Genetic Testing for Hematologic Malignancies and Suspected Myeloid Disorders

INDEPENDENT CARE HEALTH PLAN

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Medicare Advantage Medical Coverage Policy

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Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Type	Title	ID Number	Jurisdiction Medicare Administrative Contractors (MACs)	Applicable States/Territories
NCD	Next Generation Sequencing (NGS)	90.2		
LCD	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	L36815 L38176	J5 - Wisconsin Physicians Service Insurance Corporation J8 - Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE IN, MI
LCD	Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases Molecular Pathology Procedures	L37606 L35000	J6 - National Government Services, Inc. (Part A/B MAC) JK - National Government Services, Inc. (Part A/B MAC)	IL, MN, WI CT, NY, ME, MA, NH, RI, VT
LCD	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	L36117 L38070	J15 - CGS Administrators, LLC (Part A/B MAC)	KY, OH
LCD	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	L36180 L38123	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease	L36186	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY

	MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	L38125		
LCD	Biomarkers for Oncology	L35396	JH - Novitas Solutions, Inc. (Part A/B MAC) JL - Novitas Solutions, Inc. (Part A/B MAC)	AR, CO, NM, OK, TX, LA, MS DE, D.C., MD, NJ, PA
LCD	MolDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease MolDX: Next-Generation Sequencing Lab-Developed Tests for Myeloid Malignancies and Suspected Myeloid Malignancies	L36044 L38047	JJ - Palmetto GBA (Part A/B MAC) JM - Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV

Description

Genetic testing can be utilized to diagnose and monitor cancer indications including, but may not be limited to, leukemia, lymphoma, myelodysplastic syndromes (MDS) and myeloproliferative neoplasms (MPNs). This type of testing is indicated for an individual who exhibits disease symptoms and may be necessary to diagnose or rule out suspected cancer or monitor known cancer.

Comprehensive genomic profiling (also referred to as comprehensive molecular profiling) is a type of test that involves a combination of laboratory methodologies to detect genetic alterations and biomarkers in blood or bone marrow to aid in the management of hematologic malignancies and suspected myeloid disorders. Testing is performed by removing a small sample of tissue for evaluation (eg, bone marrow biopsies, bone marrow aspirates, bone marrow clots), blood draw (peripheral blood samples), or sites located outside of the bone marrow (extramedullary) suspected of harboring a myeloid malignancy. Techniques can vary from test to test and may include but are not limited to, next-generation sequencing (NGS), fluorescence in situ hybridization (FISH) and immunohistochemistry (IHC). Examples of comprehensive genomic profiling tests include, but are not limited to, **FoundationOne Heme and Neogenomics myeloid and/or heme panels**.

Multigene (or expanded) panels analyze a broad set of genes simultaneously (as opposed to single gene testing that searches for variants in one specific gene). Panels often include medically actionable genes but may also include those with unclear medical management. Targeted (or focused) multigene panels analyze a limited number of genes targeted to a specific condition.

Single gene testing may also be performed for hematologic malignancies and suspected myeloid disorders and may be indicated for an individual who exhibits disease symptoms and may be necessary to diagnose or rule out suspected cancer or monitor known cancer. These include, but are not limited to, *ASXL1, CEBPA, FLT3, IDH1, IDH2, KIT, MYD88, NPM1, NRAS, RUNX1, SF3B1, SRSF2, U2AF1* and *ZRSR2.*

***JAK2 V617F* variant analysis** is another single gene laboratory test used to assist in the diagnosis of myeloproliferative neoplasms (MPNs) which are a group of conditions characterized by an overproduction of specific types of blood or fiber cells in the bone marrow. MPNs include essential thrombocythemia (ET), polycythemia vera (PV) and primary myelofibrosis (PMF).

