



CLINICAL GUIDELINES

CMM-612: Grafts Guidelines

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eviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist and/or individual's Primary Care Physician (PCP) may provide additional insight.

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Clinical guidelines for medical necessity review of Comprehensive Musculoskeletal Management Services.

CMM-612: Grafts

CMM-612.1: General Guidelines

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CMM-612.1: General Guidelines

- The determination of medical necessity for grafts (orthobiologics) is always made on a case-by-case basis.
- For prior authorization requirements, see **CMM-600.1: Prior Authorization Requirements**.

CMM-612.2: Recombinant Human Bone Morphogenetic Protein (rhBMP-2) (InFuse®)

- The clinical criteria of this policy addresses the scope and clinical indications for Recombinant Human Bone Morphogenetic Protein – 2 (rhBMP-2) (InFuse®) in spinal fusion surgeries only and not for other indications for its use in the appendicular skeleton (e.g. tibial fracture non-union repair surgery).
- These criteria are developed to manage patients very unlikely to fuse without rhBMP. Patients very likely to fuse without rhBMP include most pediatric patients, healthy patients undergoing one level lumbar fusion procedures and undergoing routine anterior and posterior cervical fusions.

(rhBMP-2) (InFuse®) Indications

Anterior Lumbar Interbody Fusion (ALIF)

- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **medically necessary** for a stand-alone anterior lumbar interbody fusion (ALIF) for all patients except males with a strong reproductive priority.

Posterolateral Lumbar Fusion and Posterior Lumbar Interbody Fusion (PLIF and TLIF)

- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **medically necessary** for posterolateral lumbar fusion and posterior lumbar interbody fusion (PLIF and TLIF) when **ONE or MORE** of the following conditions at high risk for fusion failure is present:
 - ◆ Revision spinal fusion surgery for pseudarthrosis following one or more previous failed spinal fusion surgery(ies)
 - ◆ Spinal fusion surgery in a compromised graft bed (e.g. prior radiation therapy)
 - ◆ Thoracolumbar fusion for correction of spinal deformity performed at more than one level
 - ◆ Multilevel spinal fusion surgeries (> 3 spinal motion segments)
 - ◆ Long posterior fusions to the sacrum in adults patients undergoing correction or stabilization of spinal deformity
 - ◆ Single level anterior interbody lumbar or lumbosacral fusion (ALIF) using an FDA approved fusion device when there is Meyerding Grade III or greater spondylolisthesis.

- ◆ Metabolic or other conditions when traditional, autogenous bone grafting has a high risk of failure (**ONE or MORE** of the following):
 - Current smoker
 - Insulin diabetic with poor glycemic control
 - Chronic renal disease
 - Alcohol Use Disorder (AUD)
 - Corticosteroid dependence
 - Pediatric patients with neuromuscular scoliosis or occipitocervical pathology
- ◆ Autogenous bone graft is either not available, is inadequate volume, or of poor quality to be useful (**ONE or MORE** of the following):
 - Rheumatoid arthritis
 - Osteoporosis
 - Trauma patients with concomitant pelvic injury
 - Patients at high risk for post-harvest iliac crest fracture

(rhBMP-2) (InFuse®) Non-Indications

Not Medically Necessary

- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **not medically necessary** for **ANY** of the following:
 - ◆ Skeletally immature patients unless there is a high risk for fusion failure
 - ◆ Planned use of grafting in the vicinity of a resected or extant neoplasm
 - ◆ Known contraindications including pregnancy, hypersensitivity/allergy, infection, spinal malignancy
 - ◆ Routine anterior and/or posterior cervical fusion surgery other than in pediatric patients with a high risk of fusion failure
 - ◆ Routine pediatric spine fusion procedures including correction of adolescent idiopathic scoliosis
 - ◆ Single level anterior interbody lumbar or lumbo-sacral fusion (ALIF) using an FDA approved fusion device when there is Meyerding Grade II or less spondylolisthesis

CMM-612.3: Bone Marrow Aspirate Concentrate (BMAC)

