



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 CAP Review: 10/2009
Last Review: 10/2009

Active policy, no longer scheduled for routine literature review.

Description of Procedure or Service

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. Current treatments for ischemic heart disease seek to revascularize occluded arteries, optimize pump function, and prevent future myocardial damage. However, current treatments are not able to reverse existing damage to heart muscle. 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.

Various types of autologous cell transplantation have been researched as a technique to either stimulate regeneration of the myocardium or modify ventricular remodeling after infarct. The ideal donor cell is uncertain, and there are scientific as well as ethical concerns involved in choosing the ideal source of donor cells. The range of potential sources of donor cells includes embryonic stem cells, adult stem cell, fetal myocytes, and adult blood progenitor cells.

The mechanism of benefit following treatment with progenitor cells is not entirely understood. Differentiation of progenitor cells into mature myocytes and engraftment of progenitor cells into areas of damaged myocardium has been suggested in animal studies using tagged progenitor cells. However, there is controversy concerning whether injected progenitor cells actually engraft and differentiate into mature myocytes in humans to a degree that might result in clinical benefit.

Other mechanisms of benefit have been hypothesized. Progenitor cells may improve perfusion to areas of ischemic myocardium. Basic science research also suggests that injected stem cells secrete cytokines with antiapoptotic and pro-angiogenesis properties. Clinical benefit may result if these paracrine factors are successful at limiting cell death from ischemia. Finally, progenitor cell therapy may activate the intrinsic repair mechanisms of the heart.

There is a variety of potential delivery mechanisms for donor cells, encompassing a wide range of invasiveness. Donor cells can be delivered via thoracotomy and direct injection into areas of damaged myocardium. Injection of progenitor cells into the coronary circulation can also be done using percutaneous, catheter-based techniques. Finally, progenitor cells can be delivered intravenously via a peripheral vein. With this approach, the cells must be able to target damaged myocardium and concentrate at the site of myocardial damage.

Adverse effects of treatment with progenitor cells include the risk of the delivery procedure (e.g., thoracotomy, percutaneous catheter-based, etc.) and the risks of the donor cells themselves. Donor progenitor cells

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can differentiate into fibroblasts rather than myocytes. This may create a substrate for malignant ventricular arrhythmias. There is also a theoretical risk that tumors, such as teratomas, can arise from progenitor cells, but the actual risk of this occurring in humans is not known at present.

U.S. Food and Drug Administration (FDA) approval is not required in situations in which autologous cells are processed on site with existing laboratory procedures and injected with existing catheter devices. However, there are currently two products that require FDA approval. MyoCell™ consists of 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. Since the myoblast isolation and expansion occurs at a single reference laboratory (BioHeart), this process is subject to FDA approval. In addition, implantation may require the use of a unique catheter delivery system (MyoCath™) that also requires FDA approval.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

Active policy, no longer scheduled for routine literature review.

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.

Benefits Application

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

Not applicable.

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

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.

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Policy Guidelines

The evidence review for this policy is derived from a 2008 BCBSA TEC Assessment. While the evidence for a beneficial impact on physiologic outcomes, particularly LVEF, is fairly strong, the magnitude of effect does not appear to be large. As a result, it is not certain whether the improvement in LVEF translates to meaningful improvements in clinical outcomes. For chronic ischemic heart disease there is only very scant evidence on clinical outcomes, and no conclusions can be drawn. There are only a handful of clinical outcome events reported across the included studies, too few for meaningful analysis. Other clinical outcomes, such as NYHA class, are confined to very small numbers of patients and not reported with sufficient methodologic rigor to permit any conclusions.

Therefore, the evidence is insufficient to permit conclusions on the impact of progenitor cell therapy on clinical outcomes for patients with ischemic heart disease.

Billing/Coding/Physician Documentation Information

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. 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.

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.

Scientific Background and Reference Sources

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.

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

BCBSA Technology Evaluation Center. (2008, September). Autologous progenitor cell therapy for the treatment of ischemic heart disease. Retrieved 8/20/09 from http://blueweb.bcbs.com/global_assets/special_content/tec_assessments/vol23/23_04.pdf

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.18, 7/10/08

Policy Implementation/Update Information

- 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. (adn)
- 12/7/09 Description section extensively revised. Policy Guidelines section updated to reflect findings from BCBSA TEC Assessment. References updated. Speciality Matched Consultant Advisory Panel review 10/30/09. Policy status changed to Active Archive, no longer scheduled for routine literature review. (adn)

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.