- ET is characterized by an overproduction of platelets due to a clonal process and may be suspected when an individual's platelet count is at least 450 x 10^9/L.[2,79]

- PV is differentiated from the other MPNs by the indication of increased red blood cell volume. An individual with the following laboratory results may require further evaluation with genetic testing: elevated red cell mass greater than 25% above the mean normal predicted value and/or elevated hemoglobin (greater than 16.5 g/dL for men or greater than 16 g/dL for women) and/or increased hematocrit (greater than 49% for men and greater than 48% for women).[2,79]

- PMF is defined by the existence of bone marrow fibrosis that is not linked to another myeloid disorder such as chronic myeloid leukemia (CML), PV, ET or myelodysplastic syndromes (MDS). An individual with an increased white cell count (greater than 11 x 10^9/L) may require additional assessment.[2,79]

Laboratory results for ET, PV and PMF remain persistent over time (typically a 4-month duration) and other reasons for the unexplained laboratory values, such as medications (including testosterone), dehydration and personal habits (eg, alcohol consumption), should be eliminated as a cause.[79]

***CALR* and *MPL* gene analysis** is warranted if an individual receives a negative *JAK2 V617F* result. *CALR* and *MPL* variants are detected in an individual diagnosed with ET or PMF but not in an individual with PV.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Genetic tests must demonstrate clinical utility, analytical and clinical validity and fulfill the CMS "reasonable and necessary" criteria. Analytic validity (test accurately identifies the gene variant), clinical validity (test identifies or predicts the clinically defined disorder) and clinical utility (test measurably improves clinical outcomes) of the genetic test is supported by generally accepted standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, specialty society recommendations, and views of physicians practicing in relevant clinical areas. The test must be ordered by a physician who is treating the beneficiary and the results will be used in the management of a beneficiary's specific medical problem.

For jurisdictions with no Medicare guidance, iCare will utilize the MolDX program and Technical Assessments for molecular assays as the standard to evaluate clinical utility, analytical and clinical validity in conjunction with adhering to Medicare's reasonable and necessary requirement.

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Comprehensive Genomic Profiling or Multigene Panel Testing

Comprehensive genomic profiling or multigene panel testing (eg, 81450, 81451, 81455, 81456) will be considered medically reasonable and necessary for hematologic malignancies and suspected myeloid disorders when the following requirements are met:

- A multigene panel is defined as a test that analyzes more than one gene simultaneously. A panel will be considered medically reasonable and necessary if more than one gene impacts the clinical management of the individual being tested. The panel must evaluate genes and/or alleles in accordance with the panel's indicated use; **AND**

- Testing is performed by removing a small sample of tissue for evaluation (eg, bone marrow biopsies, bone marrow aspirates, bone marrow clots), blood draw (peripheral blood samples), or sites located outside of the bone marrow (extramedullary) suspected of harboring a myeloid malignancy;[10,11,12,13,14] **AND**

- Clinical, laboratory and pathologic assessment are nondiagnostic (such as demonstration of persistent cytopenias [eg, four months] by complete blood count, microscopic examination of a bone marrow biopsy and bone marrow cytogenetic studies. Other than the clinical feature of the number of cytopenias and specific cytogenetic changes found recurrently in myelodysplastic syndrome [MDS], all other diagnostic criteria in MDS rely upon light microscopy findings);

- **AND** one of the following:

  - Cancer of the blood and bone marrow (eg, acute myelogenous leukemia [AML]); [10,11,12,13,14] **OR**

  - MDS;[10,11,12,13,14] **OR**

  - Myeloproliferative neoplasms (MPNs) which include polycythemia vera (PV), essential thrombocythemia (ET) or primary myelofibrosis (PMF); [10,11,12,13,14] **OR**

  - For an individual that does not have a diagnosis of cancer but a myeloid malignancy but is suspected;[10,11,12,13,14] **AND**

    - Undefined cytopenia for greater than four months without a known cause; [10,11,12,13,14] **AND**
    - Other possible causes have been reasonably excluded[10,11,12,13,14]

Single Gene Testing

***ASXL1* gene analysis** (81175/81176) will be considered medically reasonable and necessary for the following indications:

- AML (includes acute promyelocytic leukemia);[3] **OR**
- Chronic myeloid leukemia (CML);[62] **OR**
- MDS;[3] **OR**
- MPNs;[3] **OR**
- Systemic mastocytosis;[67] **OR**
- Undefined cytopenia for greater than four months without a known cause [10,11,12,13,14]

