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

Extracorporeal shock wave therapy (ESWT) is a noninvasive method that may be used to treat pain using 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 may be generated at high- or low-energy intensity, and treatment protocols may include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

**Summary**

Extracorporeal shock wave therapy (ESWT) is a noninvasive method that may be used to treat pain using 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 may be generated at high- or low-energy intensity, and treatment protocols may include more than 1 treatment. ESWT has been investigated for use in a variety of musculoskeletal conditions.

**FDA REGULATORY STATUS**

Currently, 6 extracorporeal shock wave therapy (ESWT) devices have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for orthopedic use; they are summarized in Table 2. FDA product code: NBN.

**Table 2: FDA-Approved Extracorporeal Shock Wave Therapy Devices**

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Approval Date</th>
<th>Delivery System Type</th>
<th>Indication</th>
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</thead>
<tbody>
<tr>
<td>OssaTron® device (HealthTronics, Marietta, GA)</td>
<td>2000</td>
<td>Electrohydraulic delivery system</td>
<td>Chronic proximal plantar fasciitis, ie, pain persisting &gt;6 mo and unresponsive to conservative management</td>
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<tr>
<td>Epos™ Ultra (Dornier, Germering, Germany)</td>
<td>2002</td>
<td>Electromagnetic delivery system</td>
<td>Plantar fasciitis</td>
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<tr>
<td>Sonocur® Basic (Siemens, Erlangen, Germany)</td>
<td>2002</td>
<td>Electromagnetic delivery system</td>
<td>Chronic lateral epicondylitis (unresponsive to conservative therapy for &gt;6 mo)</td>
</tr>
<tr>
<td>Orthospec™ Orthopedic ESWT (Medispec, Germantown, MD)</td>
<td>2005</td>
<td>Electrohydraulic spark-gap system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y</td>
</tr>
<tr>
<td>Orbasone™ Pain Relief System (Orthometrix, White Plains, NY)</td>
<td>2005</td>
<td>High-energy sonic wave system</td>
<td>Chronic proximal plantar fasciitis in patients ≥18 y</td>
</tr>
</tbody>
</table>
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/mm²). This painful procedure requires anesthesia. A low-dose protocol consists of multiple treatments, spaced 1 week to 1 month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia. The FDA-labeled indication for the OssaTron® and Epos™ Ultra device specifically describes a high-dose protocol, while the labeled indication for the Sonocur® device describes a low-dose protocol.

In May 2007, Dolorclast® (EMS Electro Medical Systems; Nyon, Switzerland), another type of ESWT called 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. Other types of ESWT produce focused shock waves that show deeper tissue penetration with significantly higher energies concentrated to a small focus. 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.

POLICY STATEMENT

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

BENEFIT APPLICATION

FDA approved devices under Premarket Approval (PMA) cannot be denied on the basis of experimental or investigational.

RATIONALE

Summary of Evidence

For individuals who have plantar fasciitis who receive extracorporeal shock wave therapy (ESWT), the evidence includes numerous randomized controlled trials (RCTs), including several well-designed, double-blinded RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available RCTs have demonstrated mixed findings, with some studies reporting a benefit and others reporting no benefit. Where statistically significant differences have been reported, the magnitude of effect for some outcomes is of uncertain clinical significance. The most recent RCT evaluating ESWT for plantar fasciitis was fairly well designed, well conducted, and showed some reductions in pain with ESWT; additional confirmatory trials are needed to permit more certainty about the effects of ESWT. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have lateral epicondylitis, shoulder tendinopathy, Achilles tendinopathy, or patellar tendinopathy who receive ESWT, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available RCTs for these tendinopathies have methodologic limitations. Overall, although some RCTs have demonstrated benefits in pain and functional outcomes associated with ESWT, the limited amount of high-quality RCT evidence precludes conclusions about the efficacy of ESWT for tendinopathies. The evidence is insufficient to determine the effects of the technology on health outcomes.
For individuals who have medial tibial stress syndrome, osteonecrosis of the femoral head, and acute fractures and delayed fracture union who receive ESWT, the evidence includes RCTs and case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. The available comparative evidence is limited, and does not permit conclusions about the benefits of ESWT relative to alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have spasticity who receive ESWT, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. As a treatment for spasticity, several small studies have demonstrated short-term improvements in Modified Ashworth Scale scores, but direct evidence on the effect of ESWT on more clinically meaningful measures (eg, pain, function) are lacking. Differences in treatment parameters among studies, including energy dosage, method of generating and directing shock waves, and use or absence of anesthesia, limit generalizations from results of multiple studies. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Foot and Ankle Surgeons

In 2010, Thomas et al published a revised practice guideline on the treatment of heel pain on behalf of the American College of Foot and Ankle Surgeons. This guideline identifies ESWT as a third tier treatment modality in patients who have failed other interventions, including steroid injection. The guideline recommends ESWT as a reasonable alternative to surgery.

National Institute for Health and Clinical Excellence

The National Institute for Health and Clinical Excellence has published guidance on ESWT for a number of applications.

- The guidance issued in November 2003 states that current evidence on safety and efficacy for treatment of calcific tendonitis of the shoulder “appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.”
- The guidances issued in August 2009 state that current evidence on the efficacy of ESWT for refractory tennis elbow, Achilles tendinopathy, and plantar fasciitis “is inconsistent and the procedure should only be used with special arrangements for clinical governance, consent and audit or research.”
- The guidance issued in January 2011 states that evidence on the efficacy and safety of ESWT for refractory greater trochanteric pain syndrome “is limited in quality and quantity. Therefore this procedure should only be used with special arrangements for clinical governance, consent, and audit or research.”

Canadian Agency for Drugs and Technologies in Health

A 2007 summary by the Canadian Agency for Drugs and Technologies in Health (CADTH) noted that results from randomized trials of ESWT for plantar fasciitis have been conflicting. The report noted that the “lack of convergent findings from randomized trials of ESWT for chronic plantar fasciitis suggests
uncertainty about its effectiveness. The evidence reviewed in this bulletin does not support the use of this technology for this condition.” Similarly, a 2007 report by CADTH on ESWT for chronic lateral epicondylitis noted that results from randomized trials have been conflicting and half of the studies showed no benefit over placebo for any outcome measures. The report noted that “the lack of convincing evidence regarding its effectiveness does not support the use of ESWT for CLE [chronic lateral epicondylitis].” A third 2007 summary by the CADTH concluded that “the current evidence supports the use of high-energy ESWT for chronic calcific rotator cuff tendonitis that is recalcitrant to conventional conservative treatment, although more high-quality RCTs with larger sample sizes are required to provide more convincing evidence.”

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Medicare National Coverage**

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

**REFERENCES**

2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Extracorporeal shock wave treatment for musculoskeletal indications TEC Assessments. 2003;Volume 18, Tab 5.
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POLICY HISTORY

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<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>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.</td>
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<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review, references 5-7, 24-25, 30 and 34 added. No change to policy statement.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>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.</td>
</tr>
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Signature on File

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