

## Orthopedic Applications of Stem Cell Therapy

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<b>Approved By:</b>	Highmark Health Options – Market Leadership
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<b>Products:</b>	Medicaid
<b>Application:</b>	All participating hospitals and providers
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### Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

### POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary orthopedic applications of stem-cell therapy.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

### DEFINITIONS

**Highmark Health Options (HHO)** – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

**Mesenchymal Stem Cells (MSCs)** – Have the capability to differentiate into a variety of tissue types, including musculoskeletal tissues. MSCs are associated with the blood vessels within bone marrow, synovium, fat, and muscle, where they can be mobilized for endogenous repair as occurs with healing of bone fractures. Stimulation of endogenous MSCs is the basis of procedures such as bone marrow stimulation (e.g., microfracture) and harvesting/grafting of autologous bone for fusion.

### PROCEDURES

Prior authorization is required.

ALL the following orthopedic applications are considered experimental investigational and therefore noncovered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature (not an all-inclusive list):

- Mesenchymal stem cell therapy includes use in repair or regeneration of musculoskeletal tissue:
  - Nonsurgical injection treatments, including but not limited to:
    - Regenex<sup>®</sup> Procedure; or
  - Allograft bone products containing viable stem cells, including but not limited to demineralized bone matrix (DBM) with stem cells, including but not limited to:
    - Allostem<sup>®</sup> (Allosource); or
    - Allsync with Biosurge<sup>™</sup> Kit; or
    - Allosync<sup>™</sup> Pure; or
    - Map3<sup>®</sup> (RTI Surgical); or
    - Osteocel Plus<sup>®</sup> (NuVasive); or
    - Stryker BIO<sup>4</sup> Viable Bone Matrix; or
    - Trinity Evolution Matrix<sup>®</sup> (Orthofix); or
    - Vivigen Bone Matrix; or
  - Allograft or synthetic bone graft substitutes that must be combined with autologous blood or bone marrow, including but not limited to:
    - Allograft Bone Substitute DBX<sup>™</sup>; or
    - CopiOs<sup>®</sup> Bone Void Filler; or
    - DBX<sup>®</sup> Demineralized bone matrix putty, paste and mix; or
    - Formagraft<sup>™</sup> Collagen Bone Graft Matrix; or
    - Fusion Flex<sup>®</sup>; or
    - Ignite<sup>®</sup>; or
    - Integra MOZIAK<sup>™</sup> Osteoconductive Scaffold-Putty; or
    - Vitoss<sup>®</sup> Bioactive Foam Bone Graft Substitute.

### POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

### PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

Orthopedic applications of stem cell therapy are typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a comorbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

### CODING REQUIREMENTS

CPT codes	Description
20932	Allograft, includes templating, cutting, placement and internal fixation, when performed; osteoarticular, including articular surface and contiguous bone (list separately in addition to code for primary procedure).
20933	Allograft, includes templating, cutting, and placement and internal fixation, when performed; hemicortical intercalary, partial (i.e., hemicylindrical) (list separately in addition to code for primary procedure).

20934	Allograft, includes templating, cutting, and placement and internal fixation, when performed; intercalary, complete (i.e. cylindrical) (list separately in addition to code for primary procedure).
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## REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

## POLICY SOURCES

### American Association of Orthopedic Surgeons – 2020

A 2020 guideline from American Association of Orthopedic Surgeons on the management of glenohumeral joint OA, endorsed by several other societies, states that injectable biologics such as stem cells cannot be recommended in the treatment glenohumeral joint OA. There was consensus from the panel that better standardization and high-quality evidence from clinical trials is needed to provide definitive evidence on the efficacy of biologics in glenohumeral OA. The strength of evidence was rated as no reliable scientific evidence to determine benefits and harms.

### American College of Rheumatology/Arthritis Foundation - 2019

Stem cell injections are strongly recommended against in patients with knee and/or hip OA. There is concern regarding the heterogeneity and lack of standardization in available preparations of stem cell injections, as well as techniques used. This treatment has not been evaluated in hand OA and, therefore, no recommendation is made regarding OA of the hand.

### American Association of Neurological Surgeons – 2014.

The American Association of Neurological Surgeons guidelines on fusion procedures for degenerative disease of the lumbar spine relevant to this evidence review have indicated that “The use of demineralized bone matrix (DBM) as a bone graft extender is an option for 1- and 2-level instrumented posterolateral fusions. Demineralized Bone Matrix: Grade C (poor level of evidence).

## Reference

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Whitehouse MR, Howells NR, Parry MC, et al. Repair of torn avascular meniscal cartilage using undifferentiated autologous mesenchymal stem cells: From in vitro optimization to a first-in-human study. *Stem Cells Transl Med.* 2017;6(4):1237–1248.

Peppers TA, Bullard DE, Vanichkachorn JS, et al. Prospective clinical and radiographic evaluation of an allogeneic bone matrix containing stem cells (Trinity Evolution® Viable Cellular Bone Matrix) in patients undergoing two-level anterior cervical discectomy and fusion. *J Orthop Surg Res.* 2017;12(1):67.

Hayes, Inc. Hayes Comparative Effectiveness Review. Comparative Effectiveness Review of Stem Cell Therapy for Joint Pain. Lansdale, PA: Hayes, Inc.; 07/12/2018.

Nancarrow-Lei R, Mafi P, Mafi R, et al. A systemic review of adult mesenchymal stem cell sources and their multilineage differentiation potential relevant to musculoskeletal tissue repair and regeneration. *Curr Stem Cell Res Ther.* 2017;12(8):601-610.

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Kim SH, Djaja YP, Park YB, Park JG, Ko YB, Ha CW. Intra-articular injection of culture-expanded mesenchymal stem cells without adjuvant surgery in knee osteoarthritis: A systematic review and meta-analysis. *Am J Sports Med.* 2020;48(11):2839-2849.

Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee. *Arthritis Care Res (Hoboken).* 2020;72(2):149-162.

American Academy of Orthopaedic Surgeons. Management of glenohumeral joint osteoarthritis evidence-based clinical practice guideline. <https://www.aaos.org/globalassets/quality-and-practice-resources/glenohumeral/gjo-cpg.pdf>.

## POLICY UPDATE HISTORY

10/08/2021	Approved in medical policy committee
08/24/2022	Annual review, approved in medical policy committee
09/13/2022	Approved by QI/UM
10/10/2022	Approved in Governance