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**
Effective Date	**10/18/01**
Revised Date	**02/21/02, 02/20/03, 02/19/04, 02/17/05, 12/15/05, 01/18/07, 10/18/07, 09/18/08, 08/20/09, 07/15/10, 06/16/11, 06/21/12, 08/15/13, 07/17/14, 06/18/15, 06/16/16, 06/15/17, 06/21/18, 05/16/19**
Product Disclaimer	• *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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

I. Based upon our criteria and the assessment of peer-reviewed literature, extracorporeal shock wave therapy (ESWT) for the treatment of musculoskeletal conditions, including, but not limited to, chronic plantar fasciitis, tendonitis 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 the assessment of 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 regarding Experimental and Investigational Services.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

ESWT is proposed as a non-surgical treatment option for musculoskeletal conditions, including chronic plantar fasciitis and tendonitis 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, 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 ($1300 mJ/mm^2$). This painful procedure requires anesthesia. A low-dose protocol consists of 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.

Another type of ESWT is under investigation. 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.

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 (Health Tronics) was approved by the 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 approval for its Premarket Application for Epo Ultra® extracorporeal shock wave therapy device on January 15, 2002 for the treatment of plantar fasciitis. Siemens' SONOCUR® Basic System was approved in July 2002 for treatment of epicondylitis (tennis elbow). Orthometrix's Orbasone™ Pain relief System and Medispec's Orthospec™, received FDA premarket approval in 2005; both are approved to treat plantar fasciitis. 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. Radial ESWT (rESWT) received pre-market approval (PMA) in May 2007. The FDA-approved device is the Doloclast (spelled Dolorclast in the PMA summary) from EMS Electro Medical Systems, Nyon, Switzerland.

There is insufficient data published in the peer-reviewed literature to draw conclusions about the effectiveness of either focused or radial ESWT for treatment of musculoskeletal conditions. Outcomes of trials on clinically relevant measures are inconsistent and interpretation complicated by variations in treatment protocols. Published evidence for the use of ESWT to promote healing of fracture non-union consists of reports of case series only, and it cannot be concluded from such studies that ESWT results in acceleration of union.

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 approval (i.e., De Novo) 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 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The dermaPACE System is indicated for adult (22 years and older), diabetic patients presenting 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 Study 1, 206 subjects were randomized to either dermaPACE (n=107) or to sham-controls (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 Study 2, 130 subjects were randomized to dermaPACE (n=65) or sham-controls (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.*
- *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, high energy
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 (effective 1/1/19)
0513T **(E/I)**	each additional wound (List separately in addition to code for primary procedure) (effective 1/1/19)
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

HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
M72.2	Plantar fascial fibromatosis
M75.30-M75.32	Calcific tendinitis of shoulder (code range)
M77.10-M77.12	Lateral epicondylitis, elbow (code range)
M77.30-M77.32	Calcaneal spur, foot (code range)
Multiple ICD10 diagnosis codes for open wounds and burns	

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*Key Article

KEY WORDS

Lithotripsy, Orthotripsy, Ossatron

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. However, there is a local coverage determination that addresses category III codes located at: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33392&ver=95&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=All&LCntrctr=138*1&kq=1484874194&ua=highwire&displayPDFNote=Y&bc=AggAAAQBAAAA&