Overview
The purpose of this document is to describe the guidelines Neighborhood Health Plan (NHP) utilizes to determine medical appropriateness for bone growth stimulation for the treatment of acute fractures and non-union fractures, and in conjunction with spinal fusion.

Coverage Guidelines
NHP covers certain types of bone growth stimulation for the treatment of specific acute fractures, and non-union fractures, or in conjunction with spinal fusion when recommended by the member’s primary care provider or referring specialist and when the request meets medical necessity criteria indicated below.

Coverage for the use of bone growth stimulation requires prior authorization. NHP does not cover invasive electrical bone growth stimulators.

Low Intensity Pulsed Ultrasound (LIPUS)
NHP covers medically necessary LIPUS for a skeletally mature bone when all criteria are met in category 1 or category 2.

Category 1
In lieu of surgery for an acute fracture when:
1. The fracture is one of the following:
   a) Traumatic closed or grade 1 open, short oblique, or short spiral tibial diaphyseal fracture;
   b) Traumatic closed distal radius metaphyseal fracture;
   c) Traumatic closed scaphoid (i.e. carpal navicular) fracture;
   d) Traumatic or stress-induced closed tarsal navicular fracture; or
   e) Traumatic or stress-induced closed fracture of the proximal diaphysis of the 5th metatarsal (i.e. Jones fracture)
2. The member has undergone a well-aligned, closed reduction as applicable and cast immobilization.
3. The member is able to comply with weight bearing recommendations.
4. Any medication known to interfere with bone healing which can be safely discontinued has been discontinued (e.g. oral steroids, NSAIDS, bisphosphonates), and the member has been encouraged to quit smoking.
5. The member is educated about the device, and able to comply with physician advice and device instructions.

Category 2
Non-union of a humerus, radius, ulna, carpal bone, metacarpal, femur, tibia, fibula, tarsal bone, or metatarsal fracture that was secondary to trauma or occurring post-osteotomy or fusion when:
1. The bone had been stabilized by means of casting or fixation and is currently mechanically supported, and weight bearing recommendations have been and are currently being followed.
2. Three months have passed since the date of initial treatment.
3. There is documentation of the lack of progressive healing by serial radiographs (a minimum of 2 sets during the time of expected healing) taken at least 3 months apart.
4. The two portions of the non-union bone are separated by less than 1.0 cm or less than ½ the width of the bone for short bones.
5. Any medication known to interfere with bone healing that can be safely discontinued has been discontinued (e.g. oral steroids, NSAIDS, bisphosphonates), and the member has been encouraged to quit smoking.
6. The member is educated about the device and able to comply with physician advice and device instructions.

Exclusions
NHP does not provide coverage for:
1. LIPUS for conditions that do not meet the criteria noted above.
2. Acute fracture other than listed under covered services.
3. Acute fracture that requires surgical intervention or internal or external hardware fixation.
4. Acute fracture with post-reduction displacement of greater than 50% or unacceptable post-reduction angulation or malalignment.
5. Fracture non-union due to excessive malalignment since the device cannot correct or alter displacement, angulation, or other malalignment.
6. Fracture non-union in which the gap equals or exceeds 1 cm, or is greater than ½ the width of the bone for short bones, or in which a synovial pseudoarthrosis is present.
7. Fracture of any age of the axial skeleton, pectoral girdle, pelvis, phalanx, or sesmoid.
8. Treatment of sesmoiditis.
10. Stress fracture of any age other than tarsal navicular fracture or Jones fracture when criteria above are met.
11. Fracture of any age due all or in part to malignancy or bone pathology.
12. In the setting of infection or osteomyelitis.
13. Adjunct to avascular necrosis of a femoral head repair.
14. A member with any contraindications listed in the device’s package insert.
15. Replacement or repair of LIPUS when:
   a) It is still under manufacture warranty;
   b) It is lost, stolen or damaged due to improper care, or misuse, or neglect (NHP may require proof of the stolen or damaged item. Proof consist of a police report, pictures or corroborating statement); and
   c) The member has a functioning model and a newer or upgraded model is not medically necessary.

