Extracorporeal Shock Wave Therapy Indications
(Musculoskeletal and Soft Tissue)

Policy Number: 2013M0045A  Effective Date: March 1, 2014

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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.”

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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.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Extracorporeal shock wave therapy (ESWT), whether High-Energy (HE) or Low-Energy (LE), is considered MEDICALLY NECESSARY as an alternative to surgery in patients with:

- Chronic plantar fasciitis of at least 6 months duration who have failed to respond to appropriate conservative medical therapies.
- Chronic lateral epicondylitis for a minimum of 6 months who have failed to respond to appropriate conservative medical therapies.
- Chronic calcific rotator cuff tendonitis of at least 6 months’ duration with calcium deposit ≥ 0.5 cm, and who have failed to respond to appropriate conservative medical therapies.

Extracorporeal shock-wave therapy (ESWT), is considered EXPERIMENTAL AND/OR INVESTIGATIONAL 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:

- Achilles tendinitis (tendinopathy)
- Delayed unions
- Erectile dysfunction
- Low back pain
- Non-unions
- Osteonecrosis of the femoral head
- Patellar tendinopathy
- Peyronie's disease
- Stress fractures
- Wound healing (including burn wounds)
• Other musculoskeletal indications.

Clinical Considerations:
• All these conditions have high rates (70-90%) of successful treatment with simpler, less expensive and more convenient methods of non-invasive medical or orthotic treatment, although there is no clear consensus on the superiority of one approach over another. Relatively small numbers of such cases are recalcitrant, unresponsive to rest, physical therapy, oral medication, injection of local anesthetics and corticosteroids, splints or plaster casts, heel cushions and heel cups. Surgical methods, whether open or endoscopic, give frequent though inconsistent improvement in responsive cases, but are regarded in the orthopedic community as measures of last resort.
• 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 piezoelectrically (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 14, 2003) for chronic lateral epicondylitis. Additional information available at: http://www.accessdata.fda.gov/cdrh_docs/pdf/p990086a.pdf.


- 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/pdf4/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 Coverage Determination (NCD). Medicare does not have a NCD for Extracorporeal Shockwave Therapy.

Local Coverage Determinations (LCDs) L28470.

Coverage under Medicare is limited to patients with epicondylitis or plantar fasciitis, for whom more conservative therapy failed for at least six months, and as an alternative to surgery.

Use of focused ultrasound waves in treatment of musculoskeletal conditions has been mainly for chronic calcific tendonitis in the shoulder, chronic tennis elbow and painful heel due to so-called plantar fasciitis. All these conditions have high rates (70-90%) of successful treatment with simpler, less expensive and more convenient methods of non-invasive medical or orthotic treatment, although there is no clear consensus on the superiority of one approach over another. Relatively small numbers of such cases are recalcitrant, unresponsive to rest, physical therapy, oral medication, injection of local anesthetics and corticosteroids, splints or plaster casts, heel cushions and heel cups. Surgical methods, whether open or endoscopic, give frequent though inconsistent improvement in responsive cases, but are regarded in the orthopedic community as measures of last resort.

Experience with extracorporeal shock wave therapy (ESWT) in the treatment of musculoskeletal conditions is limited. This treatment method appears to offer benefit in some published case series, but has not been confirmed in random case controlled studies.

ESWT is considered not medically necessary as primary treatment for the musculoskeletal conditions.
mentioned above. It may be considered medically necessary only in those cases in which there has been a demonstrated failure of vigorous conservative therapy after six months of treatment and only in those cases in which it is being provided as an alternative to surgical treatment.

ESWT will be reimbursed only when used to treat epicondylitis or plantar fasciitis. Claims may be suspended for review of medical records documenting that simpler methods have been employed and failed.

ESWT treatment must be provided under the personal supervision of the treating physician, who is trained in the performance of this procedure.

Only services using equipment that are FDA approved for epicondylitis and plantar fasciitis will be considered for payment.

Documentation Requirements:

• The patient’s medical record must contain documentation that fully supports the medical necessity for services included within this LCD. This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.
• The patient’s record must document that previous treatments have been employed and failed, including the time frames of each treatment.
• The patient’s record must indicate which equipment was used in providing this treatment.
• Each claim must be submitted with ICD-9-CM codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-9-CM codes will be returned.

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 tendinitis 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.

COST ANALYSIS:

No cost-effectiveness analyses of ESWT were identified in the peer-reviewed published literature. Reported costs for ESWT vary depending on the type and number of treatments, the specific provider, and any associated costs, such as use of anesthesia.

Rompe et al. (2001) found ESWT was less costly than surgery. They calculated a reduction of $2970 per patient in hospital costs and $9240 per patient in costs associated with missed workdays. Conclusions from this study are seriously limited because of potential biases. Allocation to ESWT treatment was made on the basis of whether a patient’s insurance plan would or would not reimburse for ESWT. Return to work results may be confounded if there is a relationship between type of occupation and type of health plan coverage, which was related to treatment allocation.

An established ESWT treatment center in Canada stated that costs in Canada are lower than those in the United States (Shockwave Therapy – BC, 2013), and stated that the cost in the latter for a course of ESWT commonly runs $3000 to $7000.

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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<tr>
<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy</td>
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<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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<tr>
<td>719.41</td>
<td>Shoulder pain</td>
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<tr>
<td>719.48</td>
<td>Pain in joint (other specified sites) for heel pain</td>
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<tr>
<td>723.4</td>
<td>Radicular syndrome upper limb</td>
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<tr>
<td>726.11</td>
<td>Tendonitis/tendinitis (of the shoulder/rotator cuff/supraspinatus)</td>
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<td>Impingement syndrome, shoulder</td>
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<td>726.30</td>
<td>Elbow tendinitis</td>
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<tr>
<td>726.32</td>
<td>Lateral epicondylitis</td>
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<tr>
<td>726.32</td>
<td>Tennis elbow</td>
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726.73  Calcaneal spur
726.91  Exostosis of unspecified site
727.82  Calcific tendonitis/tendinitis
728.71  Plantar fascial fibromatosis

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<tr>
<td>M25.70</td>
<td>Osteophyte, unspecified joint</td>
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<tr>
<td>M72.2</td>
<td>Plantar fascial fibromatosis</td>
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<tr>
<td>M77.30</td>
<td>Calcaneal spur, unspecified foot</td>
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<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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<td>0019T</td>
<td>Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, low energy</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>
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REFERENCES:

10. Centers for Medicare & Medicaid (CMS) [website]. Medicare Coverage Database Homepage. Available at:
33. Hammer DS, Adam F, Kreutz A, Rupp S, Kohn D, Seil R. Ultrasonographic evaluation at 6-month follow-up of


78. Rompe JD, Schoellner C, Nafe B. Evaluation of low-energy extracorporeal shock-wave application for treatment of
## POLICY HISTORY:

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