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Medicare Advantage Policy Manual

Policy ID: M-MED100

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

Published: 12/01/2023

Next Review: 10/2024

Last Review: 10/2023

Medicare Link(s) Revised: 12/01/2023

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

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

MEDICARE ADVANTAGE POLICY CRITERIA

Note: Other applications for stem cell therapy are addressed in other Medicare Advantage medical policies (see Cross References).

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	See References ^[1]

NCD guidelines for stem cell transplantation state coverage for any indications not otherwise noted as covered or non-covered nationally remain at Medicare Administrative Contractor (MAC) discretion. Progenitor cell or stem cell therapy for the treatment of damaged myocardium are not addressed within the stem cell transplantation NCD.

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*

None

Progenitor cell or stem cell therapy for the treatment of damaged myocardium are not addressed within an LCD or LCA by our local MAC.

Medical Policy Manual

Medicare coverage guidance is not available for progenitor cell therapy used to treat damaged myocardium. Therefore, the health plan's medical policy is applicable.

Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia, Medicine, [Policy No. 100](#) (see *"NOTE" below*)

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation title 21, parts 1270 and 1271. Progenitor cells are included in these regulations. FDA marketing clearance is not required when autologous cells are processed on site with existing laboratory procedures and injected with existing catheter devices. Several cell products are expanded ex vivo and require FDA approval.

Multiple progenitor cell therapies such as MyoCell® (Bioheart, Sunrise, FL), ixmyelocel-T (Vericel, formerly Aastrom Biosciences), and MultiStem® (Athersys) are being commercially developed, but none have been approved by FDA so far. Medicare coverage for medical devices only includes those approved by the FDA through the pre-market approval (PMA)

process or the 510(k) process, FDA-approved IDE Category B devices, and hospital institutional review board (IRB) approved IDE devices.^[2]

- MyoCell® comprises patient autologous skeletal myoblasts that are expanded ex vivo and supplied as a cell suspension in a buffered salt solution for injection into the area of damaged myocardium.
- Ixmyelocel-T is an expanded multicellular therapeutic product produced from a patient’s bone marrow by selectively expanding bone marrow mononuclear cells for 2 weeks. The expanded cell product enriched for mesenchymal and macrophage lineages might enhance potency.
- MultiStem® is an allogeneic bone marrow–derived adherent adult stem cell product.

CROSS REFERENCES

[Cell Therapy for Peripheral Arterial Disease](#), Medicine, Policy No. M-141

[Orthopedic Applications of Stem-Cell Therapy, Including Bone Substitutes Used with Autologous Bone Marrow](#), Medicine, Policy No. M-142

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

REFERENCES

1. National Coverage Determination (NCD) for Stem Cell Transplantation (Formerly 110.8.1) (110.23) [Last Cited 10/19/2023] (*This NCD can be accessed directly from the [Medicare Coverage Database](#) website*)
2. Medicare Benefit Policy Manual, Chapter 14 – Medical Devices, [§10 – Coverage of Medical Devices](#)

CODING

NOTE: 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 (CABG); in other situations, the implantation may be performed as a unique indication for a cardiac catheterization procedure.

Codes	Number	Description
CPT	33999	Unlisted procedure, cardiac surgery
	38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
	38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
	38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
	38241	Hematopoietic progenitor cell (HPC); autologous transplantation
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.