

MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds
Policy Number	2.01.31
Category	Technology Assessment
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Current Effective Date	03/23/23
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Archive Review Date	N/A
Product Disclaimer	<ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit. • If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit. • If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. • If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY STATEMENT

- I. Based upon our criteria and assessment of the peer-reviewed literature, extracorporeal shock wave therapy (ESWT) for the treatment of musculoskeletal conditions, including, but not limited to, chronic plantar fasciitis, tendinitis of the shoulder and elbow, and non-union of fractures, has not been medically proven to be effective and, therefore, is considered **investigational**.
- II. Based upon our criteria and assessment of the peer-reviewed literature, ESWT as a treatment for wound-healing has not been medically proven to be effective and, therefore, is considered **investigational**.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

DESCRIPTION

ESWT is proposed as a non-surgical treatment option for musculoskeletal conditions, including chronic plantar fasciitis and tendinitis of the shoulder and elbow, as well as for non-union of fractures. The mechanism by which ESWT achieves a therapeutic intervention in orthopedic conditions is not completely understood, but there are several hypotheses. ESWT may disrupt fibrous tissue, allowing for the subsequent promotion of revascularization and healing of tissue. Also, it is believed that the direct and indirect effects of the shock waves may damage cell membranes, so that nociceptors cannot build up a potential to transmit pain signals. Chronic conditions such as tendinitis can be associated with a substantial degree of scarring and calcium deposition. Calcific deposits may restrict motion and encroach on nerves and blood vessels, causing pain and dysfunction. It is thought that the shock waves will break up these deposits, loosen structures, and promote resorption of calcium, thereby decreasing pain and improving function.

Both high-dose and low-dose focused ESWT have been utilized. A high-dose protocol consists of a single treatment of high-energy shock waves (1300mJ/mm²). This painful procedure requires anesthesia. A low-dose protocol consists of

Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 2 of 8

multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied. This protocol does not require anesthesia.

Radial ESWT (rESWT) 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. rESWT 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.

ESWT is being proposed as a new approach to soft tissue wound-healing. It is being studied as a treatment for delayed or chronic, non-healing wounds and also as a therapy to accelerate tissue repair in wounds, such as diabetic ulcers and burns. Although the precise mechanism by which ESWT could provide a therapeutic effect is not known, it is thought that ESWT may decrease inflammation and induce neovascularization, allowing for improved perfusion and accelerated epithelialization.

RATIONALE

The OssaTron device (HealthTronics, Inc.) was approved by the United States Food and Drug Administration (FDA) in July 2000 for chronic proximal plantar fasciitis and is also approved for use in the treatment of lateral epicondylitis. Dornier MedTech, Inc. received FDA premarket approval (PMA) for the Epos Ultra ESWT device on January 15, 2002 for the treatment of plantar fasciitis. Siemens Healthcare's SONOCUR Basic System was approved in July 2002 for treatment of epicondylitis (tennis elbow). Orthometrix, Inc.'s Orbasone Pain Relief System and Medispec Sdn Bhd (Malaysia)'s Orthospec, received FDA PMA in 2005; both are approved to treat plantar fasciitis. The FDA-labeled indication for the OssaTron and Epos Ultra devices specifically describes a high-dose protocol, while the labeled indication for the SONOCUR device describes a low-dose protocol. In May 2007, the Dolorclast from EMS Electro Medical Systems, Nyon, Switzerland, a rESWT, was approved by FDA through the PMA process.

There is insufficient data published in the peer-reviewed literature to draw conclusions about the effectiveness of either focused ESWT or rESWT for treatment of musculoskeletal conditions. Outcomes of trials on clinically relevant measures are inconsistent, and interpretation is complicated by variations in treatment protocols. Published evidence for the use of ESWT to promote healing of fracture non-union consists of several, relatively small, randomized, controlled trials (RCTs) with methodologic limitations, along with reports of case series, and it cannot be concluded from such studies that ESWT results in acceleration of union. Small RCTs have reported a benefit for pain and functional outcomes for tendinopathies, including shoulder and Achilles tendinopathies; however, many trials have been considered to be of poor quality. More high-quality trials are needed, to determine whether ESWT improves net health outcomes.

Likewise, the available evidence in the medical literature evaluating the safety and efficacy of ESWT for wound-healing is insufficient to support its use for this indication at the present time. The Sanuwave Health dermaPACE system received FDA clearance on December 28, 2017. This device provides acoustic pressure shockwaves in the treatment of chronic, full-thickness, diabetic foot ulcers with wound areas measuring no larger than 16 cm², which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The dermaPACE System is indicated for diabetic patients aged 22 years and older who present with diabetic foot ulcers greater than 30 days in duration, and is indicated for use in conjunction with standard diabetic ulcer care. The FDA reviewed clinical data from two multi-center, randomized, double-blind studies with a total of 336 diabetic patients receiving either usual care plus the dermaPACE System shockwave therapy or usual care plus sham shockwave therapy. In the first study, 206 subjects were randomized to either dermaPACE (n=107) or to a sham-controlled group (n=99). At the 24-week endpoint, the rate of wound closure in the dermaPACE cohort was 39.3%, compared to 26.3% in the control group. In the second study, 130 subjects were randomized to dermaPACE (n=65) or to a sham-controlled group (n=65). At the 24-week endpoint, the rate of wound closure in the dermaPACE cohort was 35.4%, compared to 26.2% in the control group.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*

Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 3 of 8

- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
0101T (E/I)	Extracorporeal shock wave involving musculoskeletal system, not otherwise specified
0102T (E/I)	Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving lateral humeral epicondyle
0512T (E/I)	Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound
0513T (E/I)	each additional wound (List separately in addition to code for primary procedure)
28890 (E/I)	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

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HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
G56.00-G56.03	Carpal tunnel syndrome (code range)
M72.2	Plantar fascial fibromatosis
M75.00-M75.02	Adhesive capsulitis of shoulder (code range)
M75.20-M75.22	Bicipital tendinitis (code range)
M75.30-M75.32	Calcific tendinitis of shoulder (code range)
M77.00-M77.02	Medial epicondylitis (code range)
M77.10-M77.12	Lateral epicondylitis, elbow (code range)
M77.30-M77.32	Calcaneal spur, foot (code range)
M87.051-M87.059	Idiopathic aseptic necrosis of femur (code range)
Multiple ICD10 diagnosis codes for open wounds, burns, and fracture nonunion codes	

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Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 4 of 8

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Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 5 of 8

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Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 6 of 8

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Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 7 of 8

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Medical Policy: EXTRACORPOREAL SHOCK WAVE THERAPY (ESWT) FOR MUSCULOSKELETAL CONDITIONS AND SOFT TISSUE WOUNDS

Policy Number: 2.01.31

Page: 8 of 8

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*Key Article

KEY WORDS

Lithotripsy, orthotripsy, Ossatron, extracorporeal pulse activation therapy (EPAT), extracorporeal acoustic wave therapy, pulsed acoustic cellular expression (PACE) therapy

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, extracorporeal shock wave therapy for musculoskeletal conditions is not addressed in National or Regional Medicare coverage determinations or policies.