Medica Coverage Policy

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<th>Policy Name:</th>
<th>Cell Therapy for the Treatment of Cardiac Disease</th>
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<td>6/17/2019</td>
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Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for 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 and Minnesota Health Care Programs, this policy will apply unless those 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 about this Medica coverage policy 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

Cell therapy for the treatment of cardiac disease is investigative 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

Cell therapy describes the use of multipotent cells of various types for tissue repair and/or regeneration. Multipotent cells are unspecialized cells that have the ability to self-renew for long periods of time and differentiate into specialized cells with specific functions. Cell therapy is under investigation as treatment for several cardiac diseases, including, but not limited to, ischemic heart failure and after acute myocardial infarction.

Coronary artery disease (CAD) is the leading cause of death in the United States. Myocardial infarction (MI), a heart attack, occurs when the coronary arteries that supply blood to the heart become blocked by buildup of fatty deposits called plaque. Immediately after acute MI, drug and surgical therapies are used to restore blood flow to the heart. However, scar tissue develops in the area of infarction resulting in a decrease in cardiac contractility. This damage is irreversible and can result in heart failure since cardiac cells cannot repair themselves. Heart failure is a chronic, long-term condition that causes the muscle in the heart wall to slowly weaken and enlarge, preventing the heart from pumping enough blood to meet the body’s need. The standard of care for treatment of heart failure includes pharmacotherapy and lifestyle changes.

A variety of cell types are under investigation for use in treating cardiac disease. Potential sources of donor cells (autologous or allogeneic) include, but are not limited to, skeletal myoblasts, stem cells from bone marrow or peripheral blood, endometrial and bone marrow mesenchymal stem cells, embryonic cells, mesothelial cells, and induced pluripotent stem cells. In addition, a variety of delivery mechanisms for cell therapy exist, encompassing a wide range of invasiveness. Donor cells can be delivered surgically via thoracotomy and direct injection into the damaged heart muscle. Cells can also be injected using percutaneous, catheter-based techniques or intravenously via a peripheral vein. Researchers hypothesize that cell therapy may offer potential benefits beyond standard medical and surgical care for cardiac diseases, including the potential for repair and/or regeneration of damaged heart...
muscle. However, many questions remain unanswered, including the ideal cell type and delivery method, the mechanism of action and potential adverse effects and ethical concerns.

**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 FDA has not yet issued approvals for any technology associated with the use of stem cells for the treatment of cardiac diseases.

**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:**
- 33999: Unlisted procedure, cardiac surgery
- 38999: Unlisted procedure, hemic or lymphatic system

**Original Effective Date:** 8/1/2007

**Re-Review Date(s):**
- 3/23/2010
- 3/26/2013
- 4/20/2016
- 2/10/2020 – administrative update; format