



MASSACHUSETTS

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Medical Policy

Orthopedic Applications of Stem Cell Therapy

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Policy Number: 254

BCBSA Reference Number: 8.01.52

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Mesenchymal stem cell therapy for all orthopedic applications, including use in repair or regeneration of musculoskeletal tissue, is [INVESTIGATIONAL](#).

Allograft bone products containing viable stem cells, including but not limited to demineralized bone matrix (DBM) with stem cells, is [INVESTIGATIONAL](#) for all orthopedic applications.

Prior Authorization Information

Commercial Members: Managed Care (HMO and POS)

This is **NOT** a covered service.

Commercial Members: PPO, and Indemnity

This is **NOT** a covered service.

Medicare Members: HMO BlueSM

This is **NOT** a covered service.

Medicare Members: PPO BlueSM

This is **NOT** a covered service.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38230	Bone marrow harvesting for transplantation; allogeneic
38240	Bone marrow or blood-derived peripheral stem cell transplantation; allogeneic
38241	Bone marrow or blood-derived peripheral stem cell transplantation; autologous
38243	Hematopoietic progenitor cell (HPC); HPC boost

Description

Mesenchymal stem cells (MSCs) are multipotent cells that possess the ability to differentiate into various tissues, including organs, trabecular bone, tendon, articular cartilage, ligaments, muscle, and fat. Potential uses of MSCs for orthopedic applications include treatment of damaged bone, cartilage, ligaments, tendons and intervertebral discs.

Bone-marrow aspirate is considered to be the most accessible source and, thus, the most common place to isolate MSCs for treatment of musculoskeletal disease. However, harvesting MSCs from bone marrow requires an additional procedure that may result in donor site morbidity.

Tissue engineering techniques are being developed to improve the efficiency of repair or regeneration of damaged musculoskeletal tissues. Tissue engineering focuses on the integration of biomaterials with MSCs and/or bioactive molecules such as growth factors. No products using engineered MSCs have been approved by the FDA for orthopedic applications.

An example of mesenchymal stem cell therapy for orthopedic applications is Regenexx™ from Regenerative Sciences. All mesenchymal stem cell therapy for orthopedic applications is considered investigational regardless of the commercial name or the producer.

Summary

Overall, the literature suggests a technology that is at an early stage of development, with the vast majority of studies focused on development of methods for tissue engineering along with preliminary testing in animal models. Despite this research into the methods of treatment, there are uncertainties regarding the optimal source of cells and the delivery method. Current available evidence on procedures using autologous bone-marrow-derived mesenchymal stem cells (MSCs) for orthopedic indications in humans consists primarily of case series and small non-randomized comparative trials with insufficient data to evaluate health outcomes. In addition, expanded MSCs for orthopedic applications are not FDA approved (concentrated autologous MSCs do not require FDA approval). Due the lack of evidence that clinical outcomes are improved, use of stem cells for orthopedic applications is considered investigational.

Policy History

Date	Action
7/2014	New references added from BCBSA National medical policy.
10/2013	BCBSA National medical policy review. New investigational indications described. Effective 10/1/2013.
12/2012	Updated to add new CPT code 38243
6/2011	Reviewed - Medical Policy Group – Orthopedics, Rehabilitation and Rheumatology, No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

[Medical Policy Terms of Use](#)

[Managed Care Guidelines](#)

[Indemnity/PPO Guidelines](#)

[Clinical Exception Process](#)

[Medical Technology Assessment Guidelines](#)

References

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