- Definition/technique for bone marrow aspirate concentrate:
 - ◆ A bone marrow aspirate concentrate (BMAC) is intended as a high concentration of viable connective tissue osteoprogenitor cells. The aspiration technique requires that no more than 2 mL of blood is aspirated from any given area in the iliac crest to avoid dilution with peripheral blood. The aspiration of 80 to 100 cc of marrow from the iliac crest is performed using a sequential technique (Muschler) through a small incision made over the iliac crest through different trajectories until the desired amount is obtained. A single aspiration instead of using a sequential technique produces the lowest yield of viable cells. The aspirate is then transferred to the concentrating device (centrifuge) that removes the red blood cell fractions and plasma. The BMAC can be admixed to the osteoconductive biocompatible substrates of choice e.g. collagen sponges, hydroxyapatite (HA) substrates and other porous ceramics as well as particulate demineralized bone matrix (DBM) to fabricate composite hybrid grafts.

BMAC Indications

- Bone marrow aspirate concentrate (BMAC) is considered **medically necessary** for hybrid or composite grafting (combined osteoinductive and osteoconductive) including autologous corticocancellous iliac crest bone graft (ICBG) for postero-lateral lumbar spinal fusion surgery (spondylodesis) with or without spinal instrumentation.

BMAC Non-Indications

Experimental, Investigational, or Unproven (EIU)

- Bone marrow aspirate concentrate (BMAC) is considered **experimental, investigational, or unproven (EIU)** for **ALL** of the following:
 - ◆ BMAC combined with allograft or synthetic scaffold as a substitute for autologous bone graft for spinal fusion surgery (spondylodesis) with or without spinal instrumentation
 - ◆ Application to cervical/thoracic spinal fusion surgery with or without instrumentation
 - ◆ Anterior spinal fusion surgery with or without instrumentation
 - ◆ Application to spinal decompression without fusion
 - ◆ Disc arthroplasty surgery
 - ◆ Use of lumbar interspinous devices
 - ◆ Obtaining BMAC without using the sequential technique as outlined
 - ◆ Use of unfractionated BMAC
 - ◆ Infection (e.g. discitis, epidural abscess, osteomyelitis)
 - ◆ Primary or metastatic neoplastic disease of the spine

CMM-612.4: Bone Graft Substitutes

Bone Graft Substitutes Non-Indications

Experimental, Investigational, or Unproven (EIU)

- **ALL** of the following bone graft substitutes for the enhancement of bone healing is considered **experimental, investigational, or unproven (EIU)**:
 - ◆ rhBMP-7 (i.e., OP-1™)
 - ◆ INFUSE/MASTERGRAFT™ Posterolateral Revision Device
 - ◆ Human amniotic membrane bone graft substitute
 - ◆ Cell-based substitutes other than a bone marrow aspirate (e.g. mesenchymal stem cell therapy, Osteocel®, ViviGen®, Trinity®) when used to enhance bone healing
 - ◆ Human growth factors (e.g. fibroblast growth factor, insulin-like growth) when used to enhance bone healing
 - ◆ Platelet rich plasma (e.g. autologous platelet derived growth factor) when used to enhance bone healing
 - ◆ Allograft bone graft substitutes used exclusively as stand-alone stabilization devices for fusion (e.g. TruFuse® for isolated facet fusion, NuFix™ for isolated facet fusion, BacFast® HD for isolated facet fusion)
 - ◆ Bone graft substitutes used to reduce donor site morbidity (e.g. iliac crest donor site reconstruction)
 - ◆ Ceramic-based products (e.g. b-TCP)
 - ◆ OptiMesh® deployable grafting system

CMM-612.5: Procedure (CPT®) Codes

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.	
CPT®	Code Description/Definition
+20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only (List separately in addition to code for primary procedure)
+20931	Allograft, structural, for spine surgery only (List separately in addition to code for primary procedure)
+20936	Auto graft for spine surgery only (includes harvesting the graft); local (e.g. ribs, spinous process, or laminar fragments) obtained from same incision (List separately in addition to code for primary procedure)
+20937	Auto graft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
+20938	Auto graft for spine surgery only (includes harvesting the graft); structural, bicortical or tricortical (through separate skin or fascial incision) (List separately in addition to code for primary procedure)
+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).
This list may not be all inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.	

CMM-612.6: References

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