***CCND1::IGH* t(11;14) translocation analysis** (81168) will be considered medically reasonable and necessary for mantle cell lymphoma.[3]

CEBPA gene analysis will be considered medically reasonable and necessary for the following indications:

- AML (includes acute promyelocytic leukemia);[3] **OR**
- MDS[3]

***FLT3* gene analysis** will be considered medically reasonable and necessary for any of the following indications:

- AML (includes acute promyelocytic leukemia) evaluation and initial workup; [3,59] **OR**
- AML (includes acute promyelocytic leukemia) surveillance and therapy treatment decisions for relapsed/refractory;[3,59] **OR**
- CML or chronic myelomonocytic leukemia (CMML);[3] **OR**
- MDS[3]

IDH1 (81120) **and/or *IDH2*** (81121) **gene analysis** will be considered medically reasonable and necessary for any of the following indications:

- AML (includes acute promyelocytic leukemia);[3] **OR**
- CML;[62] **OR**
- MDS;[3] **OR**
- MPNs;[65] **OR**
- Undefined cytopenia for greater than four months without a known cause[10,11,12,13,14]

***IGH@::BCL2* t(14;18) analysis** (81278) will be considered medically reasonable and necessary for follicular lymphoma.[3]

***KIT* (*c-KIT*) gene analysis** will be considered medically reasonable and necessary for any of the following indications:[3]

- AML (includes acute promyelocytic leukemia) (81272); **OR**
- CML or CMML; **OR**
- MDS; **OR**
- MPNs; **OR**
- Systemic mastocytosis (81273)

***MYD88* gene analysis** (81305) will be considered medically reasonable and necessary for Waldenstrom's macroglobulinemia (lymphoplasmacytic lymphoma).[3]

***NPM1* gene analysis** (81310, 0049U) will be considered medically reasonable and necessary for any of the following indications:

- AML (includes acute promyelocytic leukemia;[3] **OR**
- CML[62]; **OR**
- MDS[3]; **OR**
- MPNs[65]

***NRAS* gene analysis** (81311) will be considered medically reasonable and necessary for any of the following indications:

- Acute lymphoblastic leukemia (ALL):[3] **OR**
- AML (includes acute promyelocytic leukemia);[3] **OR**
- CML or CMML;[3] **OR**
- MDS[3]

***PML::RARalpha t(15;17)* gene analysis** (81315/81316) will be considered medically reasonable and necessary for AML (includes promyelocytic leukemia) (testing may be performed up to 4 times per year for monitoring response to therapy).[3]

***RUNX1* gene analysis** (81334) will be considered medically reasonable and necessary for any of the following indications:

- AML (includes acute promyelocytic leukemia);[3] **OR**
- CML;[62] **OR**
- MDS;[64] **OR**
- MPNs;[65] **OR**
- Systemic mastocytosis;[67] **OR**
- Undefined cytopenia for greater than four months without a known cause[10,11,12,13,14]

***SF3B1* gene analysis** (81347) will be considered medically reasonable and necessary for any of the following indications:

- Anemia related to MDS or MDS/MPNs with ring sideroblasts;[64] **OR**
- CLL;[3] **OR**
- CML;[62] **OR**
- MDS;[64] **OR**
- MPNs;[65] **OR**
- Undefined cytopenia for greater than four months without a known cause[10,11,12,13,14]

***SRSF2* gene analysis** (81348) will be considered medically reasonable and necessary for any of the following indications:

- AML (includes promyelocytic leukemia);[3] **OR**
- CML;[62] **OR**
- MDS;[64] **OR**
- MPNs;[65] **OR**
- Systemic mastocytosis;[67] **OR**
- Undefined cytopenia for greater than four months without a known cause [10,11,12,13,14]

***U2AF1* gene analysis** (81357) will be considered medically reasonable and necessary for any of the following indications:

- AML (includes promyelocytic leukemia);[3] **OR**
- CML;[62] **OR**
- MDS;[64] **OR**
- MPNs;[65] **OR**
- Undefined cytopenia for greater than four months without a known cause[10,11,12,13,14]

***ZRSR2* gene analysis** (81360) will be considered medically reasonable and necessary for any of the following indications:

