

Centers for Medicare & Medicaid Services

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[Back to Local Coverage Determinations \(LCDs\)](#)

Local Coverage Determination (LCD): MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease (L36180)

- Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	A and B MAC	01111 - MAC A	J - E	California - Entire State
Noridian Healthcare Solutions, LLC	A and B MAC	01112 - MAC B	J - E	California - Northern
Noridian Healthcare Solutions, LLC	A and B MAC	01182 - MAC B	J - E	California - Southern
Noridian Healthcare Solutions, LLC	A and B MAC	01211 - MAC A	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01212 - MAC B	J - E	American Samoa Guam Hawaii Northern Mariana Islands
Noridian Healthcare Solutions, LLC	A and B MAC	01311 - MAC A	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01312 - MAC B	J - E	Nevada
Noridian Healthcare Solutions, LLC	A and B MAC	01911 - MAC A	J - E	American Samoa California - Entire State Guam Hawaii Nevada Northern Mariana Islands

- LCD Information

Document Information

LCD ID
L36180

LCD Title
MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease

Proposed LCD in Comment Period
N/A

Original Effective Date
For services performed on or after
04/19/2016

Revision Effective Date
For services performed on or after
10/01/2017

Revision Ending Date
N/A

Source Proposed LCD

N/A

Retirement Date

N/A

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Notice Period Start Date

03/03/2016

Notice Period End Date

04/18/2016

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CMS National Coverage Policy

Title XVIII of the Social Security Act (SSA), §1862(a)(1)(A), states that no Medicare payment shall be made for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

Title XVIII of the Social Security Act, §1833(e), prohibits Medicare payment for any claim lacking the necessary documentation to process the claim.

42 Code of Federal Regulations (CFR) §410.32 Diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

CMS Internet Online Manual Pub. 100-02 (Medicare Benefit Policy Manual), Chapter 15, Section 80, "Requirements for Diagnostic X-Ray, Diagnostic Laboratory, and Other Diagnostic Tests".

CMS Internet-Only Manuals, Publication 100-04, Medicare Claims Processing Manual, Chapter 16, §50.5 Jurisdiction of Laboratory Claims, 60.12 Independent Laboratory Specimen Drawing, 60.2. Travel Allowance.

CMS Internet Online Manual Pub. 100-04 (Medicare Claims Processing Manual), Chapter 23 (Section 10) "Reporting ICD Diagnosis and Procedure Codes".

CMS Internet-Only Manual, Pub 100-04, Medicare Claims Processing Manual, Chapter 12, §30-Correct Coding Policy.

Coverage Guidance**Coverage Indications, Limitations, and/or Medical Necessity****Indications and Limitations of Coverage**

This policy provides coverage for multi-gene non-NGS panel testing and NGS testing for the diagnostic workup for myeloproliferative disease (MPD), and limited coverage for single-gene testing of patients with BCR-ABL negative MPD. MPD includes polycythemia vera (PV), essential thrombocytopenia (ET), and primary myelofibrosis (PMF).

For laboratories performing single gene technologies, a sequential genetic testing approach is expected. Once a positive result is obtained and the appropriate diagnosis is established, further testing should stop. Reflex testing to the next gene will be considered reasonable and necessary if the following sequence of genetic tests produce a negative result:

1. BCR-ABL negative test results, progress to #2
2. JAK 2, cv negative test results, progress to #3 or #4
3. JAK, exon 12 (JAK2 exon 12 is only done when PV is suspected)
4. CALR/MPL (CALR/MPL is only done when either ET or PMF is suspected; testing for CALR/MPL does NOT require a negative JAK2 exon 12, just a negative JAK2 V617F result)

Genetic testing of the JAK2 V617F mutation (81270) is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and
- Patient would meet World Health Organization's diagnostic criteria for myeloproliferative disease (i.e. polycythemia vera, essential thrombocytopenia, primary myelofibrosis) if JAK2 V617F were identified.

