Medica Central Coverage Policy

Policy Name:	**Synthetic Ceramic-Based and Bioactive Glass Bone Substitutes/Fillers MP9787**
Effective Date:	**01/01/2026**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica Central plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage.

Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number. https://mo-central.medica.com/Providers/SSM-employee-health-plan-for-IL-MO-OK-providers

Medica Central coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Synthetic ceramic-based and bioactive glass bone substitutes/fillers, used singly or in combination with other grafts*****, are investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

*** Note:** The Health Plan considers the following to be investigative and therefore not covered for orthopedic applications: (1) Autologous blood-derive biologics (e.g., platelet-rich plasma, autologous conditioned serum, autologous whole blood), (2) stem cell therapy (e.g. AlloStem®, Cellentra™ VCBM, Osteocel® Plus, Trinity® Evolution™), and (3) OsteoAmp™ allogeneic morphogenic protein.

Note: This policy does not apply to dental applications.

See also related coverage policies: (1) *Autologous Blood-Derived Products (Platelet-Rich Plasma, Autologous Conditioned Serum, Autologous Whole Blood; (2) Stem Cell and Cellular Bone Matrix Productsfor Orthopedic Applications;(3) Recombinant Human Bone Morphogenic Protein-2 (rhBMP-2)/InFUSE and Allogeneic Morphogenic Protein (e.g., OsteoAMP™);* (4) *Motion Preserving Posterior Interspinous/Interlaminar Decompression/Stabilization Devices; (5) mild® Procedure (mild® Device Kit); (6) Laser Spine Surgery, and (7) Percutaneous Disc Decompression Procedures. (Percutaneous Discectomies, Nucleoplasty)*

Description

Ceramics and bioactive glass fillers are synthetically produced bone substitutes/extenders and void fillers used to fill voids and gaps in bone structure. These may be located in the extremities, spine, pelvis, or cranium. These products can be obtained as injectables, pastes, putties, solid

matrices, and granules. Ceramics are made by a process called sintering - a process using high temperatures to extract individual crystals that fuse into grains of varying sizes.

Ceramic-based bone grafts are made up of collagen, calcium phosphate (CaP), calcium sulfate and one or more of the following products:

1. Synthetic hydroxyapatite (HA), a component in bone and teeth
2. Beta-tricalcium phosphates (β-TCP)
3. Biphasic calcium phosphate (BCP), which consists of both HA and β-TCP
4. Bioactive glass.

These have been proposed for use as stand-alone products or in combination with other bone substitutes and/or enhancement products (e.g., platelet rich plasma, bone morphogenic protein, demineralize bone matrices).

FDA Approval

Multiple synthetic ceramic-based and bioactive glass bone substitutes/fillers have received FDA approval, mostly through the 510(k) clearance process. To locate marketing clearance information for a specific device or manufacturer, search the Center for Devices and Radiological Health (CDRH) 510(k) database or the Premarket Approval (PMA) database by product and/or manufacturer name, located at: (https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/).

Examples of synthetically produced beta tricalcium phosphate bone fillers include, but are not limited to:

1. Bicera
2. Conduit TCP Granules
3. FM-O2
4. Formagraft Bone Graft
5. GenerOs
6. GranOS
7. Integra Mozaik
8. Integra OS
9. IsoTis Mozaik
10. OSferion
11. Osteoconductive Scaffold
12. OsteoStrux
13. OsSatura TCP
14. Osteomatrix
15. OsteoVation B-TCP
16. Synthes ChronOS
17. Vitoss
18. Vitoss Bioactive Foam-2X.

Examples of synthetic bioactive glass bone fillers include, but are not limited to:

1. Bi-Ostetic Bioactive Glass

2. BioSphere Flex
3. BioSphere Putty Bone Graft
4. BonAlive
5. CLM Bioative Scaffold
6. FIBERGRAFT BG Morsels
7. Interface
8. NanoFUSE
9. NovaBone
10. NovaBone BIOACTIVE Strip
11. NovaBone-C/M
12. Osteofuse Bioactive
13. PerioGlas
14. Signify Bioactive.

Examples of synthetic nanocrystalline hydroxyapatite bone fillers include, but are not limited to:

1. Beta-BSM (injectable form)
2. CarriGen
3. Cem-Ostetic
4. Gamma-BSM moldable putty
5. NanOss Bioactive.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

HCPC Codes:

- **A2002** - Mirragen Advanced Wound Matrix, per sq cm
- **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
- **0707T** - Injection(s), bone-substitute material (eg, calcium phosphate) into subchondral bone defect (ie, bone marrow lesion, bone bruise, stress injury, microtrabecular fracture), including imaging guidance and arthroscopic assistance for joint visualization

- **0814T** - Percutaneous injection of calcium-based biodegradable osteoconductive material, proximal femur, including imaging guidance, unilateral

Original Effective Date:	09/01/2024
Re-Review Date(s):	08/21/2025
Administrative Update:	05/15/2024