PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 8.01.55

Stem Cell Therapy for Peripheral Arterial Disease

BCBSA Ref. Policy:	8.01.55
Effective Date:	April 1, 2024
Last Revised:	Jan. 1, 2025
Replaces:	N/A

RELATED MEDICAL POLICIES:

2.01.543	Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions
8.01.52	Orthopedic Applications of Stem Cell Therapy (Including Allografts and Bone Substitutes Used with Autologous Bone Marrow)

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

Peripheral arterial disease (PAD) is a condition in which plaque builds up in the arteries. Fat, cholesterol, and other substances in the blood make up the plaque. Over time the plaque becomes so thick and hard that the blood has trouble flowing through the artery. While PAD can affect the arms, organs, or the legs, it most often affects the legs. Pain and numbness are symptoms of PAD in the legs. PAD also increases the risk of infection and tissue death. If enough tissue dies, the leg may need to be removed. Using stem cells as a way to treat PAD is being studied. The idea is to use stem cells to stimulate the body to create new blood vessels. Using stem cells to treat PAD is unproven. Larger and longer studies are needed to find out if this treatment is safe and how long it might last.

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

Treatment	Investigational
Treatment of peripheral arterial disease	**Treatment of peripheral arterial disease, including critical limb ischemia, with injection or infusion of cells from concentrated bone marrow, expanded in vitro, stimulated from peripheral blood, or from an allogeneic source, is considered investigational.**

Coding

Code	Description
CPT	
0263T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure including unilateral or bilateral bone marrow harvest
0264T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; complete procedure excluding bone marrow harvest
0265T	Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, one leg, including ultrasound guidance, if performed; unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy

Related Information

N/A

Evidence Review

Description

Peripheral arterial disease (PAD) is a common atherosclerotic syndrome associated with significant morbidity and mortality. Critical limb ischemia (CLI) is the end stage of lower-extremity PAD in which severe obstruction of blood flow results in ischemic pain at rest, ulcers, and a significant risk for limb loss. Use of autologous stem cells freshly harvested and allogeneic stem cells are reported to have a role in the treatment of PAD.

Background

Peripheral Arterial Disease

PAD is a common atherosclerotic syndrome associated with significant morbidity and mortality.[1] A less common cause of PAD is Buerger disease (also called thromboangiitis obliterans), which is a nonatherosclerotic segmental inflammatory disease that occurs in younger individuals and is associated with tobacco use.[2] The development of PAD is characterized by narrowing and occlusion of arterial vessels and eventual reduction in distal perfusion. Critical limb ischemia is the end stage of lower-extremity PAD in which severe obstruction of blood flow results in ischemic pain at rest, ulcers, and a significant risk for limb loss.

Physiology

Two endogenous compensating mechanisms may occur with occlusion of arterial vessels: capillary growth (angiogenesis) and development of collateral arterial vessels (arteriogenesis).[3] Capillary growth is mediated by hypoxia-induced release of chemokines and cytokines such as vascular endothelial growth factor and occurs by sprouting of small endothelial tubes from preexisting capillary beds. The resulting capillaries are small and cannot sufficiently compensate for a large, occluded artery. Arteriogenesis with collateral growth is, in contrast, initiated by increasing shear forces against vessel walls when blood flow is redirected from the occluded transport artery to the small collateral branches, leading to an increase in the diameter of preexisting collateral arterioles.

The mechanism underlying arteriogenesis includes the migration of bone marrow-derived monocytes to the perivascular space. The bone marrow-derived monocytes adhere to and invade the collateral vessel wall. It is not known if the expansion of the collateral arteriole is due to the incorporation of stem cells into the wall of the vessel or to cytokines released by monocytic bone marrow cells that induce the proliferation of resident endothelial cells. It has

been proposed that bone marrow-derived monocytic cells may be the putative circulating endothelial progenitor cells. Notably, the same risk factors for advanced ischemia (diabetes, smoking, hyperlipidemia, advanced age) are also risk factors for a lower number of circulating progenitor cells.

Treatment

Use of autologous stem cells freshly harvested and allogeneic stem cells are purported to have a role in the treatment of PAD.[4] Stem cells can be administered in a variety of routes, derived from different progenitors, and be grouped with different co-factors, many of which are being studied in order to determine the best clinical option for patients. The primary outcome in stem cell therapy trials regulated by the US Food and Drug Administration (FDA) is amputation-free survival defined as time to major amputation and/or death from any cause. Other outcomes for critical limb ischemia include the Rutherford criteria for limb status, healing of ulcers, the Ankle-Brachial Index (ABI), transcutaneous oxygen pressure (TcO2), and pain-free walking. The ABI measures arterial segmental pressures on the ankle and brachium, and indexes ankle systolic pressure against brachial systolic pressure (normative range, 0.95-1.2 mm Hg).

