Bone Graft Substitutes used for Spinal Fusion

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

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 determination 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: an individual's own bones, a bone bank demineralized bone matrix, bone graft substitutes, synthetic materials, ceramics (bone void fillers), collagen composites, composite cement materials, bone morphogenetic protein or recombinant human bone morphogenetic.

An autograft is taken directly from an individual and considered the gold standard for bone grafting. 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 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. Demineralized Bone Matrix (DBM) is a type of allograft that is produced by acid extraction of allograft bone (known as decalcification). DBM may be a freeze-dried powder, granules, gel, putty or strips.

Bone morphogenetic proteins (BMP) are naturally occurring proteins found in human bone and play an active role in bone formation. The INFUSE® Bone Graft product (also known as bone morphogenic, or morphogenetic protein-2, BMP-2) consists of rhBMP-2 on an absorbable collagen sponge carrier and is designed for use **ONLY** with the Infuse® Bone Graft/Medtronic Interbody Fusion Device. This device consists of two components containing three parts:

a) Recombinant human bone morphogenetic protein (rhBMP-2).

b) A carrier/scaffold for the bone morphogenetic protein and resulting bone.

c) A spinal fusion cage.

Criteria

Commercial

Prior authorization is required.

I. PacificSource considers the INFUSE Bone Graft/Medtronic Interbody Fusion Device medically necessary for spinal fusion procedures when **ALL** of the following criteria is met:

- Member is skeletally mature;
- Member has tried/failed at least 6 months of non-operative treatment;
- Member does not have greater than Grade I spondylolisthesis at the involved level;
- Member has degenerative disc disease at one level L2-S1;
- Use of autograft is unfeasible for one or more of the reasons:
    a. Member has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available;
    b. The is insufficient autogenous tissue for the intend purpose;
    c. Member is deemed an unacceptable candidate for autograft for **ANY** of the following reasons:
        - Advanced age (over 65 years of age).
        - Excessive risk of anatomic disruption (including fracture) from harvesting autograft from donor site.
        - Member has concurrent medical conditions and co-morbidities that increase the risk of autograft.
        - Member's bone is of poor quality (osteoporosis).
        - Presence of morbidity (infection or fracture) preventing harvesting at autograft donor site.

The following Interbody devices and surgical approaches may be used with Infuse Bone Graft:

These components must be used as a system for the prescribed indication described above. The bone morphogenetic protein solution component must not be used without the carrier/scaffold component or with a carrier/scaffold component different from the one described in this document. The Infuse Bone Graft component must not be used without the Medtronic Interbody Fusion Device component.

A. L-T-Cage Lumbar Tapered Fusion Device

PacificSource considers the INFUSE® Bone Graft/LT-CAGE Lumbar Tapered Fusion Device medically necessary for spinal fusion procedures when **ALL** of the above **AND** following criteria are met**:**

- Device is to be implanted via an anterior open or anterior laparoscopic approach;
- Device is to be implanted at a single level.

B. InterFix or InterFix RP Threaded Fusion Device

PacificSource considers the INFUSE Bone Graft InterFix or InterFix RP Threaded Fusion Device medically necessary for spinal fusion procedures when **All** of the above **AND** following criteria are met:

- Device is to be implanted via an anterior open approach;
- Device is to be implanted at a single level.

C. Perimeter Interbody Infusion Device

PacificSource considers the INFUSE Bone Graft Perimeter Interbody Infusion Device medically necessary for spinal fusion procedures when **All** of the above **AND** following criteria are met:

- Device is implanted either:
    - Via a retroperitoneal anterior lumbar interbody fusion (ALIF) approach for a single level from L2-S1; **OR**
    - With an oblique lateral interbody fusion (OLIF) approach at a single level from L5-S1.

D. Clydesdale Spinal System

PacificSource considers the INFUSE Bone Graft Clydesdale Spinal System necessary for spinal fusion procedures when **All** of the above **AND** following criteria are met:

- Device is implanted via an oblique lateral interbody fusion (OLIF) approach at a single level from L2-L5.

E. Pivox Oblique Lateral Spinal System

PacificSource considers the INFUSE Bone Graft Pivox Oblique Lateral Spinal System medically necessary for spinal fusion procedures when **All** of the above **AND** following criteria are met:

- Device is implanted via an OLIF approach at a single-level from L2-L5.

II. Allograft for Spinal Fusion

PacificSource considers cadaveric allograft and demineralized bone matrix medically necessary for spinal fusions when autograft is not feasible.

Examples of demineralized bone matrix 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.

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 experimental, investigational or unproven because effectiveness for clinical indications have not been established:

1. INFUSE Bone Graft - experimental, investigational or unproven for all other indications, including use in cervical fusions and multiple levels because its effectiveness for indications other than the ones listed above have not been established.

2. Ceramic Bone Void Filler – PacificSource considers the use of Vitoss, a beta-tricalcium phosphate bone void filler and Accufill, a calcium phosphate bone void filler, used alone or in combination with other bone graft materials or bone marrow aspirate experimental, investigational or unproven for spinal fusion.

3. Mesenchymal Stem Cell Therapy/Bone Marrow Aspirate/Bone Marrow Aspirate Concentrate (BMAC) - PacificSource considers the use of mesenchymal stem cell therapy used alone or in combination with other bone graft experimental, investigational or unproven for spinal fusion.

   Examples of mesenchymal stem cell therapy include: AlloStem, Bio4Th aka BIO$^{4®}$, Osteocel, Osteocel Plus, Ovation, Regenexx, Trinity Evolution aka Trinity Elite Allograft, and Vivex Via Graft)

4. Platelet Rich Plasma - PacificSource considers the use of platelet rich plasma experimental, investigational or unproven for spinal fusion.

5. PRO-DENSE – PacificSource considers the use of PRO-DENSE Injectable Regenerative Graft to be experimental, investigational or unproven.

6. Stimulan – PacificSource considers Stimulan absorbable calcium sulfate antibiotic carrier (e.g., Stimulan Rapid Cure, Stimulan Bullet Mat, Stimulan Kits) to be experimental, investigational or unproven for spinal fusion.

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.

INFUSE Bone Graft – No specific code

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 process, or laminar fragments) obtained from same incision

22548 - 22819 Arthrodesis, spine [spinal fusion]

Codes Not Covered

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

20939 Bone marrow aspiration for bone grafting, spine surgery only through separate skin or fascial incision

38220 Bone marrow; aspiration only

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)

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.

Ceramic bone void fillers - synthetically produced bone void fillers used to produce ceramics and numerous chemical compounds.

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.

Related Policies

Instrumented Spinal Surgery

New and Emerging Technologies - Coverage Status

References

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Appendix

Policy Number:

Effective: 7/1/2020 **Next review:** 7/1/2022

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: 12/2021

Government Ops: 12/2021