Genetic testing of JAK2 exon 12 (81403), performed to identify PV, is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and
- Patient would meet World Health Organization's diagnostic criteria for PV, if JAK2 exon 12 testing were positive; and
- JAK2 V617F mutation analysis was previously completed and was negative.

Genetic testing of the CALR gene (81219) (only found in ET and PMF) is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and
- JAK2 V617F mutation analysis was previously completed and negative; and
- Patient would meet World Health Organization's diagnostic criteria for MPD (i.e. ET, PMF) if a clonal marker were identified.

Genetic testing of the MPL gene (81402) is medically necessary when the following criteria are met:

- Genetic testing impacts medical management; and
- JAK2 V617F mutation analysis was previously completed and negative; and
- Patient would meet World Health Organization's diagnostic criteria for MPD (i.e. ET, MPF) if a clonal marker were identified.

Note: In a single-gene sequential approach (not mandated by this policy), CALR would be a higher priority single gene test than MPL because:

- CALR mutations is more prevalent than MPL mutations in ET/PMF patients; and
- CALR mutations are reported to predict a more indolent disease course than that of patients with JAK2 mutations.

For laboratories performing next generation sequencing (NGS or "hotspot") testing platforms: Molecular testing for BCR-ABL, JAK 2, JAK, exon 12, and CALR/MPL genes by NGS is covered as medically necessary for the identification of myeloproliferative disorders.

Summary of Evidence

Myeloproliferative Disorders

Myeloproliferative disorders are a group of conditions that cause abnormal growth of blood cells in the bone marrow. They include polycythemia vera (PV), essential thrombocytosis (ET), primary myelofibrosis (PMF), and chronic myelogenous leukemia (CML). The World Health Organization (WHO) further classifies PV, ET, and PMF as Philadelphia chromosome negative myeloproliferative neoplasms (MPNs). The diagnosis of an MPN is suspected based upon clinical, laboratory, and pathological findings (i.e. bone marrow morphology). MPNs are related, but distinct from, myelodysplastic syndromes (MDS). In general, MDS are characterized by ineffective or dysfunctional blood cells, while MPN are characterized by an increase in the number of blood cells.

Polycythemia Vera

Polycythemia vera is a chronic myeloproliferative disease characterized by increased hemoglobin, hematocrit, and red blood cell mass. There is an associated increased risk for thrombosis and transformation to acute myelogenous leukemia or primary myelofibrosis; however, patients are often asymptomatic. Criteria for a diagnosis of PV are based upon CBC and clinical features. The JAK2 V617F mutation is present in the vast majority of PV, accounting for approximately 90% of cases. Functionally similar mutations in JAK2 exon 12 account for most remaining cases of JAK2 V617F mutation-negative PV. Together, they are identified in 98% of PV cases and lead to high diagnostic certainty.

Among the proposed revised World Health Organization (WHO) criteria for diagnosis is presence of the somatic

JAK2 V617F mutation or functionally similar exon 12 mutation. Absence of a JAK2 mutation, combined with normal or increased serum erythropoietin level, greatly decreases the likelihood of a PV diagnosis. WHO proposed revision criteria for PV do not address additional molecular markers, including CALR mutation status.

Essential Thrombocythemia

Essential thrombocythemia is a disorder of sustained increased platelet count. The majority of ET patients (60%) carry a somatic JAK2 V617F mutation, while a smaller percentage (5-10%) have activating MPL mutations. Revision to the WHO criteria for diagnosis of ET has been proposed and includes exclusion of PV, PMF, CML, myelodysplastic syndrome, or other myeloid neoplasm. Also included in the proposed major criteria for diagnosis is demonstration of somatic JAK2 V617F mutation or MPL exon 10 mutation¹². Proposed criteria additionally state that 70% of patients without a JAK2 or MPL mutation carry a somatic mutation of the calreticulin (CALR) gene. Among confirmed ET cases, mutations in CALR are more common than MPL. Positive CALR mutation status is suggested as indicating a more indolent course⁵.