Summary of Evidence

For individuals who have PAD who receive stem cell therapy, the evidence includes small randomized trials and systematic reviews. The relevant outcomes are overall survival, symptoms, change in disease status, morbid events, functional outcomes, quality of life, and treatment-related morbidity. The current literature on stem cells as a treatment for CLI due to PAD consists primarily of phase 2 studies using various cell preparation methods and methods of administration. A meta-analysis of the trials with the lowest risk of bias has shown no significant benefit of stem cell therapy for overall survival, amputation-free survival, or amputation rates. Three randomized controlled trials (RCTs) have been published that used granulocyte colony-stimulating factor (GM-CSF)-mobilized peripheral mononuclear cells (PBMNC). The route of administration of the cell therapy and the primary outcomes differed between studies. In the trial that added cell therapy to guideline-based care, there were no significant differences in progression-free survival and frequency of limb amputation at one year of follow-up. There was a substantial rate of subsequent surgical intervention in both arms. Well-designed randomized controlled trials with a larger number of subjects and low-risk of bias are needed to evaluate the health outcomes of these various procedures. Several are in progress, including multicenter randomized, double-blind, placebo-controlled trials. More data on the safety and durability of

these treatments are also needed. 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 review are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03304821	Granulocyte-Macrophage Stimulating Factor (GM-CSF) in Peripheral Artery Disease: the GPAD-3 Study	176	Oct 2024
NCT02685098	A Clinical and Histological Analysis of Mesenchymal Stem Cells in Amputation (CHAMP)	81	Oct 2023
NCT02805023[a]	Phase 1/2, Double Blind Randomized Placebo Controlled Study to Assess the Safety and Efficacy of BGC101 (EnEPC) in the Treatment of PAD & CLI	50	Dec 2023
NCT04466007	Multicenter, Randomized, Dose-search, Parallel, Double-blind, and Placebo-controlled Clinical Trial to Evaluate the Safety and Efficacy of Intramuscular Administration of Allogeneic Adipose Tissue Adult Mesenchymal Stem Cells in Diabetic Patients With Critical Limb Ischemia Without Possibility of Revascularization	90	Dec 2024
Unpublished			
NCT02551679[a]	A Randomized Double Blind Placebo Controlled Clinical Study to Assess Blood-Derived Autologous Angiogenic Cell Precursor Therapy in Patients With Critical Limb Ischemia (ACP-CLI)	95	Dec 2020
NCT01745744	Clinical Trial Phase I / II, Multicentre, Open, Randomized Study of the Use of Mesenchymal Stem Cells From Adipose Tissue (CeTMAd) as Cell Regeneration Therapy in Critical Chronic Ischemic Syndrome of Lower Limb in Nondiabetic Patients	33	July 2018

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT00498069[a]	Feasibility Study of the Safety and Activity of Autologous Bone Marrow Aspirate Concentrate (BMAC) for the Treatment of Critical Limb Ischemia Due to Peripheral Arterial Occlusive Disease	48	Mar 2015
NCT02538978[a]	Safety and Effectiveness of the SurgWerksTM-CLI Kit and VXPTM System for the Rapid Intra-operative Aspiration, Preparation and Intramuscular Injection of Concentrated Autologous Bone Marrow Cells Into the Ischemic Index Limb of Rutherford Category 5 Non-Reconstructable Critical Limb Ischemia Patients	224	Mar 2019
NCT01679990[a]	A Phase II, Randomized, Double-Blind, Multicenter, Multinational, Placebo-Controlled, Parallel- Groups Study to Evaluate the Safety and Efficacy of Intramuscular Injections of Allogeneic PLX-PAD Cells for the Treatment of Subjects With Intermittent Claudication (IC)	180	Feb 2019
NCT03042572	Allogeneic Mesenchymal Stromal Cells for Angiogenesis and Neovascularization in No-option Ischemic Limbs; A Double-blind, Randomized, Placebo-controlled Trial	60	July 2021

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 US professional society, an international society with US 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 Heart Association and American College of Cardiology

In 2016, the guidelines from the American Heart Association and American College of Cardiology provided recommendations on the management of patients with lower-extremity PAD, including surgical and endovascular revascularization for critical limb ischemia (CLI).[25,26] Stem cell therapy for PAD was not addressed.

