

Policy Name:	Stem Cell Therapy for Peripheral Artery Disease
Effective Date:	6/20/2022

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member’s plan document for other specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

Coverage Policy

Stem cell therapy for the treatment of peripheral artery disease is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

Peripheral artery disease (PAD) involves a narrowing or blocking of the arteries that supply blood to the extremities, usually the legs, resulting in an insufficient blood supply. The main symptom of PAD is intermittent claudication (cramping pain and weakness in the legs). The American Heart Association estimates that 12-20% of adults 65 years of age and older are affected by this condition. Patients with severe PAD may experience critical limb ischemia, or CLI, which results in ischemic pain at rest, ulcers, and a significant risk for limb loss. The gold standard for treatment of severe ischemia is surgical or endovascular revascularization, aiming to improve blood flow to affected extremities. Up to 30% of patients, however, are not candidates for such interventions. In the event of failure, amputation may be necessary.

Infusion of bone marrow-derived mononuclear cells (BM-MNC) is hypothesized to aid in the treatment of PAD by promoting therapeutic neovascularization and thus improved blood flow in the lower extremities of patients with CLI. Another approach involves the administration of Granulocyte-Colony Stimulation Factor (G-CSF), purportedly stimulating the bone marrow to produce mononuclear stem cells and release them into the bloodstream.

FDA Approval

U.S. Food and Drug Administration (FDA) approval is not required in situations in which autologous stem cells are processed on site with existing laboratory procedures. However, the FDA does regulate cells that are processed in commercial laboratories, as well as the surgical devices used to inject them.

The SmartPreP® 2 Bone Marrow Aspirate Concentrate System (Harvest Technologies) received 510(k) clearance in November 2010 and is intended to be used in the clinical laboratory or intraoperatively at point-of-care for the concentration of stem cells from bone marrow. Another device that provides point-of-care concentration of bone marrow aspirate is the MarrowStim™ Concentration Kit and Marrow Stim™ Mini Concentration Kit (Biomet Biologics) received 510(k) clearance in November 2010.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **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.

Original Effective Date: 5/1/2013

Re-Review Date(s): 4/20/2016
4/17/2019
3/2/2020 – administrative update; format
4/20/2022