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Medicare Advantage Policy Manual **Policy ID:** M-MED141

Cell Therapy for Peripheral Arterial Disease

Published: 02/01/2025

Next Review: 10/2025

Last Review: 12/2024 ***Medicare Link(s) Revised:*** *02/01/2025*

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

Development of peripheral arterial disease (PAD) is characterized by narrowing and occlusion of arterial vessels, with eventual reduction in distal perfusion. Critical limb ischemia is the end-stage of lower extremity PAD. At this state, severe obstruction of blood flow results in ischemic pain at rest, ulcers, and a significant risk for loss of limb. The standard therapy for severe, limb-threatening ischemia is revascularization to improve blood flow to the affected extremity. If revascularization has failed or is not possible, amputation may be necessary. Injection of hematopoietic cells concentrated from bone marrow is being evaluated for the treatment of critical limb ischemia when surgical or endovascular revascularization has failed.

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 state coverage for all other indications of stem cell transplantation not otherwise noted as covered or non-covered nationally remain at Medicare Administrative Contractor (MAC) discretion. The application of stem-cell therapy to peripheral artery disease is not addressed within the stem cell transplantation NCD.
Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*	None Cell therapy for the treatment of peripheral arterial disease is not addressed within an LCD or Article by our local MAC.
Medical Policy Manual	*Medicare coverage guidance is not available for cell therapy as a treatment of peripheral artery disease (PAD). Therefore, the health plan's medical policy is applicable.* Cell Therapy for Peripheral Arterial Disease, Medicine, Policy No. 141 *(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

Two devices have been identified that provide point-of-care concentration of bone marrow aspirate:

- The SmartPReP2® Bone Marrow Aspirate Concentrate System is a microprocessor-controlled dedicated centrifuge with decanting capability and an accessory BMAC IDE PAD Pack for processing a patient's bone marrow aspirate. The system is in a Phase III trial; expected completion of the trial is in 2014.
- The MarrowStim P.A.D. kit™ (Biomet Biologics) is in a Phase III trial for the treatment of PAD with completion expected May 2014.

Ixmyelocel-T (Vericel Corporation, formerly Aastrom Biosciences) is an expanded stem cell product where bone marrow aspirate is sent to a processing facility to be cultured in a bioreactor and expanded over a 2-week period. The expanded cell population is enriched with mesenchymal precursors and alternatively-activated macrophages. This product is currently being evaluated in a pivotal Phase III trial regulated by the U.S. Food and Drug Administration's (FDAs) Center of Biologic Evaluation and Research.

Pluristem Therapeutics is developing allogeneic cell therapy derived from full-term placenta (PLX-PAD cells). This product has been tested in a Phase I trial in patients with critical limb ischemia.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Autologous Blood-Derived Growth Factors as a Treatment for Wound Healing and Other Miscellaneous Conditions, Medicine, Policy No. M-77

Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia, Medicine, Policy No. M-100

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. NCD for Stem Cell Transplantation (Formerly 110.8.1) (110.23) [Last Cited 11/25/2024]
(This reference can be found on the Medicare Coverage Database website)

CODING

Codes	Number	Description
CPT	0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest

	0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest
	0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy
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.*