

# Medicare Advantage Medical Policy



Nonprofit corporations and independent licensees  
of the Blue Cross and Blue Shield Association

## Stem Cell Therapy in the Treatment of Peripheral Artery Disease – Medicare Advantage

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### Medicare Advantage Plan

☒ Medicare Plus Blue<sup>SM</sup>

☒ BCN Advantage<sup>SM</sup>

UM Committee Approval Date: 7/15/2026

Effective Date: 8/15/2026

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### Description

Stem cell therapy is purported to have a potential role in the treatment of critical limb ischemia associated with peripheral artery disease (PAD). It has been proposed that stem cell therapy could promote angiogenesis (the formation of new blood vessels) and improve blood flow to the affected areas.

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### Related Medical Coverage Policies

- Orthopedic Applications of Platelet-Rich Plasma - Medicare Advantage
  - Orthopedic Applications of Stem-Cell Therapy (Including autologous stem cells used with Allografts and Bone Substitutes) - Medicare Advantage
  - Platelet Rich Plasma Autologous Platelet-Derived Growth Factors as a Treatment of Wound Healing and Other Non-Orthopedic Condition - Medicare Advantage
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### Policy Guidelines

Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network of Michigan (BCN) adhere to guidance from the Centers for Medicare and Medicaid Services (CMS), including when performing organization determinations for Medicare Advantage plan members. CMS Medicare statutes, regulations, manuals, National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and other sub-regulatory guidance provide the clinical guidelines for coverage determinations, payment integrity functions, and all other uses by CMS regulations. When CMS Medicare guidance is silent, incomplete, or insufficient, CMS permits BCBSM/BCN to utilize “internal coverage criteria”, such as independent criteria, health plan policy research, LCD/LCAs outside the services area or research from independent medical research repositories (i.e., Hayes) for coverage policies 42 CFR § 422.101. BCBSM/BCN internal medical coverage policies are developed and based on current evidence in widely accepted treatment guidelines or clinical literature; in addition, they address how clinical benefits may or may not outweigh member harm.

Clinical review follows guidance provided in the BCBSM Medicare Advantage Coverage Determination Hierarchy policy, which may be found at <https://www.bcbsm.com/providers/mpradmin/> by entering the policy name.

## Coverage Guidance

To ensure consistency with coverage guidance, the Medicare statutes, regulations, coverage manuals, NCD, LCD, and LCA should be reviewed and applied first. BCBSM/BCN internal coverage criteria should only be applied when CMS guidance is silent, incomplete, or insufficient for a code.

Apart from durable medical equipment (DME), Medicare Administrative Contractor (MAC) jurisdiction for the purpose of clinical determination is based upon place of service. The place of service for laboratory testing is defined as the geographic location of the reference laboratory. Non-jurisdictional LCD/LCAs may not be utilized for a determination unless they have been specifically identified as internal coverage criteria by the policy. Alternatively, jurisdiction for DME MAC is determined by the member place of residence. Please see CMS Medicare Administrative Contractors (MAC) table for state MAC assignments below.

| CMS Guidance                                                                                                                                                                                                                                                                                                           | Additional Guidance                                                                                                                                                                                                                                                                                                                                                                                 |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>National Coverage Determinations</b><br>310.1 - Routine Costs in Clinical Trials<br>for additional information related to clinical trials related to stem cell therapy in the treatment of peripheral artery disease, please refer to this URL: <a href="https://clinicaltrials.gov">https://clinicaltrials.gov</a> | BCBSM/BCN will follow CMS guidance as the primary source for coverage determinations. However, in instances where CMS guidance is silent, incomplete, or insufficient for a particular code, BCBSM/BCN internal coverage criteria will be applied to ensure consistent and informed decision-making.                                                                                                |
| <b>Local Coverage Determinations and Articles</b><br>None                                                                                                                                                                                                                                                              | In such cases, please refer to the relevant BCBSM/BCN policy for guidance:<br><br><i>Stem Cell Therapy in the Treatment of Peripheral Artery Disease</i><br><br>To access this policy, please visit the BCBSM Medical Policy Router Search page at <a href="https://www.bcbsm.com/providers/mpradmin/">https://www.bcbsm.com/providers/mpradmin/</a> and enter the policy name in the search field. |

| Code  | Description                                                                                                                                                                                                                                                             |
|-------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 0263T | Intramuscular autologous bone marrow cell therapy, with preparation of harvested cells, multiple injections, 1 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, 1 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, 1 leg, including ultrasound guidance, if performed: unilateral or bilateral bone marrow harvest only for intramuscular autologous bone marrow cell therapy |

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HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

The above information is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document.

Please refer to the Medicare Coverage Database website at <https://www.cms.gov/medicare-coverage-database/search.aspx> for the most current applicable NCD, LCD, LCA, and CMS Online Manual System Transmittals. For any code associated with a product or service determined to be noncovered by policy (either CMS or health plan policy if CMS is silent) medical record review, including prior authorization, will not be required.

