

Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
**Progenitor Cell Therapy for the Treatment of Damaged
Myocardium due to Ischemia**

Policy #: 173

Latest Review Date: May 2023

Category: Surgery

ARCHIVED EFFECTIVE 11/1/2023

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **progenitor cell therapy**, including but not limited to skeletal myoblasts or hematopoietic stem cells, as a **non-covered** benefit and as **investigational** as a treatment of damaged myocardium.

Blue Advantage will treat **infusion of growth factors (i.e., granulocyte colony stimulating factor [GCSF])** as a **non-covered** benefit and as **investigational** as a technique to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

Ischemia

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.

Treatment

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. Treatment with progenitor cells (i.e., 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). The RMAT designation may be given if: (1) the drug is a regenerative medicine therapy (i.e., 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.

KEY POINTS:

The most recent literature review was performed through March 14, 2023.

Summary of Evidence

For individuals who have acute cardiac ischemia who receive progenitor cell therapy, the evidence includes 2 phase 3 RCTs, numerous small, early-phase RCTs, and meta-analyses of these RCTs. Relevant outcomes are disease-specific survival, morbid events, functional outcomes, quality of life, and hospitalizations. Limited evidence on clinical outcomes has suggested that there may be benefits from improving LVEF, reducing recurrent MI, decreasing the need for further revascularization, and perhaps even decreasing mortality. Although a recent, large meta-analysis reported no improvement in mortality. No adequately powered trial has reported benefits in clinical outcomes (e.g., mortality, adverse cardiac outcomes, exercise capacity, quality of life). Overall, this evidence has suggested that progenitor cell treatment may be a promising intervention, but robust data on clinical outcomes are lacking. High-quality RCTs, powered to detect differences in clinical outcomes, are needed to answer this question. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic cardiac ischemia who receive progenitor cell therapy, the evidence includes 1 phase 3 RCT with more than 100 participants, 2 phase 2 RCTs with more than 100 participants, systematic reviews of smaller, early-phase RCTs, and a nonrandomized comparative trial. Relevant outcomes are disease-specific survival, morbid events, functional outcomes, quality of life, and hospitalizations. The studies included in the meta-analyses have reported only on a small number of clinical outcome events. Two phase 2 RCTs (CONCERT-HF and ixCELL-DCM) found significant benefit on heart failure-related death and other cardiac events with cell therapy compared to placebo. A well-conducted phase 3 RCT trial failed to demonstrate superiority of cell therapy for its primary composite outcome that included death, worsening heart failure events, and other multiple events. The nonrandomized STAR-Heart trial showed a mortality benefit as well as favorable hemodynamic effect, but a lack of randomization limits interpretation due to the concern about selection bias and differences in known and unknown prognostic variables at baseline between both arms. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have refractory angina who receive progenitor cell therapy, the evidence includes a systematic review of RCTs, phase 2 trials and a phase 3 pivotal trial. Relevant outcomes are disease-specific survival, morbid events, functional outcomes, quality of life, and hospitalizations. The only phase 3 trial identified was terminated early and insufficiently powered to evaluate clinical outcomes. Additional larger trials are needed to determine whether progenitor cell therapy improves health outcomes in patients with refractory angina. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Cardiology Foundation/American Heart Association

In 2015, the American College of Cardiology Foundation, American Heart Association, and the Society for Cardiovascular Angiography and Interventions issued a Focused Update on Primary Percutaneous Coronary Interventions for Patients With ST-Elevation Myocardial Infarction. This guideline was an update of the 2011 guideline for percutaneous coronary intervention and the 2013 guideline on managing ST-elevation myocardial infarction. Progenitor cell therapy was not mentioned in any of these guidelines.

The most recent guidelines on treatment of heart failure with reduced ejection fraction from the American College of Cardiology (2021) and American Heart Association/American College of Cardiology/Heart Failure Society of America (2022) do not mention progenitor cell therapy.

U.S. Preventive Services Task Force Recommendations

Not applicable

KEY WORDS:

Autologous cell transplantation, BioHeart, autologous skeletal myoblasts, cardiovascular disease, congestive heart failure, coronary disease, heart disease, myoblast transplantation, myocardial infarction, allogeneic human mesenchymal stem cell, hMSC, Prochymal, progenitor cells, post-infarct necrosis, regeneration, stem cells, transfusion, Athersys, Multistem[®], Osiris, Provacel[®], infusion of growth factors, intramyocardial stem cell injection, MyoCell[®], Ixmyelocel-T

APPROVED BY GOVERNING BODIES:

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 have been approved by the 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 (Athersys) is an allogeneic bone marrow–derived adherent adult stem cell product.

CardiAMPTM 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group-specific policy will supersede this policy when applicable.

CURRENT CODING:

There are no specific CPT codes for this procedure.

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POLICY HISTORY:

Adopted for Blue Advantage, March 2005

Available for comment May 1-June 14, 2005

Medical Policy Group, June 2006

Medical Policy Group, January 2007

Medical Policy Group, January 2008

Medical Policy Group, February 2009

Medical Policy Group, February 2010

Medical policy Group, July 2010

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Medical Policy Group, June 2015
Medical Policy Group, January 2017
Medical Policy Group, August 2017
Medical Policy Group, May 2018
Medical Policy Group, May 2019
Medical Policy Group, May 2020
Medical Policy Group, May 2021
Medical Policy Group, May 2022
Medical Policy Group, May 2023
Medical Policy Group, November 2023: Archived effective 11/1/2023.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.