



Bone Graft Substitutes used for Spinal Fusion

LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid	State(s): <input checked="" type="checkbox"/> Idaho <input checked="" type="checkbox"/> Montana <input checked="" type="checkbox"/> Oregon <input checked="" type="checkbox"/> Washington <input type="checkbox"/> Other: <input checked="" type="checkbox"/> Oregon <input type="checkbox"/> Washington
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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 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:
 - 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.

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 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 for any spinal section 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. i-Factor Peptide Enhanced Bone Graft (Cerapedic) – PacificSource considers the use of i-Factor, a biologic bone graft, used alone or in combination with other bone graft materials experimental, investigational or unproven for spinal fusion.
4. 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 BIO⁴®, Osteocel, Osteocel Plus, Ovation, Regenexx, Trinity Evolution aka Trinity Elite Allograft, Vivex Via Graft and ViviGen Cellular Bone Matrix.
5. OsteoAmp allograft – PacificSource considers the use of OsteoAmp allograft to be experimental, investigational or unproven for spinal fusion.
 6. Platelet Rich Plasma - PacificSource considers the use of platelet rich plasma experimental, investigational or unproven for spinal fusion.
 7. PRO-DENSE – PacificSource considers the use of PRO-DENSE Injectable Regenerative Graft to be experimental, investigational or unproven.
 8. 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.

CPT Codes

- 0232T Injection(s), platelet rich plasma, any tissue, including image guidance, harvesting and preparation when performed
- 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
- 38232 Bone marrow harvesting for transplantation; autologous
- 38240 Hematopoietic progenitor cell (HPC) transplantation
- 38241 Bone-marrow/Blood-derived peripheral stem cell transplantation, autologous

INFUSE Bone Graft – No specific code

HCPCS Code

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

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

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.

Deminerlized 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

Care of the Surgical Patient

Instrumented Spinal Surgery

New and Emerging Technologies - Coverage Status

References

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Appendix

Policy Number:

Effective: 7/1/2020

Next review: 7/1/2023

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: 10/2022

Government Ops: 9/2022