European Society of Cardiology

In 2011, the European Society of Cardiology guidelines on the diagnosis and treatment of PAD did not recommend for or against stem cell therapy for PAD.[27] However, in 2017, updated guidelines, published in collaboration with the European Society of Vascular Surgery, stated: "Angiogenic gene and stem cell therapy are still being investigated with insufficient evidence in favour of these treatments." The current recommendation is that stem cell/gene therapy is not indicated in individuals with chronic limb-threatening ischemia (class of recommendation: III; level of evidence: B).[28]

Global Vascular Guideline

In 2019, a Global Vascular Guideline on management of chronic limb-threatening ischemia summarized the available literature on therapeutic angiogenesis for various etiologies.[29] The guideline was a joint venture of the Society for Vascular Surgery, the European Society for Vascular Surgery, and the World Federation of Vascular Societies. Based on a moderate level of evidence, the guideline recommended that therapeutic angiogenesis in individuals with chronic limb-threatening ischemia should be limited to the context of a clinical trial (strong recommendation). The authors noted that Phase 3 clinical trials are planned or underway so additional data may be forthcoming in the future.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

Several point-of-care concentrations of bone marrow aspirate have been cleared by the FDA through the 510(k) process and are summarized in **Table 2**.

Table 2. FDA Approved Point-of-Care Concertation of Bone Marrow Aspirate Devices

Device	Manufacturer	Location	Date Cleared	510(k) No.
The SmartPrep Bone Marrow Aspirate Concentrate System, SmartPrep Platelet Concentration System	Harvest Technologies (now MD Biologix)	Lakewood, CO	12/06/2010	K103340
MarrowStim Concentration System (MSC system)	Biomet Biologics, Inc (now Zimmer Biomet)	Warsaw, IN	12/18/2009	BK090008
PureBMC SupraPhysiologic Concentrating System	EmCyte Corporation	Fort Myers, Florida	5/30/2019	K183205
Arthrex Angel System Kit	Arthrex, Inc.	Naples, Florida	5/23/2018	BK180180
Magellan Autologous Platelet Separator System	Arteriocyte Medical Systems (Medtronic)	Memphis, TN	11/09/2004	BK040068
BioCUE Platelet Concentration Kit (now BioCUE Blood and Bone Marrow Aspiration (bBMA) Concentration Kit)	Biomet Biologics, Inc. (now Zimmer Biomet)	Warsaw, IN	5/26/2010	BK1000027
ART BMC/ART BMC PLUS System	SpineSmith Holdings, LLC (now Ceiling Biosciences)	Austin, TX	Not available	Not available
PXP System (now PXP-1000)	ThermoGenesis Corp.	Rancho Cordova, CA	07/10/2008	K081345

U.S. Food and Drug Administration product code: JQC.

References

1. Kullo IJ, Rooke TW. CLINICAL PRACTICE. Peripheral Artery Disease. N Engl J Med. Mar 03 2016; 374(9): 861-71. PMID 26962905

2. Liew NC, Lee L, Nor Hanipah Z, et al. Pathogenesis and Management of Buerger's Disease. Int J Low Extrem Wounds. Sep 2015; 14(3): 231-5. PMID 26264874

3. Krishna SM, Moxon JV, Golledge J. A review of the pathophysiology and potential biomarkers for peripheral artery disease. Int J Mol Sci. May 18 2015; 16(5): 11294-322. PMID 25993296

4. Hussain MA, Al-Omran M, Creager MA, et al. Antithrombotic Therapy for Peripheral Artery Disease: Recent Advances. J Am Coll Cardiol. May 29 2018; 71(21): 2450-2467. PMID 29793635

5. Lawall H, Bramlage P, Amann B. Treatment of peripheral arterial disease using stem and progenitor cell therapy. J Vasc Surg. Feb 2011; 53(2): 445-53. PMID 21030198

6. Fadini GP, Agostini C, Avogaro A. Autologous stem cell therapy for peripheral arterial disease meta-analysis and systematic review of the literature. Atherosclerosis. Mar 2010; 209(1): 10-7. PMID 19740466

7. Rigato M, Monami M, Fadini GP. Autologous Cell Therapy for Peripheral Arterial Disease: Systematic Review and Meta-Analysis of Randomized, Nonrandomized, and Noncontrolled Studies. Circ Res. Apr 14 2017; 120(8): 1326-1340. PMID 28096194

8. Xie B, Luo H, Zhang Y, et al. Autologous Stem Cell Therapy in Critical Limb Ischemia: A Meta-Analysis of Randomized Controlled Trials. Stem Cells Int. 2018; 2018: 7528464. PMID 29977308

