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

Genetic Testing - Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, and Solid Pancreaticobiliary Lesions (e.g., PathFinderTG®, PancraGEN®) – Medicare Advantage

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

UM Committee Approval Date: 05/20/2026
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Description

Molecular diagnostic testing, including genetic analysis, for pancreatic cysts, and solid pancreaticobiliary lesions, involves examining an individual's genetic material to detect specific genetic alterations and molecular biomarkers associated with these conditions. This testing can help identify mutations, expression changes, and other genetic variations that may be linked to the development and progression of these diseases.

Pancreatic cysts are fluid-filled sacs that can develop in the pancreas. While most are benign, some can be precancerous or cancerous. Molecular testing can help differentiate between benign and potentially malignant cysts. The following molecular tests are commonly used:

- Cyst fluid analysis: Fluid is aspirated from the cyst and analyzed for genetic mutations, such as KRAS, GNAS, and VHL, which are commonly found in pancreatic cysts.
- Next-generation sequencing (NGS): This test analyzes multiple genes simultaneously to identify mutations associated with pancreatic cancer, such as TP53, SMAD4, and CDKN2A.
- Pancreatic cyst DNA analysis: This test evaluates the DNA of cells shed into the cyst fluid to detect genetic mutations, such as KRAS and GNAS.

Solid pancreaticobiliary lesions, such as pancreatic adenocarcinoma and cholangiocarcinoma, are aggressive cancers with poor prognosis. Molecular testing may help diagnose and manage these conditions. The following molecular tests are commonly used:

- KRAS mutation analysis: This test detects mutations in the KRAS gene, which are common in pancreatic cancer.
- NGS: This test analyzes multiple genes simultaneously to identify mutations associated with pancreatic cancer, such as TP53, SMAD4, and CDKN2A.
- Microsatellite instability (MSI) testing: This test evaluates the stability of microsatellites, which can be altered in pancreatic cancer.

Related Medical Coverage Policies

- Adjunctive Techniques for Screening, Surveillance, and Risk Classification of Barrett Esophagus and Esophageal Dysplasia – 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 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
National Coverage Determinations 90.2 – Next Generation Sequencing (NGS) 310.1 Routine Costs in Clinical Trials For additional information related to clinical trials related to Molecular Testing for the Management of Pancreatic Cysts and Solid Pancreaticobiliary lesions please refer to https://clinicaltrials.gov	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.

CMS Guidance	Additional Guidance
Local Coverage Determinations and Articles **WPS** L36807, A57772 - MolDX: Molecular Diagnostic Tests (MDT)* A55162 - MolDX: FDA-Approved KRAS Tests* **CGS** L36021, A56973 - MolDX: Molecular Diagnostic Tests (MDT)* A54688 - MolDX: FDA-Approved KRAS Tests* **First Coast** L39367, A59123 – Genetic Testing in Oncology: Specific Tests A58918 - Molecular Pathology and Genetic Testing **Noridian JE & JF** L35160, A57526 - MolDX: Molecular Diagnostic Tests (MDT)* A54498 - MolDX: FDA-Approved KRAS Tests* **Novitas** L39365, A59125 - Genetic Testing in Oncology: Specific Tests L35062, A56541 - Biomarkers Overview A58917 - Molecular Pathology and Genetic Testing **Palmetto** L36256, A57527 - MolDX: Molecular Diagnostic Tests (MDT)* A54472 - MolDX: FDA-Approved KRAS Tests* **Wellpoint Federal** None	In such cases, please refer to the relevant BCBSM/BCN policy for guidance: *Genetic Testing - Molecular Testing for the Diagnosis and Management of Pancreatic Cysts and Solid Pancreaticobiliary Lesions (e.g., PathFinderTG®, PancraGEN* 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.

