SUBJECT: ***Extracorporeal Shock Wave Treatment (ESWT) for Chronic Plantar Fasciitis and Other Musculoskeletal Conditions***

Number: **200510-0004**
Effective date: **10/04/05**
Revision date(s):

Important note
Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. The Centers for Medicare and Medicaid's *Coverage Issues Manual* can be found on the following Web site: http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp

Overview

Extracorporeal shock wave therapy (ESWT) is a non-invasive treatment that involves the delivery of shock waves via a device to a specific site within the body. ESWT has been FDA approved since 1984 for the treatment of kidney stones. ESWT is emerging as a non-surgical treatment option for a variety of musculoskeletal conditions, including chronic plantar fasciitis and lateral epicondylitis. The mechanism by which ESWT affects the musculoskeletal system is not well understood. The shock waves generated by the ESWT device may disrupt calcium deposits, increase the diffusion of cytokines across vessel walls, stimulate angiogenesis, and/or promote new bone formation, all of which may in turn promote healing. Devices delivering both high-energy and low-energy shock waves have been studied. High-energy protocols consist of a single treatment of high-energy shock waves. This painful procedure requires anesthesia. A low-energy protocol consists of multiple treatments, spaced one week to one month apart, in which a lower dose of shock waves is applied. Low-energy shock waves do not require anesthesia. Three ESWT devices are currently approved by the FDA:

Ossatron™ device (Healthtronics, Marietta, GA)	High-energy electrohydrolic device	FDA approved 10/12/00 for: • Chronic proximal plantar fasciitis that has failed to respond to conservative management • Chronic lateral epicondylitis that has failed to respond to conservative treatment
Epos™ Ultra (Dornier, Germering, Germany)	High-energy electromagnetic device	FDA approved 1/15/02 for the treatment of chronic plantar fasciitis for patients with symptoms for six months or more and a history of

		unsuccessful conservative therapy
Sonocur® (Seimens, Erlangen, Germany)	Low-energy electromagnetic device	FDA approved 7/19/02 for the treatment of chronic lateral epicondylitis for patients with symptoms for six months or more and a history of unsuccessful conservative therapy

Definitions

Plantar fasciitis is a common foot disorder in which symptoms may become chronic and functionally disabling. Various predisposing factors have been suggested for plantar fasciitis, including trauma, foot pronation, improperly fitted shoes, obesity and jobs that require prolonged standing. The condition likely involves a traction degeneration of the plantar fascia band at its origin in the medial calcaneal tuberosity. Many conservative treatments have been employed, including stretching exercises, shoe inserts, cortisone injections, physical therapy and night splints. When plantar fasciitis fails to respond to conservative treatment over an extended period of time, surgical fasciotomy is often recommended. Surgery may be associated with variable success, complications, prolonged recovery and loss of time from work.

Lateral epicondylitis (tennis elbow) is caused by repetitive motion that exerts stress on the grasping muscles of the forearm, which originate at the lateral epicondyle of the elbow. Conservative treatment involves rest, ice, stretching, strengthening, avoiding activity that hurts, and, as healing occurs, strengthening exercises. While the majority of cases resolve spontaneously with rest and discontinuation of the provoking activity over time, surgical treatment may be indicated for patients who fail conservative treatment.

Policy

The Technology Assessment Committee (TAC) has determined that ESWT (high-energy and low-energy) is experimental/investigational for all indications, including, but not limited to, plantar fasciitis and lateral epicondylitis.

Extracorporeal shock wave treatment (ESWT) for chronic plantar fasciitis and other musculoskeletal conditions is not covered.

Codes

Codes	Number	Description
CPT	0019T	Extracorporeal shock wave therapy; involving musculoskeletal system
	0020T	Extracorporeal shock wave therapy; involving plantar fascia
HCPCS	C9720	High-energy (greater than 0.22mJ/mm^2) extracorporeal shock wave (ESW) treatment for chronic lateral epicondylitis (tennis elbow)
	C9721	High-energy (greater than 0.22mJ/mm^2) extracorporeal shock wave (ESW) treatment for chronic plantar fasciitis
	G0279	Extracorporeal shock wave therapy; involving elbow epicondylitis
	G0280	Extracorporeal shock wave therapy; involving other than elbow epicondylitis or plantar fasciitis

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Products to which this policy applies

- ⊕ Direct & Select Care (HMO)
- ⊕ Flex Care Direct & Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment, & Bill at home
- ⊕ Medicare Plan

References

1. Blue Cross Blue Shield Association, Technology Evaluation Center. Extracorporeal Shock Wave Treatment for Chronic Plantar Fasciitis. 2005 March; 19(18).
2. Blue Cross Blue Shield Association, Technology Evaluation Center, Extracorporeal Shock Wave Treatment for Chronic Tendonitis of the Elbow (Lateral Epicondylitis). 2005 February; 19(18).
3. Speed, CA, Nichols, D, Wies, H, et al. Extracorporeal Shock Wave Therapy for Plantar Fasciitis. A Double Blind Randomized Controlled Study. *Journal of Orthopaedic Research*; 2003; 21(5):937-940.
4. Ogden, J, Alvarez, R, Levitt, R, et al. Electohydraulic High-Energy Shock-Wave Treatment for Chronic Plantar Fasciitis. *Journal of Bone and Joint Surgery*; 2004; 86-A (1):2216-2228.
5. Hayes, Inc. Extracorporeal Shock Wave Therapy for Chronic Plantar Fasciitis. May 2003; accessed 08/26/05.
6. Hayes, Inc. Extracorporeal Shock Wave Therapy for Chronic Epicondylitis of the Elbow. May 2003; accessed 08/26/05.
7. Healthronics Ossatron®. FDA Summary of Safety and Effectiveness. http://www.fda.gov/cdrh/pdf/p990086b.pdf; accessed 09/14/05.
8. Dornier Epos™ Ultra. FDA Summary of Safety and Effectiveness. http://www.fda.gov/cdrh/pdf/p000048b.html; accessed 09/14/05.
9. Sonocur®. FDA Summary of Safety and Effectiveness. http://www.fda.gov/cdrh/pdf/P010039b.pdf; accessed 09/14/05.

Mandated benefit/regulatory issues

- ∅ Federal
- ∅ Commonwealth of Massachusetts
- ∅ Medicare – National Policy
- ∅ Medicare – Local Medical Review Policy
- ∅ Not applicable

Committee review dates

Technology Assessment Subcommittee: 07/01/03, 09/28/04, 05/24/05
Technology Assessment Committee: 08/19/03, 10/04/05

Approved by: *Signature on file*
Dennis A. Batey, MD – Chief Medical Officer Date: 10/04/05