



## Bone Graft Substitutes used for Spinal Fusion

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:	LOB(s): <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Medicare <input checked="" type="checkbox"/> Medicaid
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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 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.

**Autograft** is taken directly from an individual is 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 another type of material is substituted for the bone graft.

**Allograft** is 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, the 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 (Medtronic) consists of rhBMP-2 on an absorbable collagen sponge carrier.

**Ceramic bone void fillers** are synthetically produced bone void fillers.

There are many different methods used to produce ceramics and numerous chemical compounds that can be combined including calcium phosphate, calcium sulfate with calcium phosphate composite, beta tricalcium phosphate or nanocrystalline hydroxyapatite

## Criteria

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### Commercial

**Preauthorization is required.**

#### I. **INFUSE Bone Graft (Bone Morphogenic Protein-2)**

INFUSE Bone Graft is also known as bone morphogenic, or morphogenetic protein-2, BMP-2.

##### 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 following criteria are met:

- Member is skeletally mature: and
- Member has tried/failed at least 6 months of non-operative treatment and
- Member does not have greater than Grade I spondylolisthesis at the involved level; and
- Member has degenerative disc disease at one level L2-S1
- Device is to be implanted via an anterior approach
- Device is to be implanted at a single level
- Use of autograft or cadaveric allograft is unfeasible for one or more of the reasons:
  - Member has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available; or
  - The is insufficient autogenous tissue for the intend purpose; or
  - 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; or
    - Member has concurrent medical conditions and co-morbidities that increase the risk of autograft; or
    - Member's bone is of poor quality (osteoporosis); or
    - Presence of morbidity (infection or fracture) preventing harvesting at autograft donor site.

##### B. **Perimeter Interbody Infusion Device**

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

- Member is skeletally mature; **and**
- Member has tried/failed at least 6 months of non-operative treatment; **and**

- Member does not have greater than Grade I spondylolisthesis at the involved level; **and**
- Member has degenerative disc disease at one level L2-S1, confirmed by patient history and radiographic studies; **and**
- Device is implanted **and**
  - 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**
- Use of autograft or cadaveric allograft is unfeasible for one or more of the reasons
  1. Member has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available; or
  2. There is insufficient autogenous tissue for the intended purpose; or
  3. Member is deemed an unacceptable candidate for autograft for **ANY** of the following reasons
    - Advanced age (over 65 years of age); or
    - Excessive risk of anatomic disruption (including fracture) from harvesting autograft from donor site; or
    - Member has concurrent medical conditions and co-morbidities that increase the risk of autograft; or
    - Member's bone is of poor quality (osteoporosis); or
    - Presence of morbidity (infection or fracture) preventing harvesting at autograft donor site

### C. Clydesdale Spinal System

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

- Member is skeletally mature; and
- Member does not have greater than Grade I spondylolisthesis at the involved level; and
- Member has degenerative disc disease at one level from L2-S1, confirmed by patient history and radiographic studies; and
- Member has had at least 6 months of non-operative treatment; and
- Device is implanted via an oblique lateral interbody fusion (OLIF) approach at a **single level from L2-L5**; and
- Use of autograft or cadaveric allograft is unfeasible for one or more of the reasons
  - Member has received a previous autograft and is not a candidate for further autograft procedures because the tissue is no longer available; or
  - There is insufficient autogenous tissue for the intended purpose; or
  - 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; or
    - Member has concurrent medical conditions and co-morbidities that increase the risk of autograft; or
    - Member's bone is of poor quality (osteoporosis); or
    - Presence of morbidity (infection, or fracture) preventing harvesting at autograft donor site.

## II Allograft for Spinal Fusion

PacificSource considers cadaveric allograft and demineralized bone matrix medically necessary for spinal fusions.

Examples of demineralized bone matrix include Accell, Accell Evo3, AlloFuse, Allogor DBM, Allomatrix, DBX, DynaGraft, DynaGraft, Exactech Resorbable Bone Paste, Grafton DBM, Intergro DBM, Magnifuse, Optefil, Opteform, Origen DBM, OrthoBlast, Osteofil, OsteoSelect, OsteoSponge, and Progenix (this list is not all inclusive).

## III. 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<sup>4</sup>®, Osteocel, Osteocel Plus, Ovation, Regenexx, and Trinity Evolution aka Trinity Elite Allograft)

## IV. Platelet Rich Plasma

PacificSource considers the use of platelet rich plasma experimental, investigational or unproven for spinal fusion.

## V. 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.

## Medicare

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

## Medicaid

PacificSource Medicaid 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.

## Experimental/Investigation/unproven

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

## Coding Information

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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 (List separately in addition to code for primary procedure)

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

38220 Bone marrow; aspiration only

38232 Bone marrow harvesting for transplantation; autologous

38240 - 38241 Hematopoietic progenitor cell (HPC) transplantation

### **Related Medical Policies**

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New and Emerging Technologies - Coverage Status

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## Appendix

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**Depts: Health Service**

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