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Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Progenitor cell therapy, including but not limited to skeletal myoblasts or hematopoietic cells, **is considered experimental, investigational and/or unproven** as a treatment of damaged myocardium.

Infusion of growth factors (i.e., granulocyte colony stimulating factor) **is considered experimental, investigational and/or unproven** as a technique to increase the numbers of circulating hematopoietic cells as treatment of damaged myocardium.

Policy Guidelines

There are no specific codes for this procedure, either describing the laboratory component of processing the harvested autologous cells or for the implantation procedure. In some situations, the implantation may be an added component of a scheduled coronary artery

bypass graft; in other situations, the implantation may be performed as a unique indication for a cardiac catheterization procedure.

Description

Progenitor cell therapy describes the use of multipotent cells of various cell lineages (autologous or allogeneic) for tissue repair and/or regeneration. Progenitor cell therapy is being investigated for the treatment of damaged myocardium resulting from acute or chronic cardiac ischemia and for refractory angina.

Background

Ischemia

Ischemia is the most common cause of cardiovascular disease and myocardial damage in the developed world. Despite impressive advances in treatment, ischemic heart disease is still associated with high morbidity and mortality. According to the American Heart Association, coronary heart disease has a prevalence of 5.7% among White people, 5.4% among Black people, 8.6% among American Indian/Alaska Native people, and 4.4% among Asian people. (1) For all ages, the incidence of myocardial infarction is higher in Black males than in Black females, White males, and White females. Heart failure has the highest prevalence among Black males (3.8%) followed by Black females (3.3%), White males (2.9%), Hispanic males (1.8%), Hispanic and White females (both1.6%), Asian males (1.4%), and Asian females (0.5%). Age-adjusted death rates per 100,000 individuals with coronary heart disease and heart failure are higher for Black males and females than their counterparts of other races.

Treatment

Current treatments for ischemic heart disease seek to revascularize occluded arteries, optimize pump function and prevent future myocardial damage. However, current treatments do not reverse existing heart muscle damage. (2) Treatment with progenitor cells (i.e., stem cells) offers potential benefits beyond those of standard medical care, including the potential for repair and/or regeneration of damaged myocardium. Potential sources of embryonic and adult donor cells include skeletal myoblasts, bone marrow cells, circulating blood-derived progenitor cells, endometrial mesenchymal stem cells, adult testis pluripotent stem cells, mesothelial cells, adipose-derived stromal cells, embryonic cells, induced pluripotent stem cells, and bone marrow mesenchymal stem cells, all of which can differentiate into cardiomyocytes and vascular endothelial cells for regenerative medicine advanced therapy (RMAT). (3) The RMAT designation may be given if:

1. The drug is a regenerative medicine therapy (i.e., a cell therapy), therapeutic tissue engineering product, human cell and tissue product, or any combination product:
2. The drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and
3. Preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs.

Regulatory Status
Multiple progenitor cell therapies such as MyoCell® (U.S. Stem Cell, formerly Bioheart), Ixmyelocel-T (Vericel, formerly Aastrom Biosciences), MultiStem® (Athersys), and CardiAMP™ (BioCardia) are being commercially developed, but none have been approved by the U.S. Food and Drug Administration (FDA) for the treatment of damaged myocardium.

Rationale

This policy is based on a review of relevant professional association guidelines.

Current professional guidelines do not include the use of progenitor cell therapy or infusion of growth factors (i.e., granulocyte colony stimulating factor) as a standard treatment option for individuals with damaged myocardium and/or cardiac conditions. The lack of inclusion in society guidelines suggest that these treatment options do not meet the necessary criteria for standard of care due to insufficient clinical evidence. Additionally, the United States Food and Drug Administration (FDA) has not approved these treatment options for use in individuals with cardiac conditions.

Practice Guidelines and Position Statements
In 2015, the American College of Cardiology (ACC) Foundation, American Heart Association (AHA), and the Society for Cardiovascular Angiography and Interventions (SCAI) issued a update on primary percutaneous coronary interventions for individuals with ST-elevation myocardial infarction. (4) This guideline was an update of the 2011 guideline for percutaneous coronary intervention (5) and the 2013 guideline on managing ST-elevation myocardial infarction. (6) In 2021, these same organizations published a guideline on coronary artery revascularization. (7) Progenitor cell therapy and infusion of growth factors were not mentioned in any of these guidelines.

