Medicare Advantage Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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

Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure – Medicare Advantage

Medicare Advantage Plan
☒ Medicare Plus Blue℠
☒ BCN Advantage℠

Current Policy Effective Date: 10/16/2026
(See policy history boxes for previous effective dates)

Description

Laboratory testing performed following solid organ transplantation and in patients with heart failure may include molecular and biomarker-based assays intended to evaluate allograft rejection, graft injury, immune activity, and disease status. These tests are proposed as adjunctive tools to support clinical decision-making and patient management.

Related Medical Coverage Policies

- Galectin-3 Testing in the Assessment and Management of Chronic Heart Failure – Medicare Advantage
- Measurement of Lipoprotein-Associated Phospholipase A_2 (Lp-PLA_2) and Secretory Type II Phospholipase A_2 (sPLA_2-IIA) in the Assessment of Cardiovascular Risk – Medicare Advantage
- Nontraditional Biomarkers in Risk Assessment and Management of Cardiovascular Disease – Medicare Advantage
- Skin Advanced Glycation End Products (AGE) Measurement by Multi-Wavelength Fluorescent Spectroscopy – Medicare Advantage

Policy Guidelines

Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network of Michigan (BCN) adhere to guidance from the Centers for Medicare & 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 establish the coverage criteria and requirements used for coverage determinations, payment integrity activities, and other functions governed 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, LCDs/LCAs outside the service area or research from independent medical research repositories (i.e., Hayes) for coverage policies consistent with 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, NCDs, LCDs, and LCAs 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 LCDs/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
National Coverage Determinations 260.9 – Heart Transplants 260.10 – Heartsbreath Test for Heart Transplant Rejection 310.1 – Routine Costs in Clinical Trials For additional information regarding clinical trials evaluating post-transplant and heart failure laboratory test, please visit ClinicalTrials.gov. **Local Coverage Determinations and Articles** **WPS** L40249, A60274 – MolDX: Molecular Testing for Solid Organ Allograft Rejection* L36807, A57772 – MolDX: Molecular Diagnostic Tests (MDT)* **CGS** L40140, A60161 – MolDX: Molecular Testing for Solid Organ Allograft Rejection* L36021, A56973 – MolDX: Molecular Diagnostic Tests (MDT)* **First Coast** None **Noridian JE** L40060, A60152 – MolDX: Molecular Testing for Solid Organ Allograft Rejection* **Noridian JF** L40062, A60155 – MolDX: Molecular Testing for Solid Organ Allograft Rejection* **Noridian JE & JF**	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. In such cases, please refer to the relevant BCBSM/BCN policy for guidance: *Laboratory Tests Post Transplant (Kidney, Heart, and Lung) and for Heart Failure* To access this policy, please visit the BCBSM Medical Policy Router Search page at https://www.bcbsm.com/providers/mpradmin/ and enter the policy name in the search field.

L35160, A57526 – MolDX: Molecular Diagnostic Tests (MDT)* **Novitas** L35062, A56541 – Biomarkers Overview A58917 – Billing and Coding: Molecular Pathology and Genetic Testing **Palmetto** L40058, A60146 – MolDX: Molecular Testing for Solid Organ Allograft Rejection* L35025, A56853 – MolDX: Molecular Diagnostic Tests (MDT)* **Wellpoint Federal** L35000, A56199 – Molecular Pathology Procedures	

Code	Description
81479	Unlisted molecular pathology procedure
81558	Transplantation medicine (allograft rejection, kidney), mRNA, gene expression profiling by quantitative polymerase chain reaction (qPCR) of 139 genes, utilizing whole blood, algorithm reported as a binary categorization as transplant excellence, which indicates immune quiescence, or not transplant excellence, indicating subclinical rejection
81595	Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score [AlloMap Heart – Surveillance, CA]
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1)
84999	Unlisted chemistry procedure
0018M	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma [myTAIHEART, WI]
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA [Eurofins TRAC™ dd-cfDNA, MA]
0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection [Clarava™, TN]
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection [Tuteva™, TN]
0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA [Prospera™, TX, CA, CO]
0540U	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor-derived cell-free DNA to determine probability of rejection [AlloSure®, CA]
0542U	Nephrology (renal transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus (human polyomavirus

Code	Description
	1) using real-time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status [myOLARIS™-KT-dx, MA]

CPT® codes, descriptions and materials are copyrighted by the American Medical Association (AMA).
HCPCS® codes, descriptions and materials are copyrighted by Centers for Medicare and Medicaid Services (CMS).

