



## Corporate Medical Policy

# Autologous Cell Therapy for the Treatment of Damaged Myocardium

**File Name:** autologous\_cell\_therapy\_for\_the\_treatment\_of\_damaged\_myocardium  
**Policy Number:** MED1042  
**Origination:** 11/2004  
**Last Review:** 10/2007  
**Next Review:** 10/2009

### Description of Procedure or Service

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Treatment of [ischemic](#) heart disease focuses both on various techniques of revascularization or medical therapy to improve the function of the remaining viable cardiac [myocytes](#). However, due to the limited regenerative capacity of the heart, the extent of [post-infarct](#) necrosis is a determinant of long-term cardiac function and prognosis. Various types of [autologous](#) cell transplantation have been researched as a technique to either stimulate regeneration of the [myocardium](#) or modify ventricular remodeling post infarct. For example, it is thought that normally after a myocardial infarction an increased number of [hematopoietic](#) stem cells are released into the circulation and then engrafted into the heart. While these stem cells do not result in effective myocardial regeneration, it is hoped that enhancement of this process might result in improved cardiac regeneration or remodeling. There has been interest in using infusions of [granulocyte](#) colony stimulating factor (GCSF) to prompt further release of [hematopoietic](#) stem cells into the circulation. Alternatively, harvested stem cells can be directly infused or transplanted. In animal models, embryonic stem cells, fetal cardiomyocytes, [hematopoietic](#), mesenchymal or endothelial stem cells have been successfully transplanted into the heart, followed by cardiac regeneration and improved cardiac function. Myoblasts, harvested from a muscle biopsy, or [hematopoietic](#) stem cells, harvested from the bone marrow or peripheral blood, have been the most commonly investigated. The harvested cells can be transplanted in a variety of ways, frequently as an adjunct to coronary artery bypass surgery; for example, either by injecting directly into the necrotic [myocardium](#), or injecting into a coronary artery or coronary sinus. Through mechanisms currently not well understood, circulating [hematopoietic](#) stem cells may have a natural homing ability to damaged [myocardium](#). If this is the case, relatively noninvasive systemic administration may be possible. In addition to the infusion of [autologous](#) cells, there has been interest in the infusion of cytokines, such as GCSF.

#### FDA Status

U.S. Food and Drug Administration (FDA) approval is not required in those situations in which autologous cells are processed on site with existing laboratory procedures and injected with existing catheter devices.

### Policy

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**BCBSNC does not provide coverage for Autologous Cell Therapy (including but not limited to skeletal myoblasts or hematopoietic stem cells) for the Treatment of Damaged Myocardium. It is considered investigational.**

**Infusion of growth factors (i.e., granulocyte colony stimulating factor) is considered investigational as a technique to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium. BCBSNC does not provide coverage for investigational services.**

## Policy: Autologous Cell Therapy for the Treatment of Damaged Myocardium

### Benefits Application

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Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

### When Autologous Cell Therapy for the Treatment of Damaged Myocardium is covered

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Not applicable.

### When Autologous Cell Therapy for the Treatment of Damaged Myocardium is not covered

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BCBSNC does not provide coverage for Autologous Cell Therapy [including but not limited to skeletal myoblasts or hematopoietic stem cells] for the Treatment of Damaged Myocardium. It is considered investigational. Infusion of growth factors (i.e., granulocyte colony stimulating factor) is considered investigational as a technique to increase the numbers of circulating hematopoietic stem cells as treatment of damaged myocardium. BCBSNC does not provide coverage for investigational services.

### Policy Guidelines

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A search of the MEDLINE database for the period of July 2005 through December 2006 identified a large number of placebo-controlled randomized clinical trials on the use of autologous cell therapy for the treatment of damaged myocardium. Use of GCSF alone does not appear to be effective. Intracoronary infusion of mononuclear blood cells following harvesting is at an early stage of research. The largest body of evidence is for the treatment of acute MI with autologous bone marrow progenitor cells. Evidence of improvement in health outcomes, however, remains insufficient to change the policy statement. Overall, the literature indicates that autologous cell therapy for the treatment of damaged myocardium is investigational.

### Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable codes: There is currently no specific CPT code for either the laboratory component of processing the harvested autologous cells, or for the implantation procedure. In some situations, the implantation may be an added component of a scheduled coronary artery bypass graft (CABG). In other situations, the implantation may be performed as a unique indication for a cardiac catheterization procedure. Services should be submitted in the form of an appropriate unlisted code. Medical records for the explanation of the service rendered may be necessary.*

## Policy: Autologous Cell Therapy for the Treatment of Damaged Myocardium

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### Policy Key Words

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Key Words: Autologous cell transplant, heart disease, BioHeart, Cellular cardiomyoplasty, MED1042.

### Medical Term Definitions

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#### **Autologous**

derived from the same organism, i.e., self donation.

#### **Granulocyte**

a white blood cell such as a basophil, eosinophil, or neutrophil with granule-containing cytoplasm.

#### **Hematopoietic**

pertaining to or effecting the formation of blood cells.

#### **Ischemic**

a condition of decreased oxygen to a body part, generally due to a constriction or obstruction of a blood vessel and inadequate blood flow to the body part.

#### **Myocardium**

the middle and the thickest layer of the heart wall, composed of cardiac muscle.

#### **Myocytes**

cells of muscle tissue.

#### **Post-infarct**

time period following an infarct [when circulation to a region is obstructed and cell death occurs], particularly myocardial infarction [heart attack].

### Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.18, 4/16/04.

Specialty Matched Consultant Advisory Panel - 11/05.

Penn MS, Frances GS, Ellis SG, Young JB, McCarthy PM, Topol EJ. Autologous Cell Transplantation for the Treatment of Damaged Myocardium. Progress in Cardiovascular Diseases, Vol. 45, No. 1, (July/August) 2002: pp 21-32.

Pagani FD, DerSimonian H, Zawadska A, Wetzel K, Edge AS, Jacoby DB, et al. Autologous Skeletal Myoblasts Transplanted to Ischemia-Damaged Myocardium in Humans. J Am Coll Cardiol. 2003; 41: 879-88.

Weissberg PL, Qasim A. Stem cell therapy for myocardial repair. Heart. 2005; 91: 696-702.

## **Policy: Autologous Cell Therapy for the Treatment of Damaged Myocardium**

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.18, 2/15/07.

### **Policy Implementation/Update Information**

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- 11/11/04 New policy issued. Autologous cell therapy for the treatment of damaged myocardium is considered investigational. References added. Notification 11/11/04. Effective 01/20/05.
- 11/17/05 Specialty Matched Consultant Advisory Panel review 11/7/05.
- 11/19/07 Information regarding MyoCell and MyoCath deleted from the Description section. Revised information in Policy Guidelines section to support continued investigational status. References updated. Speciality Matched Consultant Advisory Panel review meeting 10/29/07. No change in policy statement.

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.

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