9. Gao W, Chen D, Liu G, et al. Autologous stem cell therapy for peripheral arterial disease: a systematic review and meta-analysis of randomized controlled trials. Stem Cell Res Ther. May 21 2019; 10(1): 140. PMID 31113463

10. Pu H, Huang Q, Zhang X, et al. A meta-analysis of randomized controlled trials on therapeutic efficacy and safety of autologous cell therapy for atherosclerosis obliterans. J Vasc Surg. Apr 2022; 75(4): 1440-1449.e5. PMID 34788653

11. Moazzami B, Mohammadpour Z, Zabala ZE, et al. Local intramuscular transplantation of autologous bone marrow mononuclear cells for critical lower limb ischaemia. Cochrane Database Syst Rev. Jul 08 2022; 7(7): CD008347. PMID 35802393

12. Procházka V, Gumulec J, Jalůvka F, et al. Cell therapy, a new standard in management of chronic critical limb ischemia and foot ulcer. Cell Transplant. 2010; 19(11): 1413-24. PMID 20529449

13. Benoit E, O'Donnell TF, Iafrati MD, et al. The role of amputation as an outcome measure in cellular therapy for critical limb ischemia: implications for clinical trial design. J Transl Med. Sep 27 2011; 9: 165. PMID 21951607

14. Skóra J, Pupka A, Janczak D, et al. Combined autologous bone marrow mononuclear cell and gene therapy as the last resort for patients with critical limb ischemia. Arch Med Sci. Apr 25 2015; 11(2): 325-31. PMID 25995748

15. Gupta PK, Krishna M, Chullikana A, et al. Administration of Adult Human Bone Marrow-Derived, Cultured, Pooled, Allogeneic Mesenchymal Stromal Cells in Critical Limb Ischemia Due to Buerger's Disease: Phase II Study Report Suggests Clinical Efficacy. Stem Cells Transl Med. Mar 2017; 6(3): 689-699. PMID 28297569

16. Dubský M, Husáková J, Bem R, et al. Comparison of the impact of autologous cell therapy and conservative standard treatment on tissue oxygen supply and course of the diabetic foot in patients with chronic limb-threatening ischemia: A randomized controlled trial. Front Endocrinol (Lausanne). 2022; 13: 888809. PMID 36105404

17. Teraa M, Sprengers RW, Schutgens RE, et al. Effect of repetitive intra-arterial infusion of bone marrow mononuclear cells in patients with no-option limb ischemia: the randomized, double-blind, placebo-controlled Rejuvenating Endothelial Progenitor Cells via Transcutaneous Intra-arterial Supplementation (JUVENTAS) trial. Circulation. Mar 10 2015; 131(10): 851-60. PMID 25567765

18. Peeters Weem SM, Teraa M, den Ruijter HM, et al. Quality of Life After Treatment with Autologous Bone Marrow Derived Cells in No Option Severe Limb Ischemia. Eur J Vasc Endovasc Surg. Jan 2016; 51(1): 83-9. PMID 26511056

19. Walter DH, Krankenberg H, Balzer JO, et al. Intraarterial administration of bone marrow mononuclear cells in patients with critical limb ischemia: a randomized-start, placebo-controlled pilot trial (PROVASA). Circ Cardiovasc Interv. Feb 01 2011; 4(1): 26-37. PMID 21205939

20. Powell RJ, Comerota AJ, Berceli SA, et al. Interim analysis results from the RESTORE-CLI, a randomized, double-blind multicenter phase II trial comparing expanded autologous bone marrow-derived tissue repair cells and placebo in patients with critical limb ischemia. J Vasc Surg. Oct 2011; 54(4): 1032-41. PMID 21684715

21. Powell RJ, Marston WA, Berceli SA, et al. Cellular therapy with Ixmyelocel-T to treat critical limb ischemia: the randomized, double-blind, placebo-controlled RESTORE-CLI trial. Mol Ther. Jun 2012; 20(6): 1280-6. PMID 22453769

22. Poole J, Mavromatis K, Binongo JN, et al. Effect of progenitor cell mobilization with granulocyte-macrophage colony-stimulating factor in patients with peripheral artery disease: a randomized clinical trial. JAMA. Dec 25 2013; 310(24): 2631-9. PMID 24247554

23. McDermott MM, Ferrucci L, Tian L, et al. Effect of Granulocyte-Macrophage Colony-Stimulating Factor With or Without Supervised Exercise on Walking Performance in Patients With Peripheral Artery Disease: The PROPEL Randomized Clinical Trial. JAMA. Dec 05 2017; 318(21): 2089-2098. PMID 29141087