## CMS Medicare Administrative Contractors (MAC) Jurisdictions Guidance

| Part A and Part B MAC Jurisdictions                                                    |                                                                                                                                                                     |
|----------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Wisconsin Physicians Service Insurance Corporation (WPS)</b>                        | IA, IN, KS, MI, MO, NE                                                                                                                                              |
| <b>CGS Administrators, LLC</b>                                                         | KY, OH                                                                                                                                                              |
| <b>First Coast Service Options, Inc</b>                                                | FL, PR, US VI                                                                                                                                                       |
| <b>Noridian Healthcare Solutions, LLC, Jurisdiction JE</b>                             | CA, HI, NV, American Samoa, Guam, Northern Mariana Islands                                                                                                          |
| <b>Noridian Healthcare Solutions, LLC, Jurisdiction JF</b>                             | AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY                                                                                                                              |
| <b>Novitas Solutions, Inc</b>                                                          | AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX,                                                                                                                     |
| <b>Palmetto GBA</b>                                                                    | AL, GA, TN NC, SC, VA, WV                                                                                                                                           |
| <b>Wellpoint Federal</b> - Previously known as National Government Services, Inc (NGS) | CT, IL, MA, ME, MN, NH, NY, RI, VT, WI,                                                                                                                             |
| DME MAC Jurisdictions                                                                  |                                                                                                                                                                     |
| <b>CGS Administrators, LLC, Jurisdictions JB and JC</b>                                | AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NM, NC, OH, OK, Puerto Rico, SC, TN, TX, VA, Virgin Island, WI, WV                                                  |
| <b>Noridian Healthcare Solutions, LLC, Jurisdictions JA and JD</b>                     | AK, American Soamoa, AZ, CA, CT, DE, DC, Guam, HI, ID, IA, KS, MA, MD, ME, MO, MT, ND, NE, NH, NJ, NV, NY, Northern Mariana Islands, OR, PA, RI, SD, UT, VT, WA, WY |

## Important Reminder

BCBSM and BCN follow CMS Medicare coverage guidance to limit coverage to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. Medicare Advantage Medical Policies list the criteria BCBSM and BCN use to decide which medical services are considered “reasonable and necessary” when Medicare coverage rules are not fully developed, or as otherwise may permitted by CMS Medicare regulations. Individual member benefit plan documents, such as the Evidence of Coverage and Annual Notice of Change, as well as applicable laws govern benefit coverage, including any inclusion, exclusion, and/or other restrictions.

Medicare Advantage Medical policies are created when permitted by CMS Medicare regulations, reviewed regularly, and may be revised periodically. BCBSM/BCN Medical Policies are proprietary and should not be copied or disseminated without the express, prior written approval of BCBSM. All providers are required to review applicable BCBSM reimbursement policies prior to claim submission and bill for covered services in accordance with those policies. Additionally, providers contracted with BCBSM or BCN’s Medicare Advantage network(s) should review the provider manual for any additional claim submission

requirements. Providers not contracted with BCBSM or BCN's Medicare Advantage network may be required to submit documentation to BCBSM, BCN, or its delegated entity supporting billed claims, including but not limited to applicable medical records.

**Note:** U.S. Food and Drug Administration (FDA) approval for a specific indication or the issuance of a CPT code is not sufficient for a procedure to be considered medically reasonable and necessary. Similarly, the presence of a procedure/device code or payment amount for the service in the Medicare fee schedule does not necessarily indicate coverage. If a service is deemed not reasonable and necessary, to treat illness or injury for any reason (including lack of safety and efficacy because it is an experimental procedure, etc.), the procedure is considered not covered.

**Disclaimer:** This medical policy is not an authorization, certification, explanation of benefits, or a contract for the services, devices, or drugs that is referenced in the medical policy. Medical policies do not constitute medical advice and do not guarantee any results or outcomes or guarantee payment. The medical policy is not intended to replace independent medical judgment for the treatment of individuals. Treating physicians and health care providers are solely responsible for determining what care to provide for their patients. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another.

Pursuant to Section 1557 and Section 504, Blue Cross does not discriminate on the basis of race, color, national origin, age, disability, or sex (including sex characteristics, intersex traits; pregnancy or related conditions; sexual orientation; gender identity, and sex stereotypes). This includes our rules, benefit designs and medical policies.

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## BCBSM/BCN Medicare Advantage Policy History

| Policy Effective Date | UM Committee Approval Date | Comments                                                                                |
|-----------------------|----------------------------|-----------------------------------------------------------------------------------------|
| 08/17/2024            | 07/17/2024                 | Medicare Advantage policy established                                                   |
| 08/16/2025            | 07/16/2025                 | Annual Review: MA Policy Foundational Language updated. Adoption of JUMP policy updates |
| 08/15/2026            | 07/15/2026                 | Annual Review: Reformatted guidance and code tables. Adoption of JUMP policy updates    |