



Medica Central Coverage Policy

Policy Name: Stem Cell and Cellular Bone Matrix Products for Orthopedic Applications MP9758

Effective Date: 09/01/2024

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

Stem cell and cellular bone matrix products for orthopedic applications, including but not limited to, treatment of osteoarthritis, bone fractures and nonunions, and as an adjunct to spinal fusion, is 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 safety and efficacy or effects on health care outcomes.

This includes:

- Allograft bone products containing stem cells
- Allograft or synthetic bone graft substitutes that must be combined with autologous blood or bone marrow
- Amniotic products
- Bone marrow aspirate
- Cellular Bone Matrix products
- Concentrated, engineered or expanded stem cells.

Examples of products include, but are not limited to:

- AlloStem®
- ArthroCell™ Bone Allograft (Arthrex)
- AmnioCord® (MiMedx)

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- AmnioFix® (MiMedx)
- Bio4™ Viable Bone Matrix (formely known as Ovation®) (Osiris Therapeutics/Stryker)
- Bone marrow aspirate
- Cellentra™ VCBM (Viable Cell Bone Matrix) (ZimVie)
- CeLLogix™ (Omnia Medical)
- Clarix® Cord 1K (BioTissue)
- FiberCel® (Aziyo Biologics)
- Lipogems® Microfragmented Adipose Tissue Transplant System
- Magnus® Bone Graft (Royal Biologics)
- Map3® (RTI Surgical)
- Osteocel® Plus and PRO (NuVasive)
- OsteoVive™ (Xtant Medical)
- OsteoXcell® Viable Bone Matrix (Aziyo Biologics, Inc.)
- PrimaGem® Advanced Allograft (Zimmer Biomet)
- Regenexx (Regenerative Sciences)
- SCYLLA™ and SCYLLA™-F (Chamber Spine)
- Trinity Evolution® and ELITE® (Orthofix Medical Inc.)
- V92™ and V92-FC™
- VIA® Graft (Vivex Biologics)
- ViviGen® Cellular Bone Matrix and ViviGen® Formable (DePuy Synthes).

Description

Stem cell therapy (autologous or allogeneic): Has been proposed as a way to stimulate and promote bone healing. Stem cells can be harvested from iliac crest bone marrow, adipose tissue, or peripheral blood from the individual or a donor. Bone marrow aspirate is considered to be the most accessible and most common source to isolate MSCs. The stem cells are injected into affected joints or spinal discs alone or in combination with an allograft bone product, such as demineralized bone matrix (DBM), or a synthetic bone graft substitute. Potential uses of this therapy include, but are not limited to, treatment of damaged bone, cartilage, ligaments, tendons and intervertebral discs.

Amniotic Products: Are a source of mesenchymal stem cells (MSCs), are biologically active, and contain a host of growth factors and cytokines. These properties are considered to have the potential to relieve pain, promote healing and improve functional impairment by promoting tissue repair and regeneration. These products may be processed into injectable liquid, trimmable sheets or wraps.

Cellular Bone Matrix Products: Allogenic bone grafts containing mesenchymal stem cells, lineage committed bone cells or bone-derived cells.

Cell-Based Products: Bone graft substitutes that are cell-based use cells to generate new tissue either alone, with other biomaterials, or seeded onto a support matrix (e.g., in combination with an allograft material). Cell-based approaches are mainly based on mesenchymal stem cells (MSCs) used in combination with an allograft.

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Concentrated Bone Marrow Aspirate: Usually obtained from the iliac crest or local vertebrae. The bone marrow aspirate contains stem cells that have been proposed to help with the healing of some bone and joint conditions.

Osteogenesis: Is the process of bone formation. Four types of bone cells are involved in bone formation and remodeling.

- **Osteoblasts:** are bone-forming cells. Derived from mesenchymal stem cells and responsible for bone matrix synthesis and mineralization
- **Osteocytes:** are mature bone cells. These cells are osteoblasts that become trapped within the bone matrix and are responsible to keep bones healthy
- **Osteoclasts:** are cells that resorb or break down old bone
- **Bone lining cells:** cells that line the surface of all bones.

FDA Approval

Stem cell transplantation is a procedure and therefore not subject to FDA regulation. However, any medical devices, drugs or tests used as part of the procedure may be subject to FDA regulation. Stem cells, like other medical products intended to treat, cure, or prevent disease, generally require FDA approval or clearance prior to marketing.

Concentrated autologous MSCs (processed by clinicians in the office by centrifuge without manipulating or adding agents to the mix) do not require FDA approval. To date, no products using engineered or expanded MCSs have been approved by the FDA for orthopedic applications.

The FDA regulates human cells or tissues intended for implantation, transplantation, infusion, or transfer into a human recipient as human cells, tissues or cellular- or tissue-based products (HCT/P) in accordance with U.S. FDA requirements. Products under HCT/P regulation do not require 510(k) clearance or premarket approval. However, the manufacturer must meet specific FDA regulations for the collection, processing, and selling of HCT/Ps.

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.

CPT Codes:

- **20939** - Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision (List separately in addition to code for primary procedure)
- **0565T** - Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; tissue harvesting and cellular implant creation
- **0566T** - Autologous cellular implant derived from adipose tissue for the treatment of osteoarthritis of the knees; injection of cellular implant into knee joint including ultrasound guidance, unilateral



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- **0627T** - Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; first level
- **0628T** - Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with fluoroscopic guidance, lumbar; each additional level (List separately in addition to code for primary procedure)
- **0629T** - Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; first level
- **0630T** - Percutaneous injection of allogeneic cellular and/or tissue-based product, intervertebral disc, unilateral or bilateral injection, with CT guidance, lumbar; each additional level (List separately in addition to code for primary procedure)

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