Medicare Local Coverage Determination Policy

Molecular Pathology Jak2 Testing

CPT: 81270, 81338, 81339

CMS Policy for Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, and Vermont

Local policies are determined by the performing test location. This is determined by the state in which your performing laboratory resides and where your testing is commonly performed.

Medically Supportive ICD Codes are listed on subsequent page(s) of this document.

According to The American Medical Association (AMA) Current Procedural Terminology (CPT) manual, molecular pathology procedures are medical laboratory procedures involving the analyses of nucleic acid to detect variants in genes that may be indicative of germline (e.g., constitutional disorders) or somatic (e.g., neoplasia) conditions, or to test for histocompatibility antigens (e.g., HLA). Given the elimination of the stacking procedure codes (83890-83914) and the array based evaluation codes (88384-88386), molecular pathology codes now include all analytical services performed in the test (e.g., cell lysis, nucleic acid stabilization, extraction, digestion, amplification, and detection). (Note: molecular pathology procedure techniques may be described in other sections of the Pathology and Laboratory section of CPT. For microbial identification using molecular pathology techniques CPT codes 87149-87153, 87470-87801, and 87900-87904 apply. For in situ hybridization analyses, CPT codes 88271-88275 and 88365-88368 apply.) Code selection is typically based on the specific gene(s) that is being analyzed. Codes that describe tests to assess for the presence of gene variants use common gene variant names. Typically, all of the listed variants would be tested. However, these lists are not exclusive. If other variants are also tested in the analysis, they would be included in the procedure and not reported separately. Full gene sequencing should not be reported using codes that assess for the presence of gene variants unless the CPT code specifically states full gene sequence in the code descriptor. In other words, you may only assign the CPT code that is described as “full gene sequence” if the test assay performed was a full gene sequence. There are Tier 1 and Tier 2 molecular pathology procedure codes. Tier 1 codes generally describe testing for a specific gene or HLA locus. Tier 2 molecular pathology procedures represent procedures that are generally performed in lower volumes than Tier 1 molecular pathology procedures (e.g., the incidence of the disease being tested is rare). They are arranged by level of technical resources and interpretive work by the physician or other qualified healthcare professional. If the gene tested is not listed under one of the Tier 2 codes or is not represented by a Tier 1 code in CPT, use of the Not Otherwise Classified (NOC) CPT code 81479 is required.

Many applications of the molecular pathology procedures are not covered services given lack of benefit category (e.g., preventive service or screening for a genetic abnormality in the absence of a suspicion of disease) and/or failure to the reasonable and necessary threshold for coverage (e.g., based on quality of clinical evidence and strength of recommendation or when the results would not reasonably be used in the management of a beneficiary). Furthermore, payment of claims in the past (based on stacking codes) or in the future (based on the new code series) is not a statement of coverage since the service may not have been audited for compliance with program requirements and documentation supporting the reasonable and necessary testing for the beneficiary. Certain molecular pathology procedures may be subject to prepayment medical review (records requested) and paid claims must be supportable, if selected, for post payment audit by the MAC or other contractors. Molecular pathology tests for diseases or conditions that manifest severe signs or symptoms in newborns and in early childhood or that result in early death (e.g., Canavan disease) could be subject to automatic denials since these tests are not usually relevant to a Medicare beneficiary.

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Molecular pathology procedures have broad clinical and research applications. The following examples of applications may not be relevant to a Medicare beneficiary or may not meet a Medicare benefit category and/or reasonable and necessary threshold for coverage. Such examples include Genetic Testing and Genetic Counseling (when applicable) for:

- Disease Risk
- Carrier Screening
- Hereditary Cancer Syndromes
- Gene Expression Profiling for certain cancers
- Prenatal Diagnostic testing
- Diagnosis and Monitoring Non-Cancer Indications, and
- Several Pharmacogenomic applications.

Based on the Centers for Medicare & Medicaid Services (CMS) Program Integrity Manual (100-08), this Local Coverage Determination (LCD) addresses the circumstances under which the item or service may be reasonable and necessary under the Social Security Act, §1862(a)(1)(A). For laboratory services, a service may be reasonable and necessary if the service is safe and effective; and appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is furnished in accordance with accepted standards of medical practice for the diagnosis of the patient's condition; furnished in a setting appropriate to the patient's medical needs and condition; ordered and furnished by qualified personnel; one that meets, but does not exceed, the patient's medical need; and is at least as beneficial as an existing and available medically appropriate alternