I. Policy: Extracorporeal Shock Wave Treatment for Musculoskeletal Indications

II. Purpose/Objective:
To provide a policy of coverage regarding Extracorporeal Shock Wave Treatment for Musculoskeletal Indications

III. Responsibility:
A. Medical Directors
B. Medical Management Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and

the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Extracorporeal shock wave treatment is a non-invasive procedure that uses the force of an acoustic shock wave. Although there is support in the medical literature for the efficacy of this treatment for plantar fasciitis, the healing mechanism of extracorporeal shock wave treatment of this condition has not been described.

INDICATIONS:
Skeletally mature members diagnosed with chronic plantar fasciitis of six (6) months duration or more that has been refractory to three (3) conservative treatment options such as rest, anti-inflammatory medications, physical therapy, corticosteroid injections and/or heel orthotics.

LIMITATIONS:
There is inadequate evidence in the published, peer-reviewed medical literature to establish the safety and/or efficacy of Extracorporeal shock wave treatment in the following groups:

- Members on anticoagulation therapy
- Children
- Pregnant women
- Paget's disease
- History of bleeding disorder
- Diabetic neuropathy
- Severe osteoarthritis
- Rheumatoid arthritis
- Malignancy
- Significant peripheral vascular disease
- Osteomyelitis
- Tarsal tunnel syndrome
- Fracture of the foot or ankle

Coverage will be limited to ESWT using the high energy, single treatment protocol approved by the FDA. If repeat treatment is requested, services will be limited to a total of 2 treatments per foot per occurrence. There is insufficient evidence in the published, peer-reviewed medical literature to support the efficacy of this treatment beyond 2 treatment sessions.

EXCLUSIONS:
There is insufficient evidence in the published peer-reviewed medical literature to support ESWT using FDA approved low energy, multiple treatment protocols. The treatment is considered experimental, investigational or unproven and is NOT COVERED. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

The Plan does NOT provide coverage for ESWT as a treatment for any musculoskeletal indication other than plantar fasciitis, including but not limited to tendonitis of the shoulder, tendonitis of the elbow, non-union fractures or avascular necrosis of the hip because it is considered experimental, investigational or unproven. The Geisinger Technology Assessment Committee evaluated this technology and concluded that there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies.

There is insufficient evidence in the published peer-reviewed medical literature to support ESWT for indications such as, but not limited to, Peyronie's disease, erectile dysfunction, angina pectoris, breast cancer-related lymphedema, and wound healing. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this test on health outcomes when compared to established tests or technologies. Use of ESWT for the treatment of these conditions is considered experimental, investigational or unproven and is NOT COVERED.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Extracorporeal Shock Wave Treatment
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

0101T Extracorporeal shock wave involving musculoskeletal system, not otherwise specified, high energy
0102T Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, involving
lateral humeral epicondyle

Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia


LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Extracorporeal Shock Wave Treatment (Lithotripsy) for Plantar Fasciitis, Geisinger Technology Assessment Committee, July 10, 2002


ECRI Institute. Extracorporeal shockwave therapy for epicondylitis [Hotline]. Current as of 8/17/07.


http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=1926


http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm


This policy will be revised as necessary and reviewed no less than annually.

Devised: 7/02

Revised: 7/03 (add limitations); 7/04; 7/05 (reference); 8/09, 3/16 (removed P/A); 2/17 (added exclusions)

Reviewed: 7/07, 7/08, 10/10, 10/11, 10/12, 10/13, 10/14, 10/15, 2/18, 2/19