BONE GROWTH STIMULATION, ULTRASOUND

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member’s specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms “experimental" and "investigational" are considered to be interchangeable.

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BONE GROWTH STIMULATION, ULTRASOUND (cont.)

Description:

A non-invasive device used to induce the growth of bones in cases of fresh fractures, delayed fracture union or fracture nonunion. Uses a low-intensity, pulsed ultrasound signal to stimulate and accelerate fracture-healing time. A transducer is applied to the skin over the fracture site. The ultrasound signal is transmitted to the skin via a conductive coupling gel, which coats the skin surface. Device may be self-administered with daily 20-minute treatments until there is evidence of fracture repair.

Delayed Union and Fracture Nonunion:
No evidence of healing as identified in serial X-rays for at least 3 consecutive months.

Fresh Fracture:
Within 3 months of the date of fracture.

Criteria:

- Ultrasound bone growth stimulation is considered medically necessary with documentation of ALL of the following:
  1. ONE of the following fracture types:
     - Fresh, closed fracture defined as within 3 months of the date of fracture
     - Grade I or II open fracture
  2. Stimulation is used as an adjunct to conventional fracture management (e.g., closed reduction, surgical stabilization or cast/brace immobilization)
  3. Individual is skeletally mature (radiographic evidence of epiphyseal closure)
  4. Documentation of ANY of the following risk factors for delayed fracture healing or nonunion:
     - Current nicotine use
     - Alcoholism by history or diagnosis
     - Established diagnosis of chronic liver, renal or diabetic disease
     - Steroid therapy
     - Osteoporosis
     - Fracture Locations:
       - Fracture of navicular (also called the scaphoid)
       - Fracture of metatarsal (including Jones fracture)
       - Fracture associated with extensive soft tissue or vascular damage
BONE GROWTH STIMULATION, ULTRASOUND (cont.)

Criteria: (cont.)

- Ultrasound bone growth stimulation is considered *medically necessary* for treatment of a fracture, including previously surgically-treated fractures and excluding skull, vertebrae and tumor related with documentation of **ALL** of the following:
  - Delayed or fracture nonunion
  - Serial X-rays confirm no evidence of healing for at least 3 consecutive months
  - Fracture site can be adequately immobilized and individual is of age where they are likely to comply with non-weight bearing

- Ultrasound bone growth stimulation for the following indications is considered *experimental or investigational* based upon insufficient scientific evidence to permit conclusions concerning the effect on health outcomes:
  1. Arthrodesis or failed arthrodesis
  2. Congenital pseudarthrosis
  3. Stress fractures
  4. Fresh surgically-treated closed fractures

Resources:

Literature reviewed 09/13/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


BONE GROWTH STIMULATION, ULTRASOUND (cont.)

Resources: (cont.)

