Cigna Medical Coverage Policies – Musculoskeletal Grafts

Effective July 1, 2025

Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

CMM-612: Grafts

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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 additional timing and documentation requirements, see **CMM-600.1: Prior Authorization Requirements**.

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

Application of Guideline

- The clinical criteria in this policy section is intended to only address the scope and clinical indications for Recombinant Human Bone Morphogenetic Protein – 2 (rhBMP-2) (InFuse®) in **spinal fusion** surgeries.
  - This policy is not intended to address Recombinant Human Bone Morphogenetic Protein – 2 (rhBMP-2) (InFuse®) for use in the appendicular skeleton (e.g., tibial fracture non-union repair surgery).
- These criteria are developed to manage individuals that are considered **very unlikely to fuse without rhBMP-2**.
  - Individuals that are considered very likely to fuse without rhBMP-2 include the following: most pediatric individuals; healthy individuals undergoing one-level lumbar fusion procedures; and, healthy individuals undergoing routine anterior and posterior cervical fusions. For specific criteria, see the applicable surgery type for which rhBMP-2 is being requested.

Recombinant Human Bone Morphogenetic Protein (rhBMP-2) (InFuse®) Indications

Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **medically necessary** when performed for **ANY** of the following procedures when **ALL** of the associated criteria are met:

Anterior or Posterior Cervical Fusion

- The individual does not have any known contraindications including pregnancy or hypersensitivity/allergy
- Performed for an associated approved spinal fusion surgery
- The individual has **EITHER** of the following conditions that would place the individual at high-risk for fusion failure without rhBMP-2:
  - Neuromuscular scoliosis
  - Occipitocervical pathology

Anterior Lumbar Interbody Fusion (ALIF)

- Performed for an associated approved **stand-alone** anterior lumbar interbody fusion (ALIF)
- The individual does not have any known contraindications including pregnancy or hypersensitivity/allergy
- The individual is skeletally mature

Posterolateral Lumbar Fusion (PLF), Posterior Lumbar Interbody Fusion (PLIF), and Transforaminal Lumbar Interbody Fusion (TLIF)

- The individual does not have any known contraindications including pregnancy or hypersensitivity/allergy
- Performed for an associated approved spinal fusion surgery
- There is a high risk for fusion failure due to **ANY** of the following clinical scenarios:
  - High-risk for fusion failure using traditional autogenous bone grafting in **ANY** of the following planned surgeries:
    - Revision spinal fusion surgery for pseudoarthrosis 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
    - Multi-level spinal fusion (i.e., 3 or more spinal motion segments)
    - Long posterior fusions to the sacrum in adult individuals undergoing correction or stabilization of spinal deformity
    - Single-level lumbar or lumbosacral fusion with or without interbody when there is Meyerding Grade III or greater spondylolisthesis
  - High risk of fusion failure using traditional autogenous bone grafting due to **ANY** of the following metabolic or other conditions:
    - Current smoker
    - Insulin diabetic with poor glycemic control
    - Chronic renal disease
    - Alcohol Use Disorder (AUD)
    - Corticosteroid dependence
    - Neuromuscular scoliosis
    - Traditional autogenous bone graft is not available, is inadequate in volume, or is of poor quality due to **ANY** of the following:
      - Rheumatoid arthritis
      - Osteoporosis
      - Trauma with concomitant pelvic injury
      - Individuals at high risk for post-harvest iliac crest fracture

CMM-612.3: Bone Marrow Aspirate Concentrate (BMAC)

Definition/Technique for BMAC

- **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.
  - To fabricate composite hybrid grafts, 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]).

BMAC Indications

Bone marrow aspirate concentrate (BMAC) is considered **medically necessary** when **ALL** of the following criteria are met:

- BMAC is obtained using the **sequential technique** (as outlined in the **Definition/Technique for BMAC** section)
- Used as hybrid or composite grafting (combined osteoinductive and osteoconductive) including autologous corticocancellous iliac crest bone graft (ICBG)
- Performed for an associated approved **postero-lateral lumbar spinal fusion** surgery (spondylodesis) with or without spinal instrumentation.
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CMM-612.4: Bone Graft Substitutes

- See Bone Graft Substitutes in **CMM-615: Non-Indications**.
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CMM-612.5: Non-Indications

Not Medically Necessary

Recombinant Human Bone Morphogenetic Protein (rhBMP-2) (InFuse)

- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) performed without meeting the criteria in **CMM-612.1: General Guidelines** and the

applicable section of **CMM-612.2** (anterior or posterior cervical fusion; ALIF; or, PLF, PLIF, and TLIF) is considered **not medically necessary**.

