blue of california

Medical Policy

Stem-Cell Therapy for Peripheral Arterial Disease	
Type: Investigational / Experimental	**Policy Specific Section:** Medicine
Original Policy Date: January 11, 2013	**Effective Date:** January 11, 2013

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Description

Peripheral arterial disease (PAD) is a common atherosclerotic syndrome characterized by the narrowing and occlusion of arterial vessels and eventual reduction in distal perfusion. Peripheral arterial disease is associated with significant morbidity and mortality. 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. Current research is underway evaluating the effectiveness of the injection of hematopoietic stem cells concentrated from bone marrow for the treatment of critical limb ischemia when surgical or endovascular revascularization has failed.

Policy

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

Policy Guideline

There are specific CPT codes for stem-cell therapy for peripheral arterial disease:

- **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

The CPT codes allow reporting of the complete procedure and harvesting by a single physician (0263T) or separate reporting when the cell harvesting and therapy injections are performed by separate physicians (0264T and 0265T).

Internal Information

There is an MD Determination Form for this Medical Policy. It can be found on the following Web page:
http://myworkpath.com/healthcareservices/MedicalOperations/PSR_Determination_Pages.htm

Documentation Required for Clinical Review
• No records required

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on

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individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available

Click here to view the appendix for this policy

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