- AML (includes promyelocytic leukemia);[3] **OR**
- CML;[62] **OR**
- MDS;[64] **OR**
- Undefined cytopenia for greater than four months without a known cause [10,11,12,13,14]

***JAK2 V617F* gene analysis** will be considered medically reasonable and necessary when the following requirements are met:

- Genetic testing impacts medical management; **AND**

- Meets World Health Organization's (WHO) diagnostic criteria for myeloproliferative disease (ie, PV, ET or PMF);[2] **AND**

- For ET and PMF only: *BCR-ABL* mutation analysis was previously completed and was negative[2]

***JAK2* exon 12 genetic testing** will be considered medically reasonable and necessary when the following requirements are met:

- Genetic testing impacts medical management; **AND**
- Meets WHO diagnostic criteria for PV;[2] **AND**
- *JAK2 V617F* mutation analysis was previously completed and was negative[2]

***CALR* gene analysis** will be considered medically reasonable and necessary when the following requirements are met:

- Genetic testing impacts medical management; **AND**
- Meets WHO diagnostic criteria for ET or PMF;[2] **AND**
- *JAK2 V617F* mutation analysis was previously completed and was negative[2]

***MPL* gene analysis** will be considered medically reasonable and necessary when the following requirements are met:

- Genetic testing impacts medical management; **AND**
- Meets WHO diagnostic criteria for ET or PMF;[2] **AND**
- *JAK2 V617F* mutation analysis was previously completed and was negative[2]

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically

necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage

The following tests may not be considered a benefit (statutory exclusion):

- Tests considered screening in the absence of clinical signs and symptoms of disease that are not specifically identified by the law;[68] **OR**
- Tests that confirm a diagnosis or known information;[68] **OR**
- Tests to determine risk for developing a disease or condition;[68] **OR**
- Tests performed to measure the quality of a process;[68] **OR**
- Tests without diagnosis specific indications;[68] **OR**
- Tests identified as investigational by available literature and/or the literature supplied by the developer and are not a part of a clinical trial[68]

These treatments and services fall within the Medicare program's statutory exclusion that prohibits payment for items and services that have not been demonstrated to be reasonable and necessary for the diagnosis and treatment of illness or injury (§1862(a)(1) of the Act). Other services/items fall within the Medicare program's statutory exclusion at 1862(a)(12), which prohibits payment.

The following items will not be considered medically reasonable and necessary:

- Genetic tests that have not demonstrated clinical utility, analytical and clinical validity via the MolDX Program

A review of the current medical literature shows that the evidence is insufficient to determine that these services are standard medical treatments. There remains an absence of randomized, blinded clinical studies examining benefit and long-term clinical outcomes establishing the value of these services in clinical management.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
81120	IDH1 (isocitrate dehydrogenase 1 [NADP+], soluble) (eg, glioma), common variants (eg, R132H, R132C)	
81121	IDH2 (isocitrate dehydrogenase 2 [NADP+], mitochondrial) (eg, glioma), common variants (eg, R140W, R172M)	
81168	CCND1/IGH (t(11;14)) (eg, mantle cell lymphoma) translocation analysis, major breakpoint, qualitative and quantitative, if performed	
81175	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; full gene sequence	
81176	ASXL1 (additional sex combs like 1, transcriptional regulator) (eg, myelodysplastic syndrome, myeloproliferative neoplasms, chronic myelomonocytic leukemia), gene analysis; targeted sequence analysis (eg, exon 12)	
81218	CEBPA (CCAAT/enhancer binding protein [C/EBP], alpha) (eg, acute myeloid leukemia), gene analysis, full gene sequence	
81219	CALR (calreticulin) (eg, myeloproliferative disorders), gene analysis, common variants in exon 9	
81245	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; internal tandem duplication (ITD) variants (ie, exons 14, 15)	
81246	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia), gene analysis; tyrosine kinase domain (TKD) variants (eg, D835, I836)	
81270	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) gene analysis, p.Val617Phe (V617F) variant	
81272	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, gastrointestinal stromal tumor [GIST], acute myeloid leukemia, melanoma), gene analysis, targeted sequence analysis (eg, exons 8, 11, 13, 17, 18)	
81273	KIT (v-kit Hardy-Zuckerman 4 feline sarcoma viral oncogene homolog) (eg, mastocytosis), gene analysis, D816 variant(s)	