*The CMS MolDX Program, administered by Palmetto GBA and implemented by participating Medicare Administrative Contractors (MACs), including WPS, CGS, Noridian, and Palmetto, evaluates molecular and proteomic diagnostic tests for analytical validity, clinical validity, and clinical utility to determine whether they meet Medicare's reasonable and necessary standard. Coverage of MolDX-governed tests is subject to the test's current DEX™ Diagnostic Exchange Registry status, any applicable test-specific MolDX coverage determinations, and all applicable CMS Medicare coverage requirements. Tests that have not completed the required technical assessment process, have not been reviewed and approved through the MolDX Program, or are furnished prior to the effective date of an applicable coverage determination, are not considered covered by MolDX. Coverage determinations are maintained within the DEX™ Diagnostic Exchange Registry and may be designated as Covered or Not Covered. In the absence of determination, the test will not be covered. For current coding, billing, coverage, and Medicare benefit category information, including statutory exclusions, please refer to the MolDX Program website, which maintains the most current coverage determinations and program guidance.

The information contained in this policy is current as of the review date. CMS coverage policies, guidance documents, and related coverage determinations are subject to periodic updates and revisions; therefore, the most current CMS information may not be reflected in this document.

Please refer to the Medicare Coverage Database at CMS.gov for the most current NCDs, LCDs, LCAs, and CMS Online Manual System Transmittals. For any code associated with a product or service determined to be noncovered by policy, whether under CMS guidance or health plan policy when CMS is silent, medical record review, including prior authorization, will not be required.

CMS Medicare Administrative Contractor Jurisdictions

Part A and Part B MAC Jurisdictions	
Wisconsin Physicians Service Insurance Corporation (WPS)	IA, IN, KS, MI, MO, NE
CGS Administrators, LLC	KY, OH
First Coast Service Options, Inc.	FL, PR, US VI
Noridian Healthcare Solutions, LLC Jurisdiction JE	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
Noridian Healthcare Solutions, LLC Jurisdiction JF	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
Novitas Solutions, Inc.	AR, CO, DC, DE, LA, MD, MS, NJ, NM, OK, PA, TX
Palmetto GBA	AL, GA, TN, NC, SC, VA, WV
Wellpoint Federal - Formerly National Government Services, Inc. (NGS)	CT, IL, MA, ME, MN, NH, NY, RI, VT, WI
DME MAC Jurisdictions	
CGS Administrators, LLC Jurisdictions JB and JC	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NM, NC, OH, OK, Puerto Rico, SC, TN, TX, VA, US VI, WI, WV
Noridian Healthcare Solutions, LLC Jurisdictions JA and JD	AK, American Samoa, 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 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), 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 referenced in the medical policy. Medical policies do not constitute medical advice and do not guarantee clinical results, outcomes, or 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.

BCBSM/BCN Medicare Advantage Policy History

Policy Effective Date	UM Committee Approval Date	Comments
08/17/2024	07/17/2024	Medicare Advantage policy established.
10/17/2025	09/17/2025	Annual Review: MA Policy Foundational Language updated. Adopted JUMP policy updates.

10/16/2026	09/16/2026	Annual Review: Reformatted guidance and code tables. Adopted JUMP policy updates, including removal of codes 0508U, 0509U, 0526U, and 0544U. Updated CMS guidance to remove retired LCDs/LCAs and add replacement LCDs/LCAs for WPS, CGS, Noridian JE/JF, and Palmetto effective 8/30/2026. Added NCDs 260.9 and 260.10. Revised policy description and policy title. Previous title: *Laboratory Tests Post Transplant (Kidney and Heart) and for Heart Failure – Medicare Advantage*