

Corporate Medical Policy

Stem-cell Therapy for Peripheral Arterial Disease

File Name: stem_cell_therapy_for_peripheral_arterial_disease
Origination: 7/2011
Last CAP Review: 10/2011
Next CAP Review: 10/2012
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Description of Procedure or Service

Critical limb ischemia due to peripheral arterial disease (PAD) results in pain at rest, ulcers, and significant risk for limb loss. Injection of hematopoietic stem cells concentrated from bone marrow is being evaluated for the treatment of critical limb ischemia when surgical or endovascular revascularization has failed.

Background

Peripheral arterial disease (PAD) is a common atherosclerotic syndrome that is associated with significant morbidity and mortality. A less-common cause of PAD is Buerger disease, also called thromboangitis obliterans, which is a nonatherosclerotic segmental inflammatory disease that occurs in younger patients and is associated with tobacco use. Development of PAD is characterized by narrowing and occlusion of arterial vessels and eventual reduction in distal perfusion. Critical limb ischemia is the endstage of lower extremity PAD in which severe obstruction of blood flow results in ischemic pain at rest, ulcers, and a significant risk for limb loss. The standard therapy for severe, limb-threatening ischemia is revascularization aiming to improve blood flow to the affected extremity. If revascularization has failed or is not possible, amputation is often necessary.

Two endogenous compensating mechanisms may occur with occlusion of arterial vessels, capillary growth (angiogenesis) and development of collateral arterial vessels (arteriogenesis). Capillary growth is mediated by hypoxia-induced release of chemo- and cytokines such as vascular endothelial growth factor (VEGF), and occurs by sprouting of small endothelial tubes from pre-existing capillary beds. The resulting capillaries are small and cannot sufficiently compensate for a large occluded artery. Arteriogenesis with collateral growth is, in contrast, initiated by increasing shear forces against vessel walls when blood flow is redirected from the occluded transport artery to the small collateral branches, leading to an increase in the diameter of pre-existing collateral arterioles.

The rationale of hematopoietic stem-cell/bone marrow-cell therapy in PAD is to induce arteriogenesis by boosting the physiological repair processes. This requires large numbers of functionally active autologous precursor cells, and subsequently a large quantity of bone marrow (e.g., 240-500 mL). The SmartPreP2® Bone marrow Aspirate Concentrate System (Harvest Technologies) has been developed as a single-step point-of-care, bedside centrifugation system for the concentration of stem cells from bone marrow. Following isolation and concentration, the hematopoietic stem-cell/bone marrow concentrate is administered either intra-arterially or through multiple injections (20 to 60) into the muscle, typically in the gastrocnemius.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Stem-cell Therapy for Peripheral Arterial Disease

Policy

Stem-cell therapy for the treatment of peripheral arterial disease is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Stem-cell Therapy for Peripheral Arterial Disease is covered

Not applicable

When Stem-cell Therapy for Peripheral Arterial Disease is not covered

Treatment of peripheral arterial disease, including critical limb ischemia, with injection or infusion of cells concentrated from bone marrow aspirate is considered investigational.

Policy Guidelines

Based on initial evidence from case series and small randomized trials, injection of bone marrow concentrate may hold promise as a treatment for critical limb ischemia due to peripheral arterial disease. However, well-designed and well-conducted randomized controlled trials are needed to evaluate the health outcomes of this procedure. A number of trials are in progress, including several large randomized double-blind placebo controlled trials. Results from these trials are needed to adequately evaluate the impact on net health outcome of this procedure. Further information on the safety and durability of the treatment is also needed.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: Beginning in July 2011, there are specific CPT category III codes for this therapy: 0263T, 0264T, 0265T

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 8.01.55, 5/12/11

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National Institutes of Health (NIH). Clinical Trial NCT01245335. Bone Marrow Aspirate Concentrate (BMAC) for Treatment of Critical Limb Ischemia (CLI). Retrieved on May 23, 2011 from <http://clinicaltrials.gov/show/NCT01245335>

National Institutes of Health (NIH). Clinical Trial NCT00919516. Autologous Bone Marrow Mononuclear Cell Implantation for Moderate to Severe Peripheral Arterial Disease. Retrieved on May 23, 2011 from <http://clinicaltrials.gov/ct2/show/NCT00919516>

Medical Director review 7/2011

Specialty Matched Consultant Advisory Panel review 10/2011

Policy Implementation/Update Information

7/19/11 New policy implemented. Treatment of peripheral arterial disease, including critical limb ischemia, with injection or infusion of cells concentrated from bone marrow aspirate is considered investigational. Medical Director review 7/2011. (mco)

11/8/11 Specialty Matched Consultant Advisory Panel review 10/2011.No changes to Policy Statements. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.