24. Horie T, Yamazaki S, Hanada S, et al. Outcome From a Randomized Controlled Clinical Trial - Improvement of Peripheral Arterial Disease by Granulocyte Colony-Stimulating Factor-Mobilized Autologous Peripheral-Blood-Mononuclear Cell Transplantation (IMPACT). Circ J. Jul 25 2018; 82(8): 2165-2174. PMID 29877199

25. Gerhard-Herman MD, Gornik HL, Barrett C, et al. 2016 AHA/ACC Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. Mar 21 2017; 69(11): e71-e126. PMID 27851992

26. Valentine EA, Ochroch EA. 2016 American College of Cardiology/American Heart Association Guideline on the Management of Patients With Lower Extremity Peripheral Artery Disease: Perioperative Implications. J Cardiothorac Vasc Anesth. Oct 2017; 31(5): 1543-1553. PMID 28826846

27. Tendera M, Aboyans V, Bartelink ML, et al. ESC Guidelines on the diagnosis and treatment of peripheral artery diseases: Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the Diagnosis and Treatment of Peripheral Artery Diseases of the European Society of Cardiology (ESC). Eur Heart J. Nov 2011; 32(22): 2851-906. PMID 21873417

28. Aboyans V, Ricco JB, Bartelink MEL, et al. 2017 ESC Guidelines on the Diagnosis and Treatment of Peripheral Arterial Diseases, in collaboration with the European Society for Vascular Surgery (ESVS): Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteriesEndorsed by: the European Stroke Organization (ESO)The Task Force for the Diagnosis and Treatment of Peripheral Arterial Diseases of the European Society of Cardiology (ESC) and of the European Society for Vascular Surgery (ESVS). Eur Heart J. Mar 01 2018; 39(9): 763-816. PMID 28886620

29. Conte MS, Bradbury AW, Kolh P, et al. Global vascular guidelines on the management of chronic limb-threatening ischemia. J Vasc Surg. Jun 2019; 69(6S): 3S-125S.e40. PMID 31159978

History

Date	Comments
08/09/11	New policy; add to Therapy section. Policy created with literature review through March 2011; considered investigational.
07/20/12	Replace policy. Policy updated with literature review through February 2012, rationale section revised. References 4 and 10 added. Policy statement is unchanged.
10/09/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.

Date	Comments
07/08/13	Replace policy. Policy updated with literature review through April 8, 2013; references 3, 4, 6, 10, 12, 13, 15 added; references reordered; policy statement unchanged.
08/20/13	Update Related Policies. Change title to 2.02.18.
07/31/14	Annual Review. Policy updated with literature review through April, 2014. References 5,14 added; others renumbered/removed. Policy statement unchanged.
07/14/15	Annual Review. Policy updated with literature review through April 14, 2015; references 4, 9, and 23 added; policy statement unchanged. ICD-9 and ICD-10 procedure codes removed; these were listed for informational purposes only.
04/01/16	Annual Review, approved March 8, 2016. Policy updated with literature review through November 17, 2015; references 4, 7, and 9 added; some references removed. Policy statement unchanged.
09/01/17	Annual Review, approved August 22, 2017. Policy updated with literature review through June 4, 2017; references 3 and 14 added. Policy statement updated to describe specific sources of stem cells.
05/01/18	Annual Review, approved April 3, 2018. Policy updated with literature review through November 2017; references 15 and 17 added. Policy statement unchanged.
05/01/19	Annual Review, approved April 2, 2019. Policy updated with literature review through October 2018; references 4, 8 and 16 added. Policy statement unchanged.
04/01/20	Annual Review, approved March 19, 2020. Policy updated with literature review through November 2019; references added. Policy statement unchanged. Added CPT codes 20999 and 38241.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through December 1, 2020; references added. Policy statement unchanged.
04/01/22	Annual Review, approved March 21, 2022. Policy updated with literature review through October 18, 2021; no references added. Policy statement unchanged. Removed CPT codes 20999 and 38241.
04/01/23	Annual Review, approved March 20, 2023. Policy updated with literature through December 2, 2022; references added. Policy statement unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
04/01/24	Annual Review, approved March 25, 2024. Policy updated with literature review through November 10, 2023; references added. Policy statement unchanged.
08/01/24	Minor update to Related Policies, 2.02.18 Progenitor Cell Therapy for the Treatment of Damaged Myocardium Due to Ischemia was archived effective August 1, 2024.
01/01/25	Minor update to related policy. 2.01.16 was replaced with 2.01.543 Recombinant and Autologous Platelet-Derived Growth Factors for Wound Healing and Other Non-Orthopedic Conditions.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

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.