Bone Graft Substitutes used for Spinal Fusion

LOB(s):	State(s):
☒ *Commercial* ☒ *Medicare*	☒ *Idaho* ☒ *Montana* ☒ *Oregon* ☒ *Washington* ☐ *Other:*
☒ *Medicaid*	☒ *Oregon* ☐ *Washington*

Enterprise Policy

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 comes from several sources such as an autograft, harvested graft from an individual's own bones, or an allograft, which may be made solely of bone, contains stem cells or other materials besides bone, or a combination of both.

Autografts

An autograft is taken directly from an individual 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 used alone, an 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. BMPs are approved by the FDA as a bone graft substitute in lumbar interbody fusions.

- 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.
- Cadaver allografts, retrieved from donor sources processed at a bone bank, are used as grafting agents used for spinal fusion and in treatment of osteochondral defects.

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 but require further research due to insufficient evidence of efficacy.

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 lumbar spinal fusion procedures when **ALL** of the following criteria is met:

1. Member is skeletally mature;
2. Member has tried/failed at least six (6) months of non-operative treatment;
3. Member does not have greater than Grade I spondylolisthesis at the involved level;
4. Member has degenerative disc disease at one or more lumbar level(s) L2-S1;
5. 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, DBX, DynaGraft, DynaGraft, Exactech Resorbable Bone Paste, Grafton DBM, Intergro DBM, Magnifuse, Optefil, Opteform, Origen DBM, OrthoBlast, Ostefil, 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.

Medicaid

PacificSource Community Solutions follows Guideline Notes 37, 100, 101, 136, & 137 of the OHP Prioritized List of Health Services for coverage of Bone Graft Substitutes used for Spinal Fusion**.**

Medicare

PacificSource Medicare follows MCG Lumbar Fusion S-820 and MCG Cervical Fusion, Anterior S-320 for bone graft substitutes used for spinal fusions.

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.
- Ceramic Bone Void Fillers used alone or in combination with other bone graft materials or bone marrow aspirate for spinal fusion. 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
- OsteoAmp allograft
- Platelet Rich Plasma
- PRO-DENSE Injectable Regenerative Graft

- Stimulan absorbable calcium sulfate antibiotic carrier (e.g., Stimulan Rapid Cure, Stimulan Bullet Mat, Stimulan Kits)

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

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

C1713 Stimulan absorbable calcium sulfate antibiotic carrier (e.g., Stimulan Rapid Cure, Stimulan Bullet Mat, Stimulan Kits)

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

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).
HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

Related Policies

Care of the Surgical Patient

Instrumented Spinal Surgery

New and Emerging Technologies - Coverage Status

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.

References

Abjornson, C., Brecevich, A., Callanan, T., et al. (2018). ISASS recommendations and coverage criteria for bone graft substitutes used in spinal surgery. Int J Spine Surg. 2018;12(6):757-771.

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

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:** 7/1/2023

Policy type: Enterprise

Author(s):

Depts: Health Services

Applicable regulation(s): Guideline Notes 37, 100, 101, 136, & 137 of the OHP Prioritized List of Health Services

Commercial Ops: 2/2023

Government Ops: 3/2023