



Status

Active

## Medical and Behavioral Health Policy

Section: Medicine

Policy Number: II-142

Effective Date: 04/23/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

## STEM-CELL THERAPY FOR ORTHOPEDIC APPLICATIONS

**Description:** Mesenchymal stem cells (MSCs), which are progenitor cells located within the bone marrow, have the potential to differentiate into a variety of tissue types, including various musculoskeletal tissues. MSC therapy involves the harvest and processing of these stem cells, with subsequent infusion of the cells into specific anatomic sites in order to promote healing or regeneration of damaged cartilage or bone. Potential uses of MSC therapy for orthopedic applications include treatment of damaged bone, cartilage, ligaments, tendons and intervertebral discs. Concentrated autologous MSCs do not require approval from the U.S Food and Drug Administration (FDA). To date, no products using engineered or expanded MSCs have been approved by the FDA for orthopedic applications.

Stem cells may also be administered by combining the cells with a demineralized bone matrix (DBM). DBM, which is processed allograft bone, is considered minimally processed tissue and does not require FDA approval. The following are examples of DBM products that either contain viable stem cells are or intended to be mixed with bone marrow aspirate:

- Osteocel Plus® (NuVasive);
- Trinity Evolution Matrix™ (Orthofix);
- Fusion Flex™ (Wright Medical);
- Ignite® (Wright Medical).

**Policy:** I. Mesenchymal stem-cell therapy is considered **INVESTIGATIVE** for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue, due to a lack of evidence demonstrating an impact on improved health outcomes.

- II. Use of allograft bone products containing viable stem cells, including but not limited to demineralized bone matrix (DBM) with stem cells, is considered INVESTIGATIVE for all orthopedic applications, due to a lack of evidence demonstrating an impact on improved health outcomes.

**Coverage:** Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

**Coding:** *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:**

- 20999 Unlisted procedure, musculoskeletal system, general
- 22899 Unlisted procedure, spine
- 23929 Unlisted procedure, shoulder
- 26989 Unlisted procedure, hands or fingers
- 27299 Unlisted procedure, pelvis or hip joint
- 27599 Unlisted procedure, femur or knee
- 27899 Unlisted procedure, leg or ankle
- 28899 Unlisted procedure, foot or toes
- 38206 Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
- 38220 Bone marrow; aspiration only
- 38230 Bone marrow harvesting for transplantation; allogeneic

38232 Bone marrow harvesting for transplantation; autologous  
38241 Hematopoietic progenitor cell (HPC); autologous  
transplantation

**Policy  
History:**

**Developed May 12, 2010**

**Most recent history:**

Reviewed May 11, 2011

Reviewed May 9, 2012

Revised May 8, 2013

Reviewed April 9, 2014

**Cross  
Reference:**

Stem-Cell Therapy for Peripheral Arterial Disease, II-151

*Current Procedural Terminology* (CPT®) is copyright 2013 American Medical Association. All Rights Reserved. No fee schedules, basic units, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein. Applicable FARS/DFARS restrictions apply to government use.

Copyright 2014 Blue Cross Blue Shield of Minnesota.

---