81278	IGH@/BCL2 (t(14;18)) (eg, follicular lymphoma) translocation analysis, major breakpoint region (MBR) and minor cluster region (mcr) breakpoints, qualitative or quantitative	
81279	JAK2 (Janus kinase 2) (eg, myeloproliferative disorder) targeted sequence analysis (eg, exons 12 and 13)	
81305	MYD88 (myeloid differentiation primary response 88) (eg, Waldenstrom's macroglobulinemia, lymphoplasmacytic leukemia) gene analysis, p.Leu265Pro (L265P) variant	
81310	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, exon 12 variants	
81311	NRAS (neuroblastoma RAS viral [v-ras] oncogene homolog) (eg, colorectal carcinoma), gene analysis, variants in exon 2 (eg, codons 12 and 13) and exon 3 (eg, codon 61)	
81315	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; common breakpoints (eg, intron 3 and intron 6), qualitative or quantitative	
81316	PML/RARalpha, (t(15;17)), (promyelocytic leukemia/retinoic acid receptor alpha) (eg, promyelocytic leukemia) translocation analysis; single breakpoint (eg, intron 3, intron 6 or exon 6), qualitative or quantitative	
81334	RUNX1 (runt related transcription factor 1) (eg, acute myeloid leukemia, familial platelet disorder with associated myeloid malignancy), gene analysis, targeted sequence analysis (eg, exons 3-8)	
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	
81347	SF3B1 (splicing factor [3b] subunit B1) (eg, myelodysplastic syndrome/acute myeloid leukemia) gene analysis, common variants (eg, A672T, E622D, L833F, R625C, R625L)	
81348	SRSF2 (serine and arginine-rich splicing factor 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, P95H, P95L)	
81357	U2AF1 (U2 small nuclear RNA auxiliary factor 1) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variants (eg, S34F, S34Y, Q157R, Q157P)	

81360	ZRSR2 (zinc finger CCCH-type, RNA binding motif and serine/arginine-rich 2) (eg, myelodysplastic syndrome, acute myeloid leukemia) gene analysis, common variant(s) (eg, E65fs, E122fs, R448fs)	
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	
81451	Targeted genomic sequence analysis panel, hematolymphoid neoplasm or disorder, 5-50 genes (eg, BRAF, CEBPA, DNMT3A, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MLL, NOTCH1, NPM1, NRAS), interrogation for sequence variants, and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	
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	
81456	Targeted genomic sequence analysis panel, solid organ or hematolymphoid neoplasm or disorder, 51 or greater genes (eg, ALK, BRAF, CDKN2A, CEBPA, DNMT3A, EGFR, ERBB2, EZH2, FLT3, IDH1, IDH2, JAK2, KIT, KRAS, MET, MLL, NOTCH1, NPM1, NRAS, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), interrogation for sequence variants and copy number variants or rearrangements, or isoform expression or mRNA expression levels, if performed; RNA analysis	
81457	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, microsatellite instability	
81458	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis, copy number variants and microsatellite instability	
81459	Solid organ neoplasm, genomic sequence analysis panel, interrogation for sequence variants; DNA analysis or combined DNA and RNA analysis, copy number variants, microsatellite instability, tumor mutation burden, and rearrangements	

81479	Unlisted molecular pathology procedure	
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	
0046U	FLT3 (fms-related tyrosine kinase 3) (eg, acute myeloid leukemia) internal tandem duplication (ITD) variants, quantitative	
0049U	NPM1 (nucleophosmin) (eg, acute myeloid leukemia) gene analysis, quantitative	
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	
0329U	Oncology (neoplasia), exome and transcriptome sequence analysis for sequence variants, gene copy number amplifications and deletions, gene rearrangements, microsatellite instability and tumor mutational burden utilizing DNA and RNA from tumor with DNA from normal blood or saliva for subtraction, report of clinically significant mutation(s) with therapy associations	
0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
No code(s) identified		

