MEDICAL POLICY	Genetic Testing: Myeloproliferative Diseases (Medicare Only)
Effective Date: 6/01/2022  6/1/2022 Medical Officer Date	Medical Policy Number: 71 Medical Policy Committee Approved Date: 12/17; 7/18; 7/19; 2/2020; 4/2020; 12/2020; 3/2021; 4/2022

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

Medicare only

MEDICARE POLICY CRITERIA

The following Centers for Medicare & Medicaid Service (CMS) guidelines should be utilized for medical necessity coverage determinations. Click the link provided in the table below to access applicable medical necessity criteria. All listed guidelines apply.

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) **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 testing performed in the states of AK, ID, OR, WA, UT, AZ, MT, ND, SD, or WY:** Local Coverage Determination (LCD): MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36186) • **For testing performed in the states of CA or NV:** MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36180) • **For testing performed in the states of IA, KS, MO, NE, IN, and MI:** LCD: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36815)
	These panel tests are considered **not medically necessary**, based on Medicare guidelines *(See "Policy Guidelines" below)*: • Myeloproliferative Disease Panel, by University of Alabama at Birmingham (Alabama) • MyMRD® NGS Panel test, by Laboratory for Personalized Molecular Medicine (PLA code 0171U; 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)*

POLICY GUIDELINES

Medicare and Medical Necessity

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)

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).*

BILLING GUIDELINES

General

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

- LCA: Billing and Coding: MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (A57422)

CPT CODES

Medicare Only	
Prior Authorization Required	
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)*
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	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, DNA analysis, and RNA analysis when performed, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KRAS, KIT, MLL, NRAS, NPM1, NOTCH1), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed
81455	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm, DNA analysis, and RNA analysis when performed, 51 or greater genes (EG, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NPM1, NRAS, MET, NOTCH1, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, if performed
No Prior Authorization Required	
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)
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])*
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
Not Covered	
0171U	Targeted genomic sequence analysis panel, acute myeloid leukemia, myelodysplastic syndrome, and myeloproliferative neoplasms, DNA analysis, 23 genes, interrogation for sequence variants, rearrangements and minimal residual disease, reported as presence/absence *(Used to report the MyMRD® NGS Panel test, by the Laboratory for Personalized Molecular Medicine)*
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then **prior-authorization is required.**	
81479	Unlisted molecular pathology procedure

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

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.