- Recombinant human bone morphogenetic protein – 2 (rhBMP-2) (InFuse®) is considered **not medically necessary** when performed for **EITHER** of the following (unless there is a high risk for fusion failure without rhBMP-2):
  - Routine anterior or posterior cervical fusion surgery
  - Routine pediatric spine fusion procedures including correction of adolescent idiopathic scoliosis

Bone Marrow Aspirate Concentrate (BMAC)

- Bone marrow aspirate concentrate (BMAC) is considered **not medically necessary** when **ANY** of the following apply:
  - BMAC is 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
  - Use of unfractionated BMAC
  - Infection (e.g., discitis, epidural abscess, osteomyelitis)
  - Primary or metastatic neoplastic disease of the spine

Bone Graft Substitutes

- **ALL** of the following bone graft substitutes (for the enhancement of bone healing) are considered **not medically necessary**:
  - 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., β-TCP)
  - OptiMesh® deployable grafting system

Codes (CMM-612)

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Code	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).

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Evidence Discussion (CMM-612)

Grafts

Risks and complications associated with the use of recombinant human bone morphogenetic protein-2 (rhBMP-2) have been well documented in the literature. Complications include, but are not limited to, the following: swelling; edema; heterotopic ossification; osteolysis; seroma/hematoma; infection; arachnoiditis; dysphagia/airway obstruction (anterior cervical surgery); and, neurological deficits (myelopathy, radiculopathy). Given the potential possibility for serious complications, proper surgical candidacy selection is critical to minimize the risk benefit ratio.

There have been over 20 randomized control trials which have shown equivalent or superior efficacy of rhBMP-2 to iliac crest bone graft (ICBG). The literature supports the use of rhBMP-2 for stand-alone anterior lumbar interbody fusion (ALIF). rhBMP-2 is also supported for posterolateral lumbar fusion (PLF), posterior lumbar interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF) when there is high risk for nonunion with autogenous bone graft or in those individuals with inadequate or poor quality autogenous bone available. The North American Spine Society (NASS) *Coverage Policy Recommendations: Recombinant Human Bone Morphogenetic Protein (rhBMP-2)* includes the following high-risk conditions: revision posterior fusion; individuals with poor quality or unavailable iliac crest autograft (trauma with concomitant pelvic injury, rheumatoid arthritis, etc.); multilevel surgeries (>3 levels), particularly those extending to the sacrum or pelvis; elderly individuals with osteoporosis; previous radiation or other insult to the fusion bed; metabolic factors that are likely to interfere with proper autograft incorporation (e.g.,smokers and diabetics).

Use of rhBMP-2 is not recommended for routine single level posterior/posterolateral fusions in healthy adults and routine pediatric spine fusion procedures (e.g., adolescent idiopathic scoliosis). Due to risks of airway obstruction and dysphagia with the use of rhBMP-2 as an adjunct in cervical spine surgery, it is only recommended for individuals at very high risk for fusion failure (neuromuscular scoliosis, occipitocervical pathology) and not for routine anterior and posterior cervical fusion procedures. rhBMP-2 is not recommended for individuals who are skeletally immature. It should also be of note that there is insufficient evidence to support the use of rhBMP-7.

The literature pertaining to the use of bone marrow aspirate concentrate (BMAC) in spine surgery consists mainly of small observational studies. There have been few randomized controlled trials and the trials contained low numbers of participants. Although the studies have supported the use of BMAC, strong evidence-based conclusions are unable to be made at this time.

There is also lack of sufficient high-level evidentiary support for the use of the following: platelet rich plasma; mesenchymal stem cell therapy; human amniotic membrane bone graft substitute; human growth factors (e.g., fibroblast growth factor, insulin-like growth); bone graft substitutes used to reduce donor site morbidity; ceramic based products; allograft graft substitutes used exclusively as stand-alone stabilization devices for fusion; OptiMesh® deployable grafting system; and, INFUSE/MASTERGRAFT™ posterolateral revision device for the enhancement of bone healing.

As risk for major complications exists with grafting procedures, it is critical to optimally ensure that individuals receive treatment that is appropriate, safe and effective. Although the use of any coverage criteria includes the possible risk of delayed care, application of evidence based criteria best ensure patient safety and highly outweigh any clinical harms.

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