Medicare Medical Policy

Genetic Testing for Myeloproliferative Diseases

MEDICARE MEDICAL POLICY NUMBER: 71

Effective Date: 2/1/2026

Last Review Date: 1/2026

Next Annual Review: 5/2026

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Service	Medicare Guidelines
BCR-ABL Gene Testing *Examples include:* • *MRDx BCR-ABL Test by MolecularMD (Oregon; 0040U)* • *BCR–ABL1 major and minor breakpoint fusion transcripts test by University of Iowa Dept of Pathology or Asuragen*	• **For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** Local Coverage Article (LCA): Billing and Coding: MolDX: BCR-ABL (A55600) • **For testing performed in the states of CA or NV:** Local Coverage Article (LCA): Billing and Coding: MolDX: BCR-ABL (A55595) • **For testing performed in the states of IA, KS, MO, NE, IN, and MI:** LCA: Billing and Coding: MolDX: BCR-ABL (A55233) • **For testing performed in the states of AL, GA, TN, SC, NC, VA, and WV:** LCA: Billing and Coding: MolDX: BCR-ABL (A53531) • **For testing performed in the states of CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:** LCD: Biomarkers for Oncology (L35396). See also the LCA A52986 for additional diagnosis guidance for the BCR-ABL gene. **MRDx BCR-ABL Test (by MolecularMD):** The MRDx® BCR-ABL test was FDA approved as a companion diagnostic for patients with chronic myeloid leukemia (CML) in the chronic phase (CP) who are being treated with Tasigna® who may be candidates for treatment discontinuation and monitoring of treatment-free remission (TFR). When used for this FDA-approved purpose, this test would be considered **medically necessary**. Per the FDA-approval summary, this test is not intended to be used to make a diagnosis of CML. As additional indications are added to the FDA web page for List of Cleared or Approved Companion Diagnostic Devices [In Vitro and Imaging Tools]), coverage may be allowed for future approved indications for this test.

	All other BCR-ABL Testing: It is clinically appropriate to test *BCR-ABL* for patients who present with symptoms suggestive of myeloproliferative neoplasms (MPN) or myelodysplastic syndromes (MDS) and would be considered **medically necessary** for these indications. No specific coverage criteria are provided for this test because this is considered "step one" by the LCDs in the next below.
Single or Multi-Gene Testing for BCR-ABL Negative Myeloproliferative Disease (MPD) *Specific genes include: JAK2 V617F, JAK2 (exon 12), CALR, and MPL genes*	**Note:** MPD includes polycythemia vera (PV), essential thrombocythemia (ET), and primary myelofibrosis (PMF) ***For Non-Next Generation Sequencing (non-NGS) Methodology:*** Local Coverage Determination (LCD): MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms • **For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** ~~L39927~~ ***(As of 2/5/2026, see L39923 below)*** • **For testing performed in the states of CA or NV:** L39923 • **For testing performed in the states of AL, GA, TN, SC, NC, VA, or WV:** L39919 • **For testing performed in the states of IA, KS, MO, NE, IN, and MI:** L40022 ***For Next-Generation Sequencing (NGS) Methodology:*** LCD: MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies • **For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** ~~L38125~~ ***(As of 2/5/2026, see L38123 below)*** • **For testing performed in the states of CA or NV:** L38123 • **For testing performed in the states of AL, GA, TN, SC, NC, VA, or WV:** L38047 • **For testing performed in the states of IA, KS, MO, NE, IN, and MI:** L38176 Any date of service: • **For testing performed in the states of CO, NM, OK, TX, AR, LA, MS, DE, MD, NJ, PA:** LCD: Biomarkers for Oncology (L35396). See also the LCA A52986 for additional diagnosis guidance for JAK2, CALR, and MPL genes.
	The following panel tests are considered **not medically necessary** because they either have not received the require TA review as of most recent policy review date ***or*** MolDX has performed the required TA review and determined the test does

	not meet requirements for coverage *(See "Policy Guidelines" below)*: • Myeloproliferative Disease Panel, by University of Alabama at Birmingham (Alabama) • MyAML NGS Panel, by LabPMM (PLA code 0050U; California)
JAK2 Exons 12 to 15 Sequencing (JAKXR) test (PLA code 0027U; Mayo Clinic; Minnesota)	Molecular Pathology Procedures (L35000) *(Apply criteria for clinically appropriate indications related to JAK2 testing)*

