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MEDICAL POLICY – 2.02.18

Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia

BCBSA Ref. Policy:	2.02.18
Effective Date:	Aug. 1, 2023
Last Revised:	July 10, 2023
Replaces:	N/A

RELATED MEDICAL POLICIES:

8.01.52	Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used With Autologous Bone Marrow)
8.01.55	Stem Cell Therapy for Peripheral Arterial Disease

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

A progenitor cell is an immature cell that can turn into different types of mature cells. Using progenitor cells is being studied as a possible way to repair or grow new tissue, including heart tissue. While there are many procedures and drugs that treat heart disease, none of them actually repair or regrow heart tissue. Progenitor cell therapy is being explored as a way to do this. While early studies show that it might bring some benefit, there's not yet enough scientific evidence to confirm that it works. More and larger studies are needed. For this reason, progenitor cell therapy for heart disease is considered investigational (unproven).

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Investigational
Progenitor cell therapy	**Progenitor cell therapy, including but not limited to skeletal myoblasts or hematopoietic cells, is considered investigational as a treatment of damaged myocardium.**
Infusion of growth factors	**Infusion of growth factors (i.e., granulocyte colony stimulating factor [GCSF]) is considered investigational as a technique to increase the numbers of circulating hematopoietic cells as treatment of damaged myocardium.**

Coding

Code	Description
CPT	
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

Related Information

N/A

Evidence Review

Description

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.

Background

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. 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 (3.8%) followed by Black females (3.3%), White males (both 2.9%) Hispanic males (1.8%), Hispanic and White females (both 1.6%), Asian males (1.4%), and Asian females (0.5%). 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.

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.[2] 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 (MSCs), 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 (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.

Summary of Evidence

For individuals who have acute cardiac ischemia who receive progenitor cell therapy, the evidence includes two phase 3 randomized controlled trials (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 left ventricular ejection fraction (LVEF), reducing recurrent myocardial infarction (MI), decreasing the need for further revascularization, and perhaps decreasing mortality, although, a recent, large, individual patient data meta-analysis reported no improvement in these outcomes. 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 one phase 3 RCT with more than 100 participants, two phase 2 RCTs with more than 100 participants, systematic reviews of smaller, early-phase RCTs, and a nonrandomized comparative trial. The relevant outcomes are disease-specific survival, morbid events, functional outcomes, quality of life, and hospitalizations. The studies included in the meta-analyses reported only 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 Stem Cell Transplantation in 191 Patients With Chronic Heart Failure (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. The 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 individuals with refractory angina. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02323620	The Impact of Repeated Intracoronary Injection of Autologous Bone-marrow Derived Mononuclear Cells for Left Ventricle Contractility and Remodeling in Patients With STEMI Prospective Randomized Study (RACE-STEMI)	200	Dec 2022
NCT01693042	Randomized Controlled Trial to Compare the Effects of Single Versus Repeated Intracoronary Application of Autologous Bone Marrow-derived Mononuclear Cells on Total and SHFM-predicted Mortality in Patients With Chronic Post-infarction Heart Failure (REPEAT)	81	Jan 2025
NCT03455725[a]	Prospective, multi-center, 2:1 randomized (Treatment vs Sham Control), blinded trial comparing 2 parallel groups of patients with CMI treated with CardiAMP cell therapy system vs sham treatment (CardiAMP CMI)	343	Dec 2026
NCT05711849	A Phase II Randomised Sham-controlled Trial Assessing the Safety and Efficacy of Intracoronary Administration of Autologous Bone Marrow Cells in Patients With Refractory Angina	110	Sept 2025
Unpublished			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT03129568	A Prospective Phase 1 Trial of Cardiac Progenitor Cell Therapy in Children With Dilated Cardiomyopathy	5	Dec 2020
NCT01781390[a]	A Prospective, Double Blind, Randomized, Placebo-controlled Clinical Trial of Intracoronary Infusion of Immunoselected, Bone Marrow-derived Stro3 Mesenchymal Precursor Cells (MPC) in the Treatment of Patients With ST-elevation Myocardial Infarction (AMICI)	106	Apr 2021
NCT03418233[a]	Regeneration of Ischemic Damages in Cardiovascular System Using Wharton's Jelly as an Unlimited Source of Mesenchymal Stem Cells for Regenerative Medicine. Project of the National Centre for Research and Development (Poland) 'STRATEGMED II'. Randomized Clinical Trial to Evaluate the Regenerative Capacity of CardioCell in Patients With Chronic Ischaemic Heart Failure (CIHF)	115	Mar 2021
NCT02501811	A Phase II, Randomized, Placebo-Controlled Study of the Safety, Feasibility, & Efficacy of Autologous Mesenchymal Stem Cells & C-kit+ Cardiac Stem Cells, Alone or in Combination, Administered Transendocardially in Subjects With Ischemic HF	125	July 2020
NCT02032004[a]	Efficacy and Safety of Allogeneic Mesenchymal Precursor Cells (Rexlemestrocel-L) for the Treatment of Heart Failure (DREAM HF-1)	566	May 2020

