blue of california

Medical Policy

Ultrasound Bone Growth Stimulation	
Type: Medical Necessity and Investigational / Experimental	**Policy Specific Section:** Durable Medical Equipment
Original Policy Date: June 5, 1996	**Effective Date:** January 11, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Ultrasound bone growth stimulation, also as known as low-intensity pulsed ultrasound, has been investigated as a technique to accelerate healing of fresh fractures, delayed unions and non-unions. Ultrasound is delivered non-invasively with the use of a transducer applied to the skin surface overlying the fracture site. Ultrasound treatment can be self-administered with one daily

20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known. However, it is thought to be related to a mechanical effect on cell deformation.

Policy

Ultrasound bone growth stimulation of the appendicular skeleton is considered **medically necessary** for the treatment of the following:

- Fresh closed fractures when all following criteria are met:
  - Skeletally mature
  - When used as adjunct to conventional management (i.e., closed reduction and cast immobilization)
  - At high risk for delayed fracture healing or non-union including but not limited to the following:
    - Patient Comorbidities:
      - Obesity
      - Diabetes
      - Peripheral vascular disease
      - Steroid therapy
      - Osteoporosis
      - History of alcoholism
      - History of Smoking
    - Fracture locations:
      - Jones fracture
      - Clavicle fracture
      - Mid-humeral fracture
      - Scaphoid fracture
      - Navicular bone fracture in the wrist
      - Metatarsal fracture
      - Fractures associated with extensive soft tissue or vascular damage
- Delayed unions when all the following criteria are met:
  - At least 3 months have passed from the index injury or the most recent intervention
  - Clinical evaluation and serial radiographs demonstrate a decelerating healing process evidenced by lack of fracture site union, bone continuity or bone reaction
- Fracture nonunions when **all** of the following criteria are met:
  - At least three months have passed since the date of the fracture
  - Serial radiographs have confirmed no progressive signs of healing have occurred
  - The fracture gap is 1 centimeter or less

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- The patient can be adequately immobilized and is compliant with non-weight bearing

Ultrasound bone growth stimulation of the appendicular skeleton is considered **investigational** for all other indications, including, but not limited to the following:

- Arthrodesis or failed Arthrodesis
- Axial skeletal fractures, e.g., the skull and vertebrae
- Congenital pseudarthroses
- Adjunct to bunionectomy
- Open fractures
- Stress fractures
- Avascular necrosis of the femoral head

Policy Guideline

Fresh Fracture

A fracture is 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.

Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial x-rays, 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.

Nonunion

There is not a consensus for the definition of nonunions. One proposed definition by Bhandari and colleagues in 2012 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 non-union in the 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.

- At least 3 months have passed since the date of the fracture
- serial radiographs have confirmed that no progressive signs of healing have occurred
- the fracture gap is 1 cm or less
- the patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing

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Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review

• History and physical and/or consultation reports including:
  o Date of original injury
  o Initial and serial radiologic findings
  o Past medical/surgical treatment and response
  o Reason for request
  o Treatment plan
• Initial and serial radiologic reports
 	
Post Service
• Operative report(s) if applicable

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

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