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

MEDICARE AND MEDICAL NECESSITY

Diagnostic Laboratory Test Jurisdiction

The Company policy PHA Medicare Medical Policy Development and Application (MP50) describes the Plan's hierarchy with respect to Medicare medical policy development. In compliance with Medicare guidelines, some LCDs and LCAs used may be for test service areas outside of the Company service area. This is because Medicare's general rule regarding jurisdiction of claims furnished by an independent laboratory is that jurisdiction lies with the A/B MAC (B) (aka, Medicare Contractor) serving the area in which the laboratory test is performed.[1]

Laboratories performing tests in service areas which have adopted guidelines or coverage determinations made by the Medicare Molecular Diagnostics (MolDX) Program contractor are required to submit a technology assessment (TA) to establish analytical and clinical validity (AV/CV) and clinical utility (CU). Supporting LCDs regarding TA reviews include, but are not limited to, the following:

- Laboratories in CA & NV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35160)
- Laboratories in NC, SC, GA, TN, AL, VA, & WV: LCD for MolDX: Molecular Diagnostic Tests (MDT) (L35025)

- Laboratories in AK, ID, OR, WA, UT, AZ, MT, ND, SD, & WY: LCD for MolDX: Molecular Diagnostic Tests (MDT) (~~L36256~~) ***(As of 2/5/2026, see L35160 above)***

Coverage or non-coverage determinations made by MolDX are maintained in the DEX™ Diagnostics Exchange registry catalog and are available for public viewing. If a test does not have a coverage determination by the MolDX Program, then AV/CV and CU have **not** been established and the test is considered not medically reasonable and necessary under *SSA §1862(a)(1)(A)* until a MolDX review is complete and coverage is indicated by MolDX or Noridian. Therefore, tests identified in this policy as not meeting this requirement are not medically reasonable or necessary for Medicare under *SSA §1862(a)(1)(A).*

Table 1: Tests relevant to this policy include the following

This list only applies to tests which do not have an LCD or LCA specific to that individual test in the Medicare guideline table above. This list was accurate at the time of publication, but it is subject to change at any time by the Medicare MolDX Program contractor. A "MolDX TA Review Outcome" of "Covered" does not indicate the test is automatically covered. All relevant criteria from the above Medicare references as applicable to the individual test must still be met

Proprietary Test Name	Laboratory	MolDX TA Review Outcome (as listed in the DEX™ Diagnostics Exchange registry)
Myeloproliferative Disease Panel	University of Alabama at Birmingham (Alabama)	Not covered
MyAML NGS Panel (0050U)	LabPMM LLC (California)	Not covered

Test coverage or non-coverage positions included in this medical policy were accurate at the time of policy publication, but they are subject to change by the Medicare MolDX Program contractor at any time. Appeals to dispute non-coverage should include documentation by the MolDX Contractor which reflects a positive coverage decision (e.g., copy of the MolDX determination letter).

Summary

According to Medicare, jurisdiction for claims by an independent laboratory lies with the Medicare Contractor (MAC) serving the area in which the laboratory test is performed. Many Medicare contractors (MACs) have adopted guidelines developed and published by the Molecular Diagnostic Services (MolDX) Program for their service area. As called out within relevant LCDs for these service areas (i.e., ~~L36256,~~ L35160, L35025), genetic and molecular tests performed within a MolDX service area are required to undergo a technical assessment (TA) review by the MolDX Medicare Contractor, Palmetto GBA. These TA reviews assess clinical utility and analytical validity (CU/AV) to ensure the tests meets requirements for Medicare coverage. The outcome of these TA reviews is maintained in the DEX™ Diagnostics Exchange registry catalog. When possible, the coverage outcome is included within this medical policy to assist with coverage decision-making.