Primary Myelofibrosis

Primary myelofibrosis (PMF) is a rare disorder in which the bone marrow is replaced with fibrous tissue, leading to bone marrow failure. Clinical features are similar to ET. The approximate incidence is 1 in 100,000 individuals. Persons can be asymptomatic in the early stages of the disease. For such patients, treatment may not initially be necessary. Progression of the disease can include transformation to acute myeloid leukemia. Treatment is generally symptomatic and aimed at preventing complications.

Demonstration of a clonal marker is important for diagnosis. Somatic molecular markers in PMF patients are similar to those in patients with ET, and include JAK2 V617F, MPL, and CALR. Somatic mutations in JAK2 are identified in 50-60% of PMF cases, and MPL mutations in 10%. Mutations in CALR are less common than JAK2, but more common than MPL.

Molecular Genetic Testing

One JAK2 gene mutation, V617F, is most commonly reported, occurring in over 90% of all polycythemia vera (PV) cases and about 50% of ET cases. Testing for JAK2 V617F gene mutations can be useful in diagnosis and is incorporated into the WHO's diagnostic criteria for these conditions.

The thrombopoietin receptor MPL is one of several JAK2 cognate receptors and is considered essential for myelopoiesis. The mutation frequency of MPL mutations associated with myeloproliferative disorders is substantially less (<10%) than JAK2 mutations. The guideline group for the British Committee for Standards in Haematology recommended a modification to the 2008 WHO criteria for ET to include the presence of an acquired pathogenetic mutation (e.g. in the JAK2 or MPL genes)³. Therefore, MPL gene testing may be indicated for individuals who would meet World Health Organization's diagnostic criteria for myeloproliferative disease if a clonal marker were identified.

Calreticulin (CALR) mutations have been identified in patients with myeloproliferative neoplasms and recent studies have investigated the utility of CALR mutation testing for the diagnosis and classification of myeloproliferative neoplasms. The mutations themselves are variable; however, generally focused in the exon 9 region.

Studies have shown that a significant proportion of patients with myeloproliferative neoplasms and normal JAK2 V617F mutation testing have a CALR gene mutation. CALR mutations account for a large proportion of JAK2/MPL-negative ET and PMF cases. Approximately 60% of JAK2/MPL-negative ET patients are CALR-positive and 30% of JAK2/MPL-negative PMF patients are CALR-positive. Overall, CALR mutations are identified in approximately 21% of ET cases and 16% of PMF cases. CALR mutations have not been reported in PV case series².

For this reason, CALR gene testing may be indicated for individuals who would meet World Health Organization's diagnostic criteria for myeloproliferative disease if a clonal marker were identified. Proponents have argued for revised WHO criteria that includes CALR mutation status in the classification system for ET and PMF¹². Current NCCN guidelines do not make recommendations for CALR genetic testing; however, these guidelines are specific to MDS and do not broadly address myeloproliferative neoplasms, such as ET or PMF. Somatic mutations in non-MDS genes, such as CALR, are listed as being associated with conditions that can mimic other myelodysplastic syndromes.

Aside from diagnostic utility, some research suggests distinct clinical outcomes associated with CALR mutation status; however, the findings have not been confirmed in other studies. It is suggested that ET patients with CALR mutations have lower polycythemic transformation rates, but not lower myelofibrotic transformation rate, compared with ET patients harboring a JAK2 mutation. Others reported a higher platelet count, younger age of diagnosis, lower leukocyte count, and decreased risk for thrombosis, compared with a JAK2 positive ET population¹. CALR-mutated ET has also been associated with better thrombosis-free survival and lower leukocyte counts; overall survival has been reported as not different among CALR mutated and non-mutated ET^{2,15}.

