Medical Coverage Policy | Progenitor Cell Therapy for the Treatment of Damaged Myocardium due to Ischemia

EFFECTIVE DATE: 02|01|2017
POLICY LAST UPDATED: 07|06|2022

OVERVIEW
Progenitor cell therapy describes the use of multipotent cells of various cell lineages (autologous or allogeneic) for tissue repair and/or regeneration. Progenitor cell therapy is being investigated for the treatment of damaged myocardium resulting from acute or chronic cardiac ischemia and for refractory angina.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Progenitor cell therapy, including but not limited to skeletal myoblasts or hematopoietic cells, is considered not covered as a treatment of damaged myocardium as the evidence is insufficient to determine the effects of the technology on health outcomes.

Infusion of growth factors (ie, granulocyte colony stimulating factor) is considered not covered as a technique to increase the numbers of circulating hematopoietic cells as treatment of damaged myocardium as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial
Progenitor cell therapy, including but not limited to skeletal myoblasts or hematopoietic cells, is considered not medically necessary as a treatment of damaged myocardium as the evidence is insufficient to determine the effects of the technology on health outcomes.

Infusion of growth factors (ie, granulocyte colony stimulating factor) is considered not medically necessary as a technique to increase the numbers of circulating hematopoietic cells as treatment of damaged myocardium as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessity/not covered benefits/coverage.

BACKGROUND
Ischemia is the most common cause of cardiovascular disease and myocardial damage in the developed world. Despite impressive advances in treatment, ischemic heart disease is still associated with high morbidity and mortality. According to the American Heart Association, coronary heart disease has a prevalence of 5.7% among White people, 5.4% among Black people, 8.6% among American Indian/Alaska Native people, and 4.4% among Asian people.1, For all age strata, the incidence of myocardial infarction is higher in Black males than in Black females, White males, and White females. Heart failure has the highest prevalence among Black males (3.6%) followed by Black females (3.3%), Hispanic and White males (both 2.4%), Asian males (1.9%), Hispanic females (1.7%), White females (1.4%), and Asian females (0.7%). Age-adjusted death rates per 100,000

individuals with coronary heart disease and heart failure are higher for Black males and females than their counterparts of other races.

Current treatments for ischemic heart disease seek to revascularize occluded arteries, optimize pump function, and prevent future myocardial damage. However, current treatments do not reverse existing heart muscle damage.2, Treatment with progenitor cells (ie, stem cells) offers potential benefits beyond those of standard medical care, including the potential for repair and/or regeneration of damaged myocardium. Potential sources of embryonic and adult donor cells include skeletal myoblasts, bone marrow cells, circulating blood-derived progenitor cells, endometrial mesenchymal stem cells, adult testis pluripotent stem cells, mesothelial cells, adipose-derived stromal cells, embryonic cells, induced pluripotent stem cells, and bone marrow mesenchymal stem cells, all of which can differentiate into cardiomyocytes and vascular endothelial cells for regenerative medicine advanced therapy (RMAT).3,The RMAT designation may be given if: (1) the drug is a regenerative medicine therapy (ie, a cell therapy), therapeutic tissue engineering product, human cell and tissue product, or any combination product; (2) the drug is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs.

Regulatory Status
Multiple progenitor cell therapies such as MyoCell® (U.S. Stem Cell, formerly Bioheart), Ixmyelocel-T (Vericel, formerly Aastrom Biosciences), MultiStem® (Athersys), and CardiAMPTM (BioCardia) are being commercially developed, but none has been approved by the U.S. Food and Drug Administration (FDA) so far.

MyoCell comprises patient autologous skeletal myoblasts that are expanded ex vivo and supplied as a cell suspension in a buffered salt solution for injection into the area of damaged myocardium. In 2017, U.S. Stem Cell reprioritized its efforts away from seeking RMAT designation for MyoCell. The expanded cell product enriched for mesenchymal and macrophage lineages might enhance potency. Vericel has received RMAT designation for Ixmyelocel-T.

MultiStem is an allogeneic bone marrow-derived adherent adult stem cell product that has received RMAT designation.

The CardiAMP Cell Therapy system consists of a proprietary assay to identify patients with a high probability to respond to autologous cell therapy, a proprietary cell processing system to isolate process and concentrate the stem cells from a bone marrow harvest at the point of care, and a proprietary delivery system to percutaneously inject the autologous cells into the myocardium. BioCardia has received an investigational device exemption from the FDA to perform a trial of CardiAMP and is designated as an FDA Breakthrough Device.

CODING

Medicare Advantage Plans and Commercial Products
There are no specific code(s) for this procedure, either describing the laboratory component of processing the harvested autologous cells or for the implantation procedure. Claims should be filed with an unlisted CPT code(s).

RELATED POLICIES

Unlisted Procedures

PUBLISHED

Provider Update, September 2022
Provider Update, July 2021
Provider Update, August 2020
Provider Update, January 2020
Provider Update, April 2018

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