- Tests listed as "not covered" in this registry have had the CU/AV reviewed and were determined to be not medically reasonable or necessary for Medicare under *Social Security Act, §1862(a)(1)(A).*

- Tests not listed at all have not yet completed the required TA review are by default also considered to be not medically reasonable or necessary for Medicare under §1862(a)(1)(A), based on the requirements found in the LCDs noted above.
- Tests listed as "covered" in this registry have completed the required TA review and have been determined to be potentially medically reasonable or necessary for Medicare under *§1862(a)(1)(A)*; however, applicable NCD, LCD, and LCA criteria must still be met, and the member must have signs/symptoms of a relevant disease or condition.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

See associated local coverage articles (LCAs) for related coding and billing guidance:

- **For testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** LCA: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A57422) and MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (A59837)
- **For testing performed in the states of CA or NV:** LCA: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A57421) and MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (A59835)
- **For testing performed in the states of AL, GA, TN, SC, NC, VA, or WV:** LCA: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A56959) and MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (A59827)
- **For testing performed in the states of IA, KS, MO, NE, IN, and MI:** LCA: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A57570) and MolDX: Non-Next Generation Sequencing Tests for the Diagnosis of BCR-ABL Negative Myeloproliferative Neoplasms (A59939)

CODES*		
CPT	0016U	Oncology (hematolymphoid neoplasia), RNA, BCR/ABL1 major and minor breakpoint fusion transcripts, quantitative PCR amplification, blood or bone marrow, report of fusion not detected or detected with quantitation *(Used to*

		report the BCR–ABL1 major and minor breakpoint fusion transcripts by University of Iowa, Department of Pathology or Asuragen)
	0017U	Oncology (hematolymphoid neoplasia), JAK2 mutation, DNA, PCR amplification of exons 12-14 and sequence analysis, blood or bone marrow, report of JAK2 mutation not detected or detected *(Used to report the JAK2 Mutation test, by the University of Iowa)*
	0027U	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, targeted sequence analysis exons 12-15 *(Used to report the JAK2 Exons 12 to 15 Sequencing (JAKXR) test, by the Mayo Clinic)*
	0040U	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis, major breakpoint, quantitative *(Used to report the MRDx BCR-ABL Test, by MolecularMD [Oregon])*
	0050U	Targeted genomic sequence analysis panel, acute myelogenous leukemia, DNA analysis, 194 genes, interrogation for sequence variants, copy number variants or rearrangements *(Used to report the MyAML NGS Panel, by LabPMM LLC)*
	81206	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; major breakpoint, qualitative or quantitative
	81207	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; minor breakpoint, qualitative or quantitative
	81208	BCR/ABL1 (t(9;22)) (eg, chronic myelogenous leukemia) translocation analysis; other breakpoint, qualitative or quantitative
	81219	CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9
	81270	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant
	81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)
	81338	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; common variants (eg, W515A, W515K, W515L, W515R)
	81339	MPL (MPL proto-oncogene, thrombopoietin receptor) (eg, myeloproliferative disorder) gene analysis; sequence analysis, exon 10
	81402	Molecular pathology procedure level 3 – which includes MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), common variants (eg, W515A, W515K, W515L, W515R)
	81403	Molecular pathology procedure, Level 4 – which includes JAK2 (Janus kinase 2) (eg, myeloproliferative disorder), exon 12 sequence and exon 13 sequence, if performed and MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), exon 10 sequence.
	81450	Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis
	81451	Hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 5-50 genes, interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
	81455	Solid organ or hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 51 or greater genes, interrogation for sequence variants and copy number

		variants or rearrangements or isoform expression or mRNA expression levels, if performed; DNA analysis or combined DNA and RNA analysis
	81456	Solid organ or hematolymphoid neoplasm or disorder, genomic sequence analysis panel, 51 or greater genes, interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis
	81479	Unlisted molecular pathology procedure
HCPCS	None	

***Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, §50.5 - Jurisdiction of Laboratory Claims. Updated 9/19/2014. Available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c16.pdf. Accessed 4/3/2025.

yes soPOLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
5/2023	Annual review; added clarifying information regarding testing performed in a MolDX service area; added 0049U and 0050U
7/2023	Interim update; added LCD/LCA for Palmetto GBA service areas
1/2024	Q1 2024 code updates
6/2024	Annual review; add Palmetto GBA LCA for BCR/ABL testing
10/2024	Interim update; add LCD/LCA for Novitas service areas
6/2025	Annual review, no changes (8/22/2025: Updated LCD policies retired and effective as of 8/17)
2/2026	Interim update, transferred MRD tests (NPM1 MRD and MyMRD) to separate MRD policy, clarified Medicare policies for NGS vs. non-NGS testing (2/13/2026: Replaced multiple MolDX LCDs and LCAs due to Noridian JF consolidation with JE LCD policies)