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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

Bone and Tendon Graft Substitutes Policy

Indication/Usage:

Osteogenic proteins, also referred to as bone morphogenetic, or morphogenic proteins (BMPs), are a family of bone-matrix polypeptides isolated from a variety of mammalian species. Implantation of OPs induces a sequence of cellular events that lead to the formation of new bone. Some of the potential clinical applications of OPs are for bone graft substitute to promote spinal fusion and to aid in the incorporation of metal implants, to improve the performance of autograft and allograft bone, and as an agent for osteochondral defects. Biologic allograft materials can include allografts made from bone, allografts containing stem cells or other materials besides bone, or a combination of both.

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Medical Indications for Authorization Commercial and Medicare Members

SummaCare considers the following bone and tendon graft/substitutes medically necessary for the enhancement of bone healing.

1. **FDA Approved Bone graft materials**
   - Autografts
   - Demineralized bone matrix (DBM)
   - Allograft-based products

2. **Infuse® Bone Graft (Recombinant human bone morphogenetic protein-2)(rhBMP- 2)**

   Lumbar spine when the following criteria are met:
   - The member meets medical necessity criteria for lumbar spinal fusion
   - The approach is anterior or oblique AND used in conjunction with an INFUSE bone graft FDA-approved cage (interbody fusion device)
   - Skeletally mature person with degenerative disc disease
   - The fusion involves vertebral bodies L2-S1, without or with spondylolisthesis of no more than grade 1 (25% displacement) at the involved level
   - The fusion is single level

   In surgical repair of an acute, open tibial shaft fractures when BOTH of the following criteria are met:
   - Fracture is stabilized with intramedullary (IM) nail fixation
   - rhBMP–2 is applied within 14 days of the fracture

INFUSE Bone Graft is experimental and investigational for all other indications, including its use in ankle fusions and cervical fusions, because its effectiveness for indications other than the ones listed above has not been established.

3. **Polymethylmethacrylate (PMMA) or Calcium Antibiotic Beads**

   PMMA antibiotic beads or calcium sulfate antibiotic beads are medically necessary for use in conjunction with intravenous antibiotics in the treatment of chronic osteomyelitis.

4. **Bone Marrow injections**

   Bone marrow injections are medically necessary in the treatment of bone cysts (unicameral/simple).

5. **Hydroxyapatite Bone Substitute**

   Hydroxyapatite bone substitute medically necessary for middle ear surgery.

6. Beta Tri-Calcium Phosphate (B-TCP)-Based Bone Graft Extenders and Substitutes Products

Beta tri-calcium phosphate (b-TCP)-based bone graft extenders and substitutes are medically necessary for spinal fusions.

CPT Codes

20930	Allograft for spine surgery only; morselized
20931	Allograft for spine surgery only; structural
20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)
C1762	Connective tissue, human (includes fascia lata)
C9359	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Putty, Integra OS Osteoconductive Scaffold Putty), per 0.5 cc
C9362	Porous purified collagen matrix bone void filler (Integra Mozaik Osteoconductive Scaffold Strip), per 0.5 cc
0707T	Injection(s), bone substitute material (eg, calcium phosphate) into subchondral bone defect (ie, bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization
11981	Insertion, non-hyphenbiodegradable drug delivery implant
11982	Removal, non-hyphenbiodegradable drug delivery implant
11983	Removal with reinsertion, non-hyphenbiodegradable drug delivery implant

There is currently no NCD or LCD per CMS

Limitations

SummaCare considers all other bone and tendon graft substitutes experimental and investigational because there is insufficient evidence to support their use for these indications.

Coverage Decisions

Coverage decisions made per CMS Guidelines, Hayes Research and industry standards research

Plans Covered By This Policy

Commercial and Medicare
Self-funded Commercial groups refer to plan document for coverage

Sources Reviewed

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https://global.medtronic.com/xg-en/e/response/infuse-bone-graft.html

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