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Comments and Responses Regarding Draft Local Coverage Determination: Extracorporeal Shockwave Therapy (ESWT) for Musculoskeletal Indications

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As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Extracorporeal Shockwave Therapy (ESWT) for Musculoskeletal Indications LCD. The official notice period for the final LCD begins on November 17, 2008, and the final determination will become effective on January 1, 2009.

Comment:
From the Indiana CAC meeting, the Podiatry CAC member stated that they use per policy. The PM&R representative stated that he does not use the procedure and is concerned about its effectiveness.

Response:
We appreciate the Podiatry representative's satisfaction with the draft LCD. The PM&R representative's concern is consistent with the limited literature on this service. We are aware of literature supporting its use, but only in those patients who have failed conservative therapy for at least six months. We believe that this LCD provides access to this treatment for just such beneficiaries, while also limiting it to those select few in whom surgery may be the only other remaining alternative. We await further scientific literature describing the validity and use of this service.

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Comment:
A company representing Electro Medical Systems submitted electronic copies of the most recent literature related to Electro Medical System's Swiss DolorClast ESWT, as indicated for plantar fasciitis. The manufacturer is asking that their system be included in the LCD coverage for beneficiaries who have failed to respond to six months of conservative care therapy, who have unremitting pain, and who have had no history of prior surgery for this condition. The EMS Swiss DolorClast® system was granted pre-market approval from the FDA in June 2007.
Literature submitted was:

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American Journal of Sports Medicine, "Radial Extrcorporeal Shock Wave Therapy is Safe and Effective in the Treatment of Chronic Recalcitrant Plantar Fasciitis";

Journal of Orthopaedic Research, "Repetitive low-energy shock wave application without local anesthesia is more efficient than repetitive low-energy shock wave application with local anesthesia in the treatment of chronic plantar fasciitis";

"Clinical Evidence for Radial Extracorporeal Shock Wave Therapy (ESWT)", Dossier of Information, EMS Swiss DolorClast® Shock Wave Device For the Indication of Plantar Fasciitis, May 8, 2008.

The company asked that NGS expand the existing draft LCD to cover this product, pursuant to labeling, and given 6+ mos failed conservative care therapeutic options (as well as all other conditions and restrictions in the current draft).

Response:
The draft LCD identifies shock wave therapy as a modality for the treatment of plantar fasciitis and lateral epicondylitis. The LCD does not identify any one manufacturer or brand of equipment for which there is coverage of this service. The LCD does, in fact, state that "*Only services using equipment that is FDA approved for epicondylitis and plantar fasciitis will be considered for payment*." Individual brands of equipment must be FDA-approved for the specific treatment for which they will be employed, but they do not have to be vetted through the LCD process.

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Comment:
The Connecticut Podiatry CAC representative indicated that he has done this procedure in his podiatric office as well as within an orthopaedic practice with these mobile units. He would like to increase the diagnosis code listing to include Achilles tendonitis. It follows the same theories of neovascularization.

Response:
When this additional indication was suggested at the CAC Meeting, the Medical Director requested that the representative provide literature supporting the effectiveness of ESWT for this diagnosis. No articles from the scientific medical literature supporting this use have been submitted. Therefore, we cannot expand the indications at this time. At such time when such literature is made available, we would reconsider this indication.

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Comment:
A Kentucky CAC member wanted to clarify anesthesia requirements for CPT 28890 (*Extracorporeal shock wave, high energy, performed by a physician, requiring anesthesia other than local, including ultrasound guidance, involving the plantar fascia*) reviewed for regional (compared to local) anesthesia requirements.

Response:
Because of the high energy ultrasound used, the procedure requires the use of regional anesthetic (i.e., heel block). This anesthesia service is separately payable to an anesthesiologist, although not separately reimbursable to the provider performing the ESWT.

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