (LCD) for these services.

The CPT codes for ESWT listed below are included in the Category III CPT® Codes LCD, L33392. These codes are not considered medically necessary and will be denied.

- 0019T - Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy
- 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
3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding ESWT in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

SUMMARY:

There is consistent evidence that single-session high-energy extracorporeal shock wave therapy (HE ESWT) (with energy flux density [EFD] > 0.12 millijoules per square millimeter [mJ/mm²]) may provide a moderate degree of pain relief in selected patients with chronic plantar fasciitis who have failed appropriate conservative therapy, with relatively few adverse effects. Improvement was maintained at follow-up up to 1 year. Low-energy (LE) ESWT (EFD ≤ 0.12 mJ/mm²) produced inconsistent results. There is evidence that plantar fasciitis improves without treatment in a substantial proportion of patients.

Evidence regarding the efficacy of ESWT for lateral epicondylitis is conflicting. While some studies suggest that ESWT can provide pain relief in patients with chronic lateral epicondylitis, others have failed to find a treatment effect above that provided by sham treatment. In addition, optimal treatment parameters have not been established, patient selection criteria have not been adequately defined, and there is a lack of information regarding the durability of treatment effect or any long-term adverse effects of ESWT.

There is some evidence from randomized, controlled trials that ESWT at sufficiently high levels can provide pain relief and improve shoulder function in some patients with chronic tendonitis of the rotator cuff, with the strongest effect in patients with calcific tendonitis who are treated with HE ESWT. However, optimal treatment parameters have not been established, and patient selection criteria have not been adequately defined.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

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<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy</td>
</tr>
<tr>
<td>0101T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy</td>
</tr>
<tr>
<td>0102T</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle</td>
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<tr>
<td>0299T</td>
<td>Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound</td>
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<tr>
<td>0300T</td>
<td>Each additional wound (list separately in addition to code for primary procedure)</td>
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<th>ICD-9 Codes</th>
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<td>719.41</td>
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<td>M25.70</td>
<td>Osteophyte, unspecified joint</td>
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<td>M75.92</td>
<td>Shoulder lesions</td>
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<tr>
<td>M72.2</td>
<td>Plantar fascial fibromatosis</td>
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<td>M77.30</td>
<td>Calcaneal spur, unspecified foot</td>
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<tr>
<td>28890</td>
<td>Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia</td>
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<tr>
<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy</td>
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<tr>
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REFERENCES:


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<td>02/01/2014</td>
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