Medical Policy
Stem-Cell Therapy for Peripheral Arterial Disease

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Policy Number: 348
BCBSA Reference Number: 8.01.55

Related Policies
- Recombinant and Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Conditions, #186
- Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia, #424
- Orthopedic Applications of Stem Cell Therapy, #254

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

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

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
</tr>
<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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</tbody>
</table>
CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0263T</td>
<td>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</td>
</tr>
<tr>
<td>0264T</td>
<td>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</td>
</tr>
<tr>
<td>0265T</td>
<td>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.</td>
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</table>

Description

Peripheral artery disease (also called peripheral arterial disease) is a common circulatory problem in which narrowed arteries reduce blood flow to limbs. In peripheral artery disease (PAD), extremities — usually legs — do not receive enough blood flow to keep up with demand. This causes symptoms, most notably leg pain when walking (intermittent claudication). Peripheral artery disease is also likely to be a sign of a more widespread accumulation of fatty deposits in arteries (atherosclerosis).

The mechanism underlying arteriogenesis includes the migration of bone marrow-derived monocytes to the perivascular space. The bone marrow-derived monocytes adhere to and invade the collateral vessel wall. It is not known if the expansion of the collateral arteriole is due to the incorporation of stem cells into the wall of the vessel or to cytokines released by monocytic bone marrow cells that induce the proliferation of resident endothelial cells.

Standard outcomes for critical limb ischemia include the Rutherford criteria for limb status, healing of ulcers, the ankle-brachial index (ABI), transcutaneous oxygen pressure (TcO2), and pain-free walking. The Rutherford criteria include ankle and toe pressure, the level of claudication, ischemic rest pain, tissue loss, nonhealing ulcer, and gangrene. The ABI measures arterial segmental pressures on the ankle and brachium, and indexes ankle systolic pressure against brachial systolic pressure (normal range 0.95 – 1.2). An increase greater than 0.1 is considered to be clinically significant. TcO2 is measured with an oxymonitor; the normal value is 70-90 mm Hg. Pain-free walking may be measured by time on a treadmill, or more frequently, by distance in a 400-meter walk.

The SmartPreP2® Bone Marrow Aspirate Concentrate System is a device for stem cell treatment of peripheral arterial disease. All devices for stem cell treatment of peripheral arterial disease are considered investigational regardless of the commercial name, the manufacturer or FDA approval status.

Summary

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. Therefore, infusion or injection of stem cells (bone marrow concentrate) for peripheral arterial disease is considered investigational.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>12/2015</td>
<td>Added coding language.</td>
</tr>
<tr>
<td>7/2015</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>6/2013</td>
<td>New references from BCBSA National medical policy.</td>
</tr>
<tr>
<td>5/1/12</td>
<td>New policy describing ongoing non-coverage</td>
</tr>
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</table>

**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:
- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**

12. Powell RJ, Comerota AJ, Berceli SA, et al. Interim analysis results from the RESTORE-CLI, a randomized, double-blind multicenter phase II trial comparing expanded autologous bone marrow-