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a U.S. professional society, an international society with U.S. representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Cardiology Foundation, American Heart Association, and the Society for Cardiovascular Angiography and Interventions

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.[33] This guideline was an update of the 2011 guideline for percutaneous coronary intervention[34] and the 2013 guideline on managing ST-elevation myocardial infarction.[35] In 2021, these same organizations published a guideline on coronary artery revascularization.[36] 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 foundation (2021) and American Heart Association/American College of Cardiology/Heart Failure Society of America (2022) do not mention progenitor cell therapy.[37,38]

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

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

MyoCell comprises individual 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 individuals 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.

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History

Date	Comments
07/13/04	Add to Medicine section, Cardiology subsection - New Policy
06/14/05	Replace Policy - Policy updated with literature review; no change to policy statement.
04/11/06	Replace Policy - Policy updated with literature review; no change to policy statement.
05/26/06	Update Scope and Disclaimer - No other changes.

Date	Comments
04/10/07	Replace Policy - Policy updated with literature search; references added. No change in policy statement.
08/12/08	Replace Policy - Policy updated with literature search; no change to the policy statement. Description, Rationale, and References sections completely revised based on 2008 TEC Assessment. Title also updated to include "Progenitor" after Autologous and "due to Ischemia" after Damaged Myocardium.
12/08/09	Replace Policy - Policy updated with literature search; no change to the policy statement. References added.
09/14/10	Replace Policy - Policy updated with literature review through May 2010; no change to the policy statement. References have been added, deleted and reordered.
08/09/11	Replace Policy – Policy updated with literature search through April 2011; references added and reordered; policy statements unchanged.
08/20/12	Replace policy. Policy updated with literature search through March 2012; references 12, 14, 22 added and references reordered; 1 reference removed; policy statements unchanged. Title changed to Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia.
09/17/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
08/16/13	Replace policy. Policy updated with literature search through May 15, 2013; references 15, 22, 29 and 30 added and references reordered; policy statements unchanged.
09/03/14	Annual Review. Policy updated with literature review through May 7, 2014; references 13-14, 22, 27, 32-34, 39-40 added; others renumbered or removed. Policy statements unchanged.
08/11/15	Annual Review. Policy updated with literature review through May 18, 2015; references 15, 29-30, and 33-34 added; references 35-36 deleted. Policy statements unchanged.
09/01/16	Annual Review, approved August 9, 2016. Policy updated with literature review through July 14, 2016; no change to the policy statement. Removed code 38206
03/01/17	Annual Review, approved February 14, 2017. Policy updated with literature review through October 10, 2016; references 4-5, 8, and 21 added; Rationale revised and some references removed. Policy statements unchanged.
06/09/17	Coding update; updated description for CPT code 38241.
10/01/17	Interim Review, approved September 21, 2017. Policy updated with literature review through June 22, 2017; references 10, 19, and 21-22 added. Removed CPT code33999. Policy statements unchanged.
08/01/18	Annual Review, approved July 13, 2018. Policy updated with literature review through March 2018; references 3, 16, 21, and 30 added. Policy statements unchanged.

Date	Comments
08/01/19	Annual Review, approved July 25, 2019. Policy updated with literature review through March 2019; reference 31 added. Policy statements unchanged.
08/01/20	Annual Review, approved July 2, 2020. Policy updated with literature review through March, 2020; references added. Policy statements unchanged.
08/01/21	Annual Review, approved July 9, 2021. Policy updated with literature review through March 16, 2021; reference added. Policy statements unchanged.
08/01/22	Annual Review, approved July 11, 2022. Policy updated with literature review through March 16, 2022; references added. Policy statements unchanged.
08/01/23	Annual Review, approved July 10, 2023. Policy updated with literature review through March 14, 2023; reference added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

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Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 800-722-1471 (TTY: 711).

注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

ማስታወሻ: የሚናገሩት ቋንቋ ኣማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 800-722-1471 (መስማት ለተሳናቸው፡ 711).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-722-1471 (TTY: 711).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-722-1471 (رقم هاتف الصم والبكم: 711).

ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-722-1471 (TTY: 711).

ATANSYON: Si w pale Kreyòl Ayisyen, gen sèvis èd pou lang ki disponib gratis pou ou. Rele 800-722-1471 (TTY: 711).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-722-1471 (ATS : 711).

ATENÇÃO: Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-722-1471 (TTY: 711).

ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-722-1471 (TTY: 711).

توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.