ICD-10 Codes for PCR Molecular Biomarkers (JAK2 V617, CALR & BCR/ABL1)

The emergence of personalized laboratory medicine has been characterized by a multitude of testing options which can more precisely pinpoint management needs of individual patients. As a result, the growing compendium of products described as biomarkers requires careful evaluation by both clinicians and laboratorians as to what testing configurations are reasonable and necessary under the Medicare Act. There are a plethora of burgeoning tools, including both gene-based (genomic) and protein-based (proteomic) assay formats, in tandem with more conventional (longstanding) flow cytometric, cytogenetic, etc. biomarkers. Classified somewhat differently, there are highly diverse approaches ranging from single mutation biomarkers to multiple biomarker platforms, the latter of which often depend upon sophisticated biomathematical interpretative algorithms.

The term "biomarker" refers to a broad subcategory of medical signs (i.e., objective indications of medical state observed from outside the patient) which can be measured accurately and reproducibly. Medical signs stand in contrast to medical symptoms, which are limited to indications of health or illness perceived by the patient. In 1998, the National Institute of Health (NIH) defined a biomarker as: "a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes pathogenic processes, or pharmacologic response to a therapeutic intervention."1

There are separate Local Coverage Determinations (LCDs) that address other biomarkers, which include a multitude of assays which are not specifically discussed below. (Please refer to the Novitas website for a complete listing of LCDs.)

Local Medicare coverage of such biomarkers must be predicated upon four fundamental principles:

1. The biomarkers must have proven clinical validity/utility (CVU).
2. To support the medical necessity of the service, there must be acceptance/uptake of specific testing into patient management. It is essential that physicians be familiar enough with all specific biomarkers, of which they order, such that all test results may become clinically actionable.
3. Providers managing oncological conditions must demonstrate that the use of biomarkers will be used to assist in the management/treatment of the beneficiary.
4. Peer-reviewed full manuscript evidence is required to support combination panels for multiple biomarkers, particularly regarding their alleged composite clinical validity/utility. For example, such potential billing for multiple, diverse biomarkers (e.g., diagnostic/monitoring/prognostic/predictive) can only achieve medical necessity when it is evident how each requested biomarker can be individually contributory.

It is useful to categorize oncology biomarkers into functional clusters which reflect both (1) The predominant intent of testing (with the caveat that individual assays may cross over into more than one category) and (2) the relative evidentiary expectations:

1. **Oncology Biomarkers Used for Diagnosis/Classification/Monitoring/Surveillance:** These types of assays are supportable by case-control sensitivity/specificity studies, with appropriate designs in place to minimize the extent of bias and confounding.

2. **Oncology Biomarkers Used for Prognosis/Prediction:** Oncology biomarkers used for prognosis/prediction (i.e., a predictive biomarker is associated with response [benefit] or lack of response to a particular therapy, relative to other available therapy, whereas a prognostic biomarker provides information on the likely outcome of the disease in an untreated individual).

ICD-10 Codes for PCR Molecular Biomarkers (JAK2 V617, CALR & BCR/ABL1)

Complete the 5-digit codes with a 5th digit

Not having achieved remission	0
In remission	1
In relapse	2

JAK2 81270

Acute lymphoblastic leukemia	C91.0_
Chronic myeloid leukemia, BCR/ABL-positive	C92.1_
Acute promyelocytic leukemia	C92.4_
Acute myelomonocytic leukemia	C92.5_
Acute myeloid leukemia with 11q23-abnormality	C92.6_
Acute myeloid leukemia with multilineage dysplasia	C92.A_
Acute myelomonocytic leukemia	C93.1_
Polycythemia vera	D45
Refractory anemia without ring sideroblasts, so stated	D46.0
Refractory anemia with ring sideroblasts	D46.1
Refractory anemia with excess of blasts, unspecified	D46.20
Refractory anemia with excess of blasts 1	D46.21
Refractory anemia with excess of blasts 2	D46.22
Refractory anemia, unspecified	D46.4
Myelodysplastic syndrome, unspecified	D46.9
Refractory cytopenia with multilineage dysplasia	D46.A
Refractory cytopenia with multilineage dysplasia and ring sideroblasts	D46.B
Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality	D46.C
Other myelodysplastic syndromes	D46.Z
Chronic myeloproliferative disease	D47.1
Essential (hemorrhagic) thrombocythemia	D47.3
Myelofibrosis	D75.81

CALR 81219

Polycythemia vera	D45
Chronic myeloproliferative disease	D47.1
Essential (hemorrhagic) thrombocythemia	D47.3
Myelofibrosis	D75.81

BCR/ABL1 81206 & 81207

Acute lymphoblastic leukemia	C91.0_
Chronic myeloid leukemia, BCR/ABL-positive	C92.1_
Chronic myelomonocytic leukemia	C93.1_
Polycythemia vera	D45
Chronic myeloproliferative disease	D47.1
Essential (hemorrhagic) thrombocythemia	D47.3
Myelofibrosis	D75.81

The following ICD-10-CM codes support medical necessity and provide coverage for the molecular biomarkers of:

Acute lymphoid leukemia (ALL)

JAK2 81270 & BCR/ABL1 81206 & 81207

Acute lymphoblastic leukemia	C91.0_

Acute myeloid leukemia (AML, and including acute promyelocytic leukemia)

JAK2 81270

Acute myeloblastic leukemia	C92.0_
Acute promyelocytic leukemia	C92.4_
Acute myelomonocytic leukemia	C92.5_
Acute myeloid leukemia with 11q23-abnormality	C92.6_
Acute myeloid leukemia with multilineage dysplasia	C92.A_

Myeloproliferative diseases (MPD - essential thrombocytosis [ET], myelofibrosis & polycythemia vera [PV])

JAK2 81270 & CALR 81219 & BCR/ABL1 81206 & 81207

Polycythemia vera	D45
Chronic myeloproliferative disease	D47.1
Essential (hemorrhagic) thrombocythemia	D47.3
Myelofibrosis	D75.81*

*Requires principal DX

Chronic myeloid leukemia (CML) and chronic myelomonocytic leukemia (CMML)

JAK2 81270 & BCR/ABL1 81206 & 81207

Chronic myeloid leukemia, BCR/ABL-positive	C92.1_
Chronic myelomonocytic leukemia	C93.1_

Myelodysplastic syndrome (MDS)

JAK2 81270

Refractory anemia without ring sideroblasts, so stated	D46.0
Refractory anemia with ring sideroblasts	D46.1
Refractory anemia with excess of blasts, unspecified	D46.20
Refractory anemia with excess of blasts 1	D46.21
Refractory anemia with excess of blasts 2	D46.22
Refractory cytopenia with multilineage dysplasia	D46.A
Refractory cytopenia with multilineage dysplasia and ring sideroblasts	D46.B
Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality	D46.C
Refractory anemia, unspecified	D46.4
Other myelodysplastic syndromes	D46.Z
Myelodysplastic syndrome, unspecified	D46.9

***Additional codes may be needed for billing purposes. Call us at 1.877.617.4445 if you have any questions.**
This list is subject to change and is not all-inclusive.

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Please refer to the most current version of the **Coding Manual of the American Medical Association (AMA)** for a complete list of ICD-10 codes. Information has been obtained through the **Centers for Medicare and Medicaid Services (CMS)** and Local Coverage Determination for Flow Cytometry. Codes listed are effective as of October 1, 2024.