Electrical/Electromagnetic Bone Growth Stimulators, Noninvasive (EBGS noninvasive)
NHP covers medically necessary EBGS for a skeletally mature bone when all criteria are met in category 1 or category 2:

Category 1
Non-union of a humerus, radius, ulna, carpal bone, metacarpal, femur, tibia, fibula, tarsal bone, or metatarsal fracture that was secondary to trauma or occurring post osteotomy or fusion when:
1. The bone had been stabilized by means of casting or fixation and is currently mechanically supported, and weight bearing recommendations have been and are currently being followed.
2. Three months have passed from the date of initial treatment.
3. There is documentation of the lack of progressive healing by serial radiographs (a minimum of 2 sets during the time of expected healing) taken at least 3 months apart.
4. The two portions of the non-union bone are separated by less than 1.0 cm or less than ½ the width of the bone for short bones.
5. Any medication known to interfere with bone healing which can be safely discontinued has been discontinued (e.g. oral steroids, NSAIDS, bisphosphonates), and the member has been encouraged to quit smoking.
6. The member is educated about the device and able to comply with physician advice and device instructions.

Category 2
In conjunction with spinal fusion surgery* when:
1. A member has one of the following risk factors for spine fusion failure:
   a) Prior spinal fusion failure evidenced by serial imaging with greater than 9 months past initial surgery and 3 months of lack of progressive healing
   b) Fusion for grade III or IV spondylolisthesis
   c) Multiple level fusions are planned
2. The member has discontinued any medication known to interfere with bone healing that can be safely discontinued (e.g. oral steroids, NSAIDS, bisphosphonates), and the member has been encouraged to quit smoking.
3. The member is educated about the device and able to comply with physician advice and device instructions.

Exclusions
Neighborhood Health Plan does not provide coverage for:
1. EBGS non-invasive for the conditions that do not meet all criteria in category 1 or category 2 above.
2. The conditions excluded under LIPUS.
3. All acute fractures.
4. Replacement or repair of EBGS when:
   a) It is still under manufacture warranty;
   b) It is lost, stolen or damaged due to improper care, or misuse, or neglect (NHP may require proof of the stolen or damaged item. Proof consist of a police report, pictures or corroborating statement);
   c) The member has a functioning model and a newer or upgraded model is not medically necessary.

Definitions
Gustilo Grading for open fractures:
Grade I: Clean wound smaller than 1 cm in diameter, appears clean, simple fracture pattern, no skin crushing.
Grade II: A laceration larger than 1 cm but without significant soft-tissue crushing, including no flaps, degloving, or contusion. Fracture pattern may be more complex.
Grade III: An open segmental fracture or a single fracture with extensive soft-tissue injury. Also included are injuries older than 8 hours. Type III injuries are subdivided into three types:
   Grade III A: Adequate soft-tissue coverage of the fracture despite high-energy trauma or extensive laceration or skin flaps.
   Grade III B: Inadequate soft-tissue coverage with periosteal stripping. Soft-tissue reconstruction is necessary.
   Grade III C: Any open fracture that is associated with vascular injury that requires repair.

Long bone fracture non-unions: Having no visible evidence of healing for at least 3 months as confirmed by a minimum of 2 sets of radiographs taken a minimum of 90 days apart. Each radiograph must show multiple views of the fracture site.

Failed spinal fusion: Spinal fusion that has not healed as evidenced by serial imaging with greater than 9 months past initial surgery and 3 months of lack of progressive healing.

Spondylolisthesis Grading
Grade I: 0-25% vertebral slippage
Grade II: 25-50% vertebral slippage
Grade III: 50-75% vertebral slippage
Grade IV: 75-100% vertebral slippage
Grade V: Greater than 100% vertebral slippage.

* Spinal fusion surgery is subject to separate clinical criteria. Authorization for an EBGS in conjunction with spinal fusion surgery is not an authorization for the surgery itself.
Related Policies

Effective
October 2015: Annual review, no substantial change in the literature.
October 2014: Annual review without substantial changes in medically necessary indicators.
August 2013: Annual update, added invasive bone growth stimulators to exclusions after literature and independent practitioner review.
August 2012: Annual update, no changes.
August 2011: Effective date

References