Code	Description
84999	Unlisted chemistry procedure [PancraGEN® (aka Pathfinder TG®), Interspace Diagnostics, Pennsylvania]
89240	Unlisted miscellaneous pathology test [PancraGEN® (aka Pathfinder TG®), Interspace Diagnostics, Pennsylvania]
0313U	Oncology (pancreas), DNA and mRNA next-generation sequencing analysis of 74 genes and analysis of CEA (CEACAM5) gene expression, pancreatic cyst fluid, algorithm reported as a categorical result (i.e., low probability of neoplasia or positive, high probability of neoplasia) [PancreaSeq® Genomic Classifier, Molecular and Genomic Pathology Laboratory, University of Pittsburgh Medical Center, Pennsylvania]

* CMS MolDX Program

The MolDX Program, administered by Palmetto GBA, is a Medicare Molecular Diagnostic Program that aims to identify and establish coverage and reimbursement for molecular diagnostic tests. This program is implemented by several Medicare Administrative Contractors (MACs), including **WPS, CGS, Noridian, and Palmetto**.

The MolDX Program evaluates genetic tests to determine their analytical and clinical validity (AV/CV) and clinical utility (CU), ensuring that each test meets Medicare criteria.

The program's coverage determinations are maintained in the DEX™ Diagnostic Exchange registry. Dex Diagnostic Exchange Registry Coverage Determinations:

1. Not Covered: Not covered tests in the Dex Registry have undergone a review of their clinical utility and analytical validity and have been determined to not meet the requirements for medical necessity under Section 1862(a)(1)(A) of the Social Security Act. As a result, they are not considered medically reasonable or necessary for Medicare coverage.
2. No Determinations: Tests that have not completed the required technical assessment (TA) review are, by default, also considered not medically reasonable or necessary for Medicare under Section 1862(a)(1)(A) until the review is completed. The MolDX Program does not provide coverage for tests provided with dates of services prior to the effective date of approval.
3. Covered: Covered Tests in Dex Registry have completed the required TA review and have been determined to be medically reasonable and necessary for Medicare under Section 1862(a)(1)(A). However, coverage is not automatic and is subject to the following conditions:
    a. The test must meet the applicable criteria outlined in NCDs, LCDs, and LCAs; and
    b. The patient must exhibit signs or symptoms of a relevant disease or condition, making the test medically necessary for their care.

For specific coding and billing information on covered and excluded tests, please refer to the MolDX website at https://www.palmettogba.com/MolDX. This website provides up-to-date information on the program's coverage determinations and guidelines.

NOTE: Per § 2.3.3. of the Molecular Diagnostic Program [MolDX®] Manual, the MolDX Program does not provide coverage for tests that have not been reviewed and approved through the MolDX process or for tests provided with dates of services prior to the effective date of approval. For additional information regarding what tests will fall into a Medicare benefit category or which tests are statutory excluded (e.g., predictive, prenatal, and carrier testing and tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law) please refer to https://www.palmettogba.com/palmetto/moldxv2.nsf/DID/DPR5GEM991

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	
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 - Previously known as 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, Virgin Island, WI, WV
Noridian Healthcare Solutions, LLC, Jurisdictions JA and JD	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.

BCBSM/BCN Medicare Advantage Policy History

Policy Effective Date	UM Committee Approval Date	Comments
08/17/2024	07/17/2024	Medicare Advantage policy established
06/21/2025	05/21/2025	Annual Review: MA Policy Foundational Language updated. Adoption of JUMP policy updates
06/20/2026	05/20/2026	Annual Review: Reformatted guidance and code tables. Adopted JUMP policy's updates including title change. Previous title was *Genetic Testing - Molecular Testing for the Diagnosis and Management of Pancreatic Cysts, Barrett's Esophagus, and Solid Pancreaticobiliary Lesions (e.g., PathFinderTG®, PancraGEN®, BarreGEN®) – Medicare Advantage.* Codes 0108U and 0114U removed from this policy and added to *Adjunctive Techniques for Screening, Surveillance, and Risk Classification of Barrett Esophagus and Esophageal Dysplasia – Medicare Advantage* (new policy).