# Bone and Tendon Graft Substitutes

| LOB(s): | State(s): |
|---|---|
| ☒ *Commercial*<br>☒ *Medicare* | ☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:* |
| ☒ *Medicaid* | ☒ *Oregon* ☐ *Washington* |

## Enterprise Policy

*PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.*

*Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.*

## Background

Bone grafts may be used during spinal fusion procedures to bridge bone defects or fill cavities created by tumor removal, cysts, or other causes.

Bone graft material may come from autografts, allografts, or synthetic sources.

### Autografts

An autograft is taken directly from an individual's own body and considered the gold standard for spinal arthrodesis. The usual site for an autograft harvest is the posterior iliac crest. When autograft material is not available in sufficient volume, is of poor quality or cannot be used for any other reason, a different material is substituted for the bone graft. An Allograft may be used when autografting is not an option.

### Allografts

Allografts are obtained from cadaveric bone and/or tissue from a bone bank and may be used alone or in combination with another material. Even when a cadaveric bone is used alone the allograft must be processed to decrease the likelihood of disease transmission and immunogenic response. Examples of allografts include bone morphogenetic proteins, demineralized bone matrix products and cadaver donor bone.

**Bone Morphogenetic Proteins (BMP)** are naturally occurring proteins found in human bone and play an active role in bone formation. The allograft consists of rhBMP-2 on an absorbable collagen sponge carrier and is designed for use with a fusion device.

**Demineralized Bone Matrix (DBM)** products are a class of commercially available grafting agents produced by acid extraction of allograft bone (known as decalcification). DBM may be a freeze-dried powder, granules, gel, putty, or strips.

### Synthetic grafts

This type of bone graft uses artificially produced materials made from a variety of porous substances such as polymers, ceramics, composites, and cell-based techniques. Some also contain proteins that support bone development and may also enhance bone fracture healing or bone fusion.

## Criteria

### Commercial

**Prior authorization is required**

**I. Allograft for Spinal Fusion**

**A. Bone Morphogenetic Proteins (BMP)**

PacificSource considers the use of bone morphogenetic proteins (e.g., INFUSE®) with a spinal fusion device (i.e., cage) medically necessary for single-level lumbar spinal fusion procedures when **ALL** of the following criteria is met:

1. BMP is requested for single-level spinal fusion
2. Member is skeletally mature
3. Member has tried/failed at least six (6) months of conservative treatment
4. Member does not have greater than Grade I spondylolisthesis at the involved level
5. Member has degenerative disc disease at one or more lumbar level(s) L2-S1
6. Use of autograft is not feasible for one or more of the following reasons:
    a. Member has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available or is insufficient for the intended purpose
    b. Member is deemed an unacceptable candidate for autograft for **ANY** of the following reasons:
        - Over 65 years of age
        - Excessive risk of anatomic disruption (including fracture) from harvesting of an autograft
        - Member has co-morbidities or health-related behaviors (e.g., current tobacco use, chronic steroid use, osteoporosis, malnutrition, obesity, diabetes, pseudoarthrosis, etc.) which increases the risk of an autograft
        - Presence of an infection or fracture which prevents harvesting of an autograft

**B. Demineralized Bone Matrix (DBM)**

PacificSource considers demineralized bone matrix products medically necessary for spinal fusions and for filling osteochondral defects when autograft is not feasible.

- Examples of DBM include, but are not limited to the following: Accell, Accell Evo3, AlloFuse, Allogor DBM, Allomatrix, Cortico-Cancellous, DBX, DynaGraft, DynaGraft, Exactech Resorbable Bone Paste, Grafton DBM, Intergro DBM, Magnifuse, Optefil, Opteform, Origen DBM, OrthoBlast, Ostefil, OsteoAmp allograft. OsteoSelect, OsteoSponge, OsteoStrand, OsteoStrand Plus and Progenix.

