09-E0000-32

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Reviewed: 09/22/22

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Subject: Ultrasound Osteogenesis Stimulators, Non-Invasive

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Depending on their function, bones are composed of a varying combination of cortical and trabecular bone. However, at the cellular level, the type of bone cannot be distinguished histologically. The inclusion of all bones regardless of the anatomic site is based on this histologic similarity of all bones; it is not anticipated that the effectiveness of ultrasound-accelerated healing would vary according to the anatomic site and function of the bone.

Low-intensity pulsed ultrasound (LIPUS) can be delivered non-invasively by the use of a transducer applied to the skin surface over the fracture site through a window cut into a cast or directly at the fracture line with a gelled head unit connected to a generator. It is important that the ultrasound is directly over the fracture or gap; this treatment location is determined by x-ray and the skin is marked. The portable, battery powered treatment system is administered by the patient or his caregiver for 20 minutes daily for the period of time needed. Compliance with the protocol for use can be checked when the unit is turned in, unless the battery has run low enough to erase the data. The low-intensity pulsed ultrasound level is comparable to diagnostic ultrasound used in sonogram (fetal monitoring) procedures and is 1 – 5% the intensity used for conventional therapeutic ultrasound. Neither physician nor patient can select or change the signal specifications of the device.

The Sonic Accelerated Fracture Healing System, SAFHS® (the device is also known as Exogen e.g., 2000, 3000, 4000) was initially cleared for marketing by the U.S. Food and Drug Administration (FDA) in October 1994 as a treatment of fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull

and vertebra. The FDA labeling suggests that a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the time frame of observation. However, it is suggested that a reasonable time period lack of visible signs of healing is 3 months.

POSITION STATEMENT:

Low-intensity ultrasound treatment **meets the definition of medical necessity** for:

1. The treatment of fresh closed fractures in skeletally mature individuals when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) . Candidates for low-intensity ultrasound treatment are those at high risk for delayed fracture healing or nonunion. These risk factors may include either fracture locations or patient comorbidities that include the following:

   Patient comorbidities:

   - Diabetes
   - Steroid therapy
   - Osteoporosis
   - History of alcoholism
   - History of smoking

   Fracture locations:

   - Jones fracture [fracture of the diaphysis of the fifth metatarsal of the foot]
   - Fracture of navicular bone in the wrist (also called the scaphoid)
   - Fracture of metatarsal
   - Fractures associated with extensive soft tissue or vascular damage

   OR

2. For treatment of delayed union of bones, including delayed union of previously surgically-treated fractures, excluding the skull and vertebra. (Delayed union is determined by serial radiographs, along with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention);

   OR

3. For treatment of fracture nonunions of bones, including nonunion of previously surgically-treated fractures, excluding the skull and vertebra.

   The following selection criteria are for treatment of nonunion fractures (FDA):

   - At least 3 months have passed since the date of the fracture; **AND**
   - Serial radiographs have confirmed that no progressive signs of healing have occurred; **AND**
   - The fracture gap is 1 cm or less; **AND**

- The member can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

Other applications of low-intensity ultrasound treatment are considered **experimental or investigational** including application for the treatment of the following as there is insufficient clinical evidence to determine health outcomes (this is not an all inclusive list):

- Congenital pseudarthroses; **OR**
- Open fractures; **OR**
- Fresh surgically-treated closed fractures; **OR**
- Stress fractures; **OR**
- Arthrodesis; **OR**
- Failed arthrodesis.

LOINC Codes:

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Attending physician progress note	18741-9	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Physician operative note	28573-4	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Radiology report	18726-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.

BILLING/CODING INFORMATION:

CPT Coding:

20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (non-operative)

HCPCS Coding:

E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

ICD-10 Diagnosis Codes That Support Medical Necessity:

S42.201K – S42.496K	Fractures of humerus, nonunion
S52.001A, B, D, E, K, or M – S52.92xA, B, D, E, K, or M	Fractures of radius, nonunion
S59.001K – S59.009K	Fractures of ulna, nonunion

S59.101K – S59.299K	Fractures of radius, nonunion
S62.001A, B, D, E, K, or M – S62.92xA, B, D, E, K, or M	Fractures of navicular [scaphoid] bone of wrist
S72.001K or M – S72.92xK or M	Fractures of femur, nonunion
S79.001K – S79.199K	Physeal fractures of femur, nonunion
S82.101A, B, D, E, K, or M – S82.399A, B, D, E, K, or M	Fractures of tibia, nonunion
S82.401K or M – S82.499K or M	Fractures of fibula, nonunion
S89.001K – S89.199K	Physeal fractures of tibia, nonunion
S89.201K – S89.399K	Physeal fractures of fibula, nonunion
S92.001A, B, D, E, K, or M – S92.919A, B, D, or K	Fractures of calcaneus

REIMBURSEMENT INFORMATION:

Ultrasound osteogenic stimulation is typically performed by the individual in the home setting. Therefore, it is not expected that 20979 would be reported more than once per occurrence of injury.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) located at www.cms.gov was reviewed on the last guideline revised date: Ultrasound Osteogenetic Stimulators, Publication 100-3, Section 150.2

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determination (LCD) located at www.cms.gov was reviewed on the last guideline revised date: Osteogenesis Stimulators (L33796).

DEFINITIONS:

Colles fracture: a fracture of the distal radius with displacement and/or angulation of the distal fragment dorsally.

Delayed union: a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

Diaphyseal: pertaining to or affecting the shaft of a long bone (diaphysis).

Fresh (acute) fracture: most commonly defined as "fresh" for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care (i.e., closed reduction and cast immobilization).

Index injury: initial injury.

Nonunion fractures: There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture-healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing).

The definition of nonunion in FDA labeling suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the timeframe of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months. The following patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions:

a) At least 3 months have passed since the date of the fracture; **AND**

b) serial radiographs have confirmed that no progressive signs of healing have occurred; **AND**

c) the fracture gap is 1 cm or less; **AND**

d) the patient can be adequately immobilized and is of an age when he/she is likely to comply with nonweight bearing.

Skeletally mature: when bone growth is complete; the growth plates (epiphyseal plates) have closed.

RELATED GUIDELINES:

Invasive Electrical Bone Growth Stimulator (EBGS), 02-20000-22
Non-Invasive Electrical Bone Growth Stimulators, 09-E0000-22

OTHER:

None applicable

REFERENCES:

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/22/22.

GUIDELINE UPDATE INFORMATION:

08/15/00	Medical Coverage Guideline Reformatted.
08/23/01	Reviewed – no changes.
03/15/03	Reviewed.
02/15/04	Reviewed; no change in coverage.
08/15/04	Revision; statement regarding coverage of nonunion fractures older than 5 years re-worded for clarification.
03/15/05	Scheduled review; no change in coverage statement.
10/15/07	Guideline reviewed, reformatted, and reinstated as active.
01/01/11	Revisions; related ICD-10 codes added.
09/15/11	Revision; formatting changes.
10/15/14	Review with revisions to position statement; update Program Exception section; update Billing/Coding section; update references.

12/15/15	Revision; updated position statement (Low-intensity ultrasound: deleted “for the treatment of fresh closed fractures in skeletally mature individuals” and added selection criteria for treatment of non-union fractures (FDA)). Reformatted position statement. Added definition for index injury. Updated references.
10/15/17	Review; no change in position statement. Updated references.
03/15/19	Review; no change in position statement. Updated references.
07/15/21	Review; no change in position statement. Updated references.
10/15/22	Review; no change in position statement. Updated references.