Although they are useful for establishing a diagnosis, the presence of specific clonal markers does not dictate treatment. Controversy exists generally regarding the treatment of asymptomatic individuals with ET. Some argue against treatment if there are no associated complications. In general, the main goal of treatment with

PV and ET is to identify persons at high risk for thrombosis and prevent complications. Persons with PV and ET are determined to be at high-risk due to age >60 years and past history of thrombotic event(s). CALR mutational status is not currently used for risk stratification. ¹¹

Analysis of Evidence (Rationale for Determination)

Level of evidence

Quality – Strong

Strength – Strong

Weight – Moderate

In summary, multiple studies have demonstrated the diagnostic value of CALR mutation status in a population of JAK2 and MPL negative patients with suspected ET and PMF. The presence of a somatic CALR mutation can prove useful in obtaining an accurate diagnosis. Emerging evidence suggests possible differences in clinical phenotype among the associated clonal markers, including CALR-positive ET cases. However, CALR mutation status is currently not incorporated into clinical risk stratification and more research is needed in this area.

– Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

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Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes

Group 1 Paragraph: N/A

Group 1 Codes:

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

81402	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 3 (EG, >10 SNPS, 2-10 METHYLATED VARIANTS, OR 2-10 SOMATIC VARIANTS [TYPICALLY USING NON-SEQUENCING TARGET VARIANT ANALYSIS], IMMUNOGLOBULIN AND T-CELL RECEPTOR GENE REARRANGEMENTS, DUPLICATION/DELETION VARIANTS OF 1 EXON, LOSS OF HETEROZYGOSITY [LOH], UNIPARENTAL DISOMY [UPD])
81403	MOLECULAR PATHOLOGY PROCEDURE, LEVEL 4 (EG, ANALYSIS OF SINGLE EXON BY DNA SEQUENCE ANALYSIS, ANALYSIS OF >10 AMPLICONS USING MULTIPLEX PCR IN 2 OR MORE INDEPENDENT REACTIONS, MUTATION SCANNING OR DUPLICATION/DELETION VARIANTS OF 2-5 EXONS)
81445	TARGETED GENOMIC SEQUENCE ANALYSIS PANEL, SOLID ORGAN NEOPLASM, DNA ANALYSIS, AND RNA ANALYSIS WHEN PERFORMED, 5-50 GENES (EG, ALK, BRAF, CDKN2A, EGFR, ERBB2, KIT, KRAS, NRAS, MET, PDGFRA, PDGFRB, PGR, PIK3CA, PTEN, RET), INTERROGATION FOR SEQUENCE VARIANTS AND COPY NUMBER VARIANTS OR REARRANGEMENTS, IF PERFORMED
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
81479	UNLISTED MOLECULAR PATHOLOGY PROCEDURE

ICD-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

ICD-10 CODES	DESCRIPTION
C88.8	Other malignant immunoproliferative diseases
C92.10	Chronic myeloid leukemia, BCR/ABL-positive, not having achieved remission
C92.11	Chronic myeloid leukemia, BCR/ABL-positive, in remission
C92.12	Chronic myeloid leukemia, BCR/ABL-positive, in relapse
C92.20	Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21	Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22	Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C93.10	Chronic myelomonocytic leukemia not having achieved remission
C94.40	Acute panmyelosis with myelofibrosis not having achieved remission
C94.41	Acute panmyelosis with myelofibrosis, in remission
C94.42	Acute panmyelosis with myelofibrosis, in relapse
C94.6	Myelodysplastic disease, not classified
D45	Polycythemia vera