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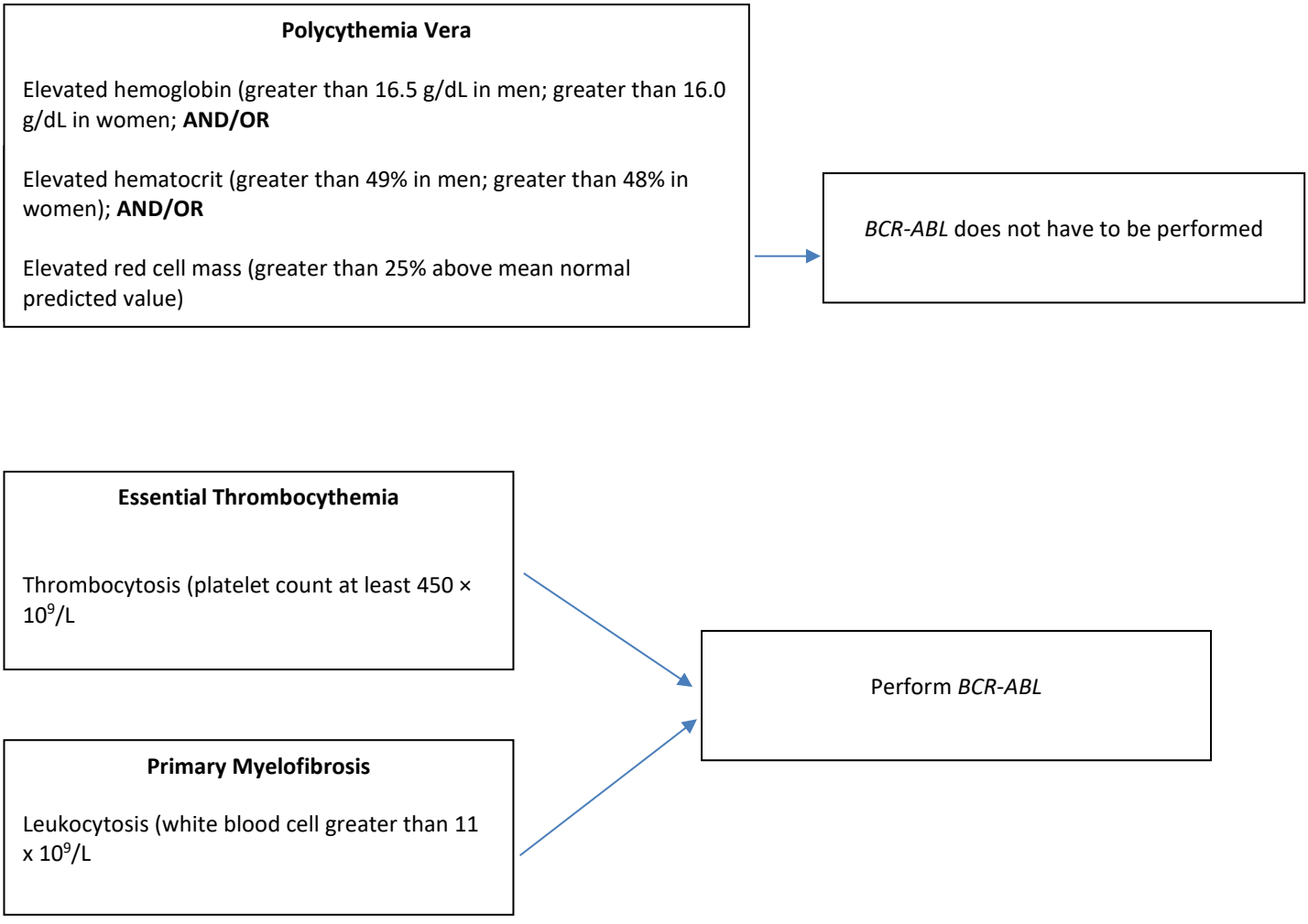
Appendix

Appendix A

World Health Organization Diagnostic Criteria for Myeloproliferative Disease: Laboratory Values[2,79]



Change Summary

- 01/01/2024 New Policy.