**C. Cadaveric Allograft**

PacificSource considers the use of cadaveric allograft medically necessary for spinal fusions and for filling osteochondral defects when autograft is not feasible.

**D. Synthetic Grafts**

PacificSource considers the use of Polymethylmethacrylate (PMMA) or Calcium Sulfate Antibiotic Beads to be medically necessary for, or in conjunction with intravenous antibiotics, in the treatment of chronic osteomyelitis.

### Medicaid

PacificSource Community Solutions follows Guideline Notes 37, 41, 100, 101, 136, & 137 of the OHP Prioritized List of Health Services and Oregon Administrative Rules (OARs) 410-141-3820 through 410-141-3830 and 410-151-0000 through 410-151-0003 for coverage of Bone Graft Substitutes used for Spinal Fusion**.**

PacificSource Community Solutions (PCS) considers HCPCS code 0232T to have insufficient evidence of effectiveness and HCPCS code 20939 as unproven treatment per Guideline Note 173 of the Oregon Health Plan (OHP) OHP Prioritized list of Health Services.

### Medicare

PacificSource Medicare follows CMS guidelines and criteria. In the absence of CMS guidelines and criteria, PacificSource Medicare will follow internal policy for determination of coverage and medical necessity.

## Experimental/Investigational/Unproven

PacificSource considers the following bone grafts or materials to be experimental, investigational, or unproven:

- INFUSE® Bone Graft for all other indications, including use in cervical fusions and multiple levels for any spinal section.
- Bioactive bone graft matrix (synthetic bone grafts) and combination bioactive substitutes Examples include, but are not limited to the following:
    - Augment Regenerative Solutions
    - Beta tricalcium phosphate combined with bioactive glass and hydroxyapatite (e.g., SignaFuse)
    - Bioactive glass and alpha tricalcium phosphate)

    - Bioactive glass combined with hyaluronic acid and collagen (e.g., Kinix)
    - BioSphere Putty Bioactive Bone Graft, Tornado Bioactive
    - DBM combined with bioactive glass (e.g., NanoFuse)
    - FIBERGRAFT BG Morsels
    - FIBERGRAFT BG Putt
    - Hydroxyapatite combined with beta tricalcium phosphate
    - Vitoss BA (Bioactive) Vitoss BiModal (Bioactive)
- Ceramic Bone Void Fillers used alone or in combination with other bone graft materials or bone marrow aspirate, or antibiotic eluding material. Examples include, but are not limited to the following:
    - beta-tricalcium phosphate bone fillers (e.g., Vitoss)
    - calcium phosphate bone filler (e.g., Accufill),
    - collagen/ceramic-based substitutes (e.g., Integra MOZAIK™)
- i-Factor Peptide Enhanced Bone Graft (e.g., Cerapedic) used alone or in combination with other bone graft materials.
- Mesenchymal Stem Cell Therapy/Bone Marrow Aspirate/Bone Marrow Aspirate Concentrate (BMAC) used alone or in combination with other bone graft(s). Examples include, but are not limited to the following:
    - AlloStem, Bio4Th aka BIO$^{4®}$, Osteocel, Osteocel Plus, Ovation, Regenexx, Trinity Evolution aka Trinity Elite Allograft, Vivex Via Graft and ViviGen Cellular Bone Matrix
- Platelet Rich Plasma
- Polymethylmethacrylate (PMMA) or Calcium Sulfate Antibiotic Beads for any other indications than listed above
- PRO-DENSE Injectable Regenerative Graft

## Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

No specific Code - INFUSE  Bone Graft

0232T Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed

11981 Insertion, drug-delivery implant (e.g., bioresorbable, biodegradable, non-biodegradable)

20900 Bone graft, any donor area; minor or small (e.g., dowel or button)

20930 Allograft, morselized, or placement of osteopromotive material, for spine surgery only

20931 Allograft, structural, for spine surgery only

20936 Autograft for spine surgery only (includes harvesting the graft); local (e.g., ribs, spinous)

| | |
|---|---|
| 20939 | Bone marrow aspiration for bone grafting, spine surgery only through separate skin or fascial incision |
| 20999 | Unlisted procedure, musculoskeletal system, general |
| 38230 | Bone marrow harvesting for transplantation; allogeneic |
| 38232 | Bone marrow harvesting for transplantation; autologous |
| 38240 | Hematopoietic progenitor cell (HPC) transplantation |
| 38241 | Bone-marrow/Blood-derived peripheral stem cell transplantation, autologous |
| C1602 | Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable) |
| 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 |



## Definitions

**Allograft** - a graft of tissue transplanted between individuals of the same species.

**Autograft** - a graft of tissue transferred into a new position in the body of the same person.

**Bone Morphogenetic Proteins (BMP)** - naturally occurring proteins found in human bone that play an active role in bone formation.

**Demineralized Bone Matrix (DBM)** - a type of allograft that is produced by acid extraction of allograft bone (decalcification). DBM may be a freeze-dried powder, granules, gel, putty, or strips.

**Pseudoarthrosis** – failure of fusion which results in pain, deformity, neurocompression, or hardware failure.

## Related Policies

Care of the Surgical Patient

Instrumented Spinal Surgery

New and Emerging Technologies - Coverage Status

## References

Abjornson, C., Brecevich, A., Callanan, T., Dowe, C., Cammisa, F. P., & Lorio, M. P. (2018). ISASS Recommendations and Coverage Criteria for Bone Graft Substitutes used in Spinal Surgery. International journal of spine surgery, 12(6), 757–771. https://doi.org/10.14444/5095

Baldwin, P., Li, D. J., Auston, D. A., Mir, H. S., Yoon, R. S., & Koval, K. J. (2019). Autograft, Allograft, and Bone Graft Substitutes: Clinical Evidence and Indications for Use in the Setting of Orthopaedic Trauma Surgery. Journal of orthopaedic trauma, 33(4), 203–213. https://doi.org/10.1097/BOT.0000000000001420

Bhatt, R. A., & Rozental, T. D. (2012). Bone graft substitutes. Hand clinics, 28(4), 457–468. https://doi.org/10.1016/j.hcl.2012.08.001

Fatima, N., Massaad, E., Shankar, G. M., & Shin, J. H. (2020). Structural Allograft versus Polyetheretherketone Implants in Patients Undergoing Spinal Fusion Surgery: A Systematic Review and Meta-Analysis. World neurosurgery, 136, 101–109. https://doi.org/10.1016/j.wneu.2020.01.006

Hayes Knowledge Center. (October 11, 2022). Health Technology Assessment: Comparative Effectiveness Review Of Recombinant Human Bone Morphogenetic Protein (RhBMP) For Use In Spinal Fusion.

Medtronic. Healthcare Professionals: “Infuse Bone Graft” Bone grafting – Spinal and Orthopaedic.” https://www.medtronic.com/us-en/healthcare-professionals/products/spinal-orthopaedic/bone-grafting/infuse-bone-graft.html

Sage, K., and Levin, L. S., (2022). Basic Principles of bone grafts and bone substitutes. UpToDate.

Weisbrod, L. J., Arnold, P. M., & Leever, J. D. (2019). Radiographic and CT Evaluation of Recombinant Human Bone Morphogenetic Protein-2-assisted Cervical Spinal Interbody Fusion. *Clinical spine surgery*, *32*(2), 71–79. https://doi.org/10.1097/BSD.0000000000000720

## Appendix

**Policy Number:**

**Effective:** 7/1/2020 **Next review:** 7/31/2025

**Policy type:** Enterprise

**Author(s):**

**Depts:** Health Services

**Applicable regulation(s):** OARs 410-141-3820 through 410-141-3830; OARs 410-151-0000 through 410-151-0003

**Commercial OPs:** 9/2024

**Government Ops:** 8/2024