D46.0	Refractory anemia without ring sideroblasts, so stated
D46.1	Refractory anemia with ring sideroblasts
D46.20	Refractory anemia with excess of blasts, unspecified
D46.21	Refractory anemia with excess of blasts 1
D46.22	Refractory anemia with excess of blasts 2
D46.A	Refractory cytopenia with multilineage dysplasia
D46.B	Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D46.C	Myelodysplastic syndrome with isolated del(5q) chromosomal abnormality
D46.4	Refractory anemia, unspecified
D46.Z	Other myelodysplastic syndromes
D46.9	Myelodysplastic syndrome, unspecified
D47.02	Systemic mastocytosis
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.4	Osteomyelofibrosis
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D72.821	Monocytosis (symptomatic)
D72.829	Elevated white blood cell count, unspecified
D75.1	Secondary polycythemia
D75.81	Myelofibrosis
D75.89	Other specified diseases of blood and blood-forming organs
D75.9	Disease of blood and blood-forming organs, unspecified

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

ICD-10 Additional Information

– General Information

Associated Information

Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Coverage Indications, Limitations, and/or Medical Necessity") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the MAC upon request.

This final LCD, effective 04/19/2016, combines JEA DL36098 into the JEB LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number.

Sources of Information

N/A

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- Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
10/01/2017	R5	Added ICD-10 code D47.02, effective 10/1/2017. Added 21st Century Act required fields. Added ICD-10 codes C92.11 and C92.12 effective 10/13/2016.	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction
01/01/2017	R4	Changed MPD to MPL in reference to the MPL gene mutation. MPD refers to myeloproliferative disease.	<ul style="list-style-type: none"> • Creation of Uniform LCDs Within a MAC Jurisdiction • Creation of Uniform LCDs With Other MAC Jurisdiction
01/01/2017	R3	CPT code 81402 descriptor was changed in Group 1, under CPT/HCPCS Codes. There may not be any change in how the code displays in the document. Minor typographical errors were corrected: Indications and Limitations of Coverage- (bullet 13)	<ul style="list-style-type: none"> • Revisions Due To CPT/HCPCS Code Changes

		<ul style="list-style-type: none"> • CALR mutations are reported to predict a more indolent disease course than (added "that of") patients with JAK2 mutations and changed CALF to CALR. <p>Molecular Genetic Testing- (3rd paragraph)</p> <p>Studies have shown that a significant proportion of patients with myeloproliferative neoplasms and normal JAK2 (added "v")617F mutation testing have a CALR gene mutation.</p>	
04/19/2016	R2	The acronym for myeloproliferative disease was previously noted primarily as MPL with a few notations as MPD. LCD was revised to consistently use MPD to describe myeloproliferative disease.	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction
04/19/2016	R1	LCD is revised to include the following diagnoses per the MoIDX contractor effective 04/19/2016: C88.8, C92.10, C93.10, C94.40, C94.41, C94.42, C94.6, D46.0-D46.9, D46.Z, D47.4, D47.9, D47.Z9, D72.821, D72.829 and D75.9	<ul style="list-style-type: none"> • Creation of Uniform LCDs With Other MAC Jurisdiction

[Back to Top](#)

- Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

A55595 - MoIDX: BCR-ABL Billing and Coding Guidelines

A54927 - Response to Comments: MoIDX: Genetic Testing for BCR-ABL Negative Myeloproliferative Disease

LCD(s)

DL36098 - (MCD Archive Site)

DL36180 - (MCD Archive Site)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 09/29/2017 with effective dates 10/01/2017 - N/A

Updated on 03/16/2017 with effective dates 01/01/2017 - 09/30/2017

Updated on 01/04/2017 with effective dates 01/01/2017 - N/A

Updated on 08/04/2016 with effective dates 04/19/2016 - 12/31/2016

Updated on 04/25/2016 with effective dates 04/19/2016 - N/A

Updated on 02/18/2016 with effective dates 04/19/2016 - N/A

- Keywords

- MoIDX
- Genetic
- BCR-ABL
- Myeloproliferative
- 81206
- 81207
- 81208
- 81219
- 81270
- 81403

- 81402
- 81445
- 81455
- 81450
- 81479
- JAK
- MPD
- CALR
- V617F
- Polycythemia
- thrombocythemia
- myelofibrosis

Read the **LCD Disclaimer**