

**PUBLIC COMMENTS
FOR ULTRASOUND STIMULATION
FOR NONUNION FRACTURE HEALING
CAG-00022R
July 27-August 27, 2004**

Commenter: Campbell Clinic Orthopaedic Physicians

Organization: Campbell Clinic Orthopaedics

Date: August 23, 2004

Comment:

We, the undersigned, are writing to support removal of the surgical requirement currently included in the guidelines for the ultrasound fracture healing system. Rationale includes but is not limited to the following:

AVOIDING SURGERY

The ultrasound fracture healing system is a useful adjunct post-surgically. However, in many cases, this device is prescribed to assist in healing difficult fractures in attempts to *avoid surgical intervention*. Medicare patients are often poor surgical candidates due to the same comorbidities that contribute to nonunions. These comorbidities include advanced age, diabetes, osteoporosis, cardiac disease, smoking, obesity, and more.

CONSERVATIVE TREATMENT OPTION

Ultrasound stimulation is an excellent conservative treatment option for mature fracture patients. There is high compliance with the device among this population due ease of use and treatment time of only 20-minutes per day. If the ultrasound fracture healing system guidelines include a surgical caveat, successful outcomes may be at risk without the option of conservative treatment.

COST SAVINGS

Costs to the health care system are lower for patients who heal fractures quickly and without surgery. Surgical and lengthy rehabilitation costs are spared, and the patient resumes normal activities more readily. The patient is more productive while burdens on the system, society and families are reduced.

Please revise Medicare guidelines to *omit the surgical requirement for the ultrasound fracture healing system*. Thank you very much for your consideration.

Commenter: Cordell, Larry D., M.D.

Organization: Coffey County Medical Center

Date: July 20, 2004

Comment:

Re: Use of bone stimulators for the treatment of delayed/non-union of bone fractures.

1. It has been brought to my attention that CMS has a coverage policy that limits the use of bone stimulators in the treatment of delayed/non-union of bone fractures to patients who have failed at least one prior surgery for the treatment of such fractures.

2. I do not believe this to be the standard of care in regards to the general population. In fact, I believe the medical literature would support a similar long term result of healing the bone fracture in patients being treated with bone stimulators compared to those undergoing surgical intervention.
3. I also believe there are many-instances where it would not be in the best interest of the patient to undergo surgery (e.g. medical co-morbidities, expense of surgery, etc.).

SUMMARY:

I would request that CMS remove their current policy requiring prior surgery in the treatment of delayed/non-union of fractures. This clearly seems to be contrary to allowing physicians to offer the best possible medicine to their patients. The medical literature supports the use of bone stimulators as an alternative to surgical intervention. This also seems to be a re-imbursement issue and not a quality of medicine issue.

Thank you for your consideration.

Commenter: Dollard, Mark D., DPM

Organization: Loudoun Foot and Ankle Center

Date: August 16, 2004

Comment:

Thank you for entertaining my letter in public response to an open review of pulsed ultrasound stimulation for nonunion fracture healing. May I present my credentials? I presently serve as the Podiatric medical representative to the Trailblazer's Medicare Carrier Advisory Committee for the Metro-Washington D.C. area. May I provide as a reference, Lawrence Clark MD, Medical Director for Trailblazer's Medicare (Mid-Atlantic States). I also serve as the executive director of the Mid-Atlantic Podiatric Medical Association and have served as the American Podiatric Medical Association's 2003 Scientific Chairman. I will be lecturing on the concepts of bone stimulation for fracture repair utilizing either pulsed ultrasound vs. electrical stimulation at the 2004 APMA National Scientific Meeting in Boston on August 24, 2004. I have been independently reviewing the physiological effects of pulsed ultrasound stimulation on bone healing in preparation for this meeting. Clinically, I have practical patient care experience using Low Intensity Pulsed Ultrasound Bone Stimulation.

Allow me to commend CMS for reopening the medical review policy on ultrasound stimulation for nonunion fracture healing? It appears from your tracking sheet that CMS opens the question regarding the caveat requiring a failed open surgical intervention for non-union repair prior to qualifying coverage for pulsed ultrasound stimulation utilization. I would fully support removing this caveat. In my own experience with diabetic charcot fractures, I have found that the pulsed ultrasound unit has been exceptionally successful in promoting accelerated fracture healing in these difficult co-morbid conditions. Diabetic charcot foot fractures often present as long standing non-healing fractures with marked delay either in healing rates or non-union. Indeed, as long as severe anatomic malposition is not present, application of a pulsed ultrasound bone stimulator for the diabetic charcot fracture has been very rewarding for my patients. In fact, it has unquestionably helped avoid primary or secondary surgical interventions in many cases. Both rational fracture immobilization and convenient application of low intensity pulsed ultrasound units have together achieved significant functional unions of major charcot non-union fractures in my patients. In other instances where urgent surgical debridement of diabetic osteomyelitic bone had caused wide defects in bone structure, I have been able to avoid secondary bone graft surgical procedures by attaining septic fusions across wide bony gaps with pulsed ultrasound bone stimulation.

I would certainly recommend further modifying the national medical policy to include coverage for the use of low intensity pulsed ultrasound for fresh fractures in well established and defined co-morbid conditions. Those co-morbid conditions would typically be: poor circulation, smoking, diabetes, and certain other conditions that are well presented in the literature. Pulsed ultrasound has been documented to accelerate healing time by 38-40% in fresh fractures, saving substantial costs in case management.

May I make reference to the following articles: Duncan, R. L. et.al, *Calcific Tissues International*, 1995; Ruben C, et al, *Journal of Bone and Joint Surgery*, 2001; and Mayr E, et al, *Arch Orthop Trauma Surgery* (2000) as landmark publications on the effectiveness of pulsed ultrasound in bone remodeling? In my own literature review, I have become acquainted with the physiologic nature of bone healing as it is presently postulated. In keeping with both the "MechanoStat Theory of Bone Modeling" by Frost and the "Mechano-Transduction Theory of Bone Healing" by Duncan, low intensity pulsed ultrasound would appear compliant with the most likely physiologic basis for bone healing. By stimulating the Integrin mechano-sensors in bone lining osteocytes and by promoting the osteoblastic process early in fracture repair, pulsed ultrasound appears to effectively mimic the cyclic loading principles within osteocytes causing gene expression for various paracrine growth factors. In addition, bone deformation from the application of a pulsed ultrasound sonic shock wave stimulates the formation of stretch activated negative cation channels in osteocyte cell walls that further induces an influx of intra-cellular Calcium ions. This Ca⁺ influx instigates a cascading process for collagen matrix formations and osteoblastic cell recruitment.

Since I have a didactic PowerPoint presentation completely prepared for the APMA National Podiatric Scientific Conference, I would be most willing to attend any meeting at CMS headquarters in providing a presentation on low intensity pulsed ultrasound stimulation for bone healing. I am at your avail for further discussion and encourage open correspondence with my practice if I can be of further consult in this matter.

Commenter: Evans, R. D. Lee, D.P.M.

Organization: Des Moines Orthopaedic Surgeons, P.C.

Date: August 25, 2004

Comment:

I have been taking care of patients particularly for non-unions of lower extremity fractures for seven years now. I found the Exogen to be a very good device to prevent surgery in an effort to heal non-united fractures. I certainly appreciate the opportunity to use the Exogen bone stimulator in the absence of surgery particularly in those patients that do not tolerate surgery well which would fall under the Medicare and Medicaid population.

I would appreciate your consideration regarding Exogen bone stimulators for non-operative patients.

Commenter: Jacofsky, David J., M.D.

Organization: Mayo Clinic

Date: July 22, 2004

Comment:

It has come to my attention that CMS is currently considering a re-evaluation of its current surgical requirement for Medicare patients in need of an Exogen ultrasound bone-healing device. I have been greatly pleased with the success of the Exogen and feel that patients are more compliant in its usage due to the relatively short, 20 minutes per-day, treatment time. Often times there are certain patients who, due to age, bone density or chronic illness are not candidates for surgery, but who would benefit from the use of an

Exogen unit. However, Medicare does not offer reimbursement for patients who have not had surgery. I look forward to the possible removal of this surgical restriction, so that I might offer the same technological benefits to all my patients.

Thank you for your attention to my concerns regarding this current surgical restriction.

Commenter: Luscher, Harry A., Jr., M.D.

Organization: The Orthopaedic Group P.C.

Date: August 20, 2004

Comment:

I have been using the Exogen Ultrasound Bone Growth Stimulator for some time now. It has been very helpful on fractures in the acute stage in my practice, particularly on fractures of the foot and ankle. It has an outstanding compliance because of the short duration of treatment per day. In my opinion it has greatly reduced the "down time" for patients and I highly recommend it to other physicians.

Commenter: Mandracchia, Vincent J., DPM, MS

Organization:

Date:

Comment:

The treatment of non-united fractures can be very difficult for many reasons. The use of Exogen in our patients is proving to be of great benefit, however, not all patients that may benefit are post-operative. It is an easy system to use and we are able to monitor patient compliance. Removing the caveat will help us make this available to more patients. Thank you for your consideration in this matter.

Commenter: McCollum, Michael J., M.D.

Organization: University Orthopaedic Surgeons

Date: July 10, 2004

Comment:

It has come to my attention that CMS is currently considering a reevaluation of its current surgical requirement for Medicare patients, who are in need of an Exogen ultrasound bone-healing device. It has been my experience, within my practice, that the use of the Exogen has been highly successful. However, it has also been my experience that, although I prefer the Exogen, I am unable to get the units paid for by Medicare for patients who have not had surgery. Often times there are certain patients who, due to age, bone density or chronic illness, are not candidates for surgery, but who would benefit from the use of an Exogen. I look forward to the possible removal of this surgical restriction, so that I might afford the same technological benefits to all of my patients.

Thank you for considering the removal of this current surgical restriction and for hearing my concerns on this matter.

Commenter: Newman, Joseph, D.P.M.

Organization: The Foot Center, PLC

Date: August 25, 2004

Comment:

I am writing to you in regards to Exogen ultrasound bone stimulators. I support the removal of the surgical caveat from the requirements for Exogen approval from CMS. Most patients who receive Medicare benefits are elderly and/or disabled and therefore do not make good surgical candidates. Many times when an Exogen bone stimulator is needed, I am trying to avoid surgery altogether because of the patient's general health condition. Please allow for the removal of the surgical requirements for Exogen.

Commenter: Nickles, W. Ashton, DPM

Organization:

Date:

Comment:

The use of Exogen in our patients with non-united fractures is of great benefit. Whether the patient had undergone surgical correction of a fracture or not, it is proving to be effective. It is an easy system to use and compliance can be monitored. Removing the caveat will help us make this available to more patients. Thank you for your consideration in this matter.

Commenter: Park, William I., IV, M.D.

Organization: The Orthopaedic Group, P.C.

Date: August 20, 2004

Comment:

This letter is in reference to the use of the Exogen ultrasound bone growth stimulator. I understand that it is under review at the current time whether the Exogen ultrasound bone growth stimulator should be indicated for the treatment of patient's with difficult fractures that have a tendency not to heal. Apparently currently the restriction is to use this only in postoperative patients. In my opinion, this should be changed and the indications should be expanded to include non-postoperative patients. This is a very useful adjunct to the treatment of difficult fractures and often can preclude the need for surgery. It also is comparable to other bone growth stimulators in its efficacy; however, it requires shorter treatment periods of 20 minutes versus 3 to 10 hours. I think it is certainly worth consideration by the Center of Medicare and Medicaid Services to consider the indication for this in non-post surgical patients.

Commenter: Rydlewicz, James, M.D.

Organization: Milwaukee Clinic of Orthopedic Surgery, Ltd.

Date: July 8, 2004

Comment:

I am an Orthopedic Surgeon in Milwaukee, Wisconsin, who utilizes the Exogen ultrasound bone growth stimulator to help heal fractures in my patients. I am pleased with the high patient compliance rate and results I see with the Exogen unit. Many of my patients that are on Medicare are poor candidates for surgery. Therefore, the surgical intervention requirement for those Medicare patients unfortunately prevents them from getting the same benefit of the Exogen device that is available to non-Medicare patients. Please

consider removing the surgical intervention restriction regarding the Exogen unit in order to level the playing field with the other bone growth stimulators.

Commenter: Engerson, Todd D.

Organization: Orthopaedic & Sports Medicine of Mobile

Date: August 20, 2004

Comment:

It was pointed to me recently that Medicare/Medicaid patients are not eligible to use an Exogen bone stimulator without prior surgery. Apparently this is not the case with other insurers and there are ample studies in the literature to support the use of an Exogen unit for treatment of problematic fractures without surgery.

Please consider changing this policy as oftentimes use of a bone stimulator can actually help prevent a surgery and all of the associated morbidity and mortality with surgery on a non-union. I think in the end this will benefit patients greatly. If I can provide any further information feel free to contact me at the office.