The most recent guidelines from the AHA/ACC/Heart Failure Society of America (2022) for the management of heart failure (8), the 2024 ACC consensus decision pathway for individuals with heart failure (9), and the 2025 multi-society guideline for the management of individuals with acute coronary syndromes (10) do not include progenitor cell therapy and/or infusion of growth factors as a treatment option within the context of their guidelines.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	38205, 38206, 38230, 38232, 38240, 38241
HCPCS Codes	C9782

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

References

1. Tsao CW, Aday AW, Almarzooq ZI, et al. Heart disease and stroke statistics-2023 update: A report from the American Heart Association. Circulation. Feb 21 2023; 147(8):e93-e621. PMID 36695182
2. Schaun M, Eibel B, Kristocheck M, et al. Cell therapy in ischemic heart disease: interventions that modulate cardiac regeneration. Stem Cells Int. Jan 2016; 2016:2171035. PMID 26880938
3. U.S. Food and Drug Administration (FDA). Regenerative Medicine Advanced Therapy Designation (Nov 2025). Available at <https://www.fda.gov> (accessed December 10, 2025).
4. Levine GN, Bates ER, Blankenship JC, et al. 2015 ACC/AHA/SCAI focused update on primary percutaneous coronary intervention for patients with ST-elevation myocardial Infarction: An update of the 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention and the 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: A report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv. May 2016; 87(6):1001-1019. PMID 26489034
5. Levine GN, Bates ER, Blankenship JC, et al. 2011 ACCF/AHA/SCAI Guideline for Percutaneous Coronary Intervention: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. Circulation. Dec 06 2011; 124(23):e574-e651. PMID 22064601
6. O'Gara PT, Kushner FG, Ascheim DD, et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. J Am Coll Cardiol. Jan 29 2013; 61(4):e78-e140. PMID 23256914
7. Lawton JS, Tamis-Holland JE, Bangalore S, et al. 2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. J Am Coll Cardiol. Jan 18 2022; 79(2):e21-e129. PMID 34895950
8. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. J Card Fail. May 2022; 28(5):e1-e167. PMID 35378257
9. Hollenberg S, Warner Stevenson L, Ahmad T, et al. 2024 ACC Expert Consensus Decision Pathway on Clinical Assessment, Management, and Trajectory of Patients Hospitalized With Heart Failure Focused Update: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. Sep 2024; 84(13):1241-1267. PMID 39127954
10. Rao S, O'Doaghue M, Ruel M, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the Management of Patients With Acute Coronary Syndromes: A Report of the American

College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. Apr 2025; 151(13):e771-e862. PMID 40014670

Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
01/01/2026	Document updated. Coverage unchanged. Added references 2, 10; others updated and/or removed.
12/15/2024	Document updated with literature review. Coverage unchanged. Added references 19 and 39.
01/01/2024	Document updated with literature review. Coverage unchanged. Reference 38 added; others updated.
01/15/2023	Document updated with literature review. Simplified “stem- or progenitor-cell therapy” to “progenitor cell therapy” throughout document, without change to policy intent. Added the following references: 1, 19, 21, 22, 36 and 37. Title changed from “Stem-Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia”.
08/01/2021	Reviewed. No changes.
07/15/2020	Document updated with literature review. Coverage unchanged. References 9, 30, 31 were added and some references removed.
08/01/2019	Reviewed. No changes.
10/01/2018	Document updated with literature review. Coverage unchanged. References 3, 7, 9, 15, 19-20, 24-29 added, and some references removed.
06/01/2017	Reviewed. No changes.
10/01/2016	Document updated with literature review. Coverage unchanged.
11/01/2015	Reviewed. No changes.
12/01/2014	Document updated with literature review. Coverage unchanged. Rationale and References significantly reorganized and revised. “Due to Ischemia” was added to the policy title.
01/01/2012	Document updated with literature review. Policy titled changed from Autologous Cell Therapy for the Treatment of Damaged Myocardium to

	Stem-Cell Therapy for the Treatment of Damaged Myocardium. Coverage unchanged.
09/15/2009	Routine scheduled review; Revised/updated entire document; no changes to coverage statement.
09/15/2007	Revised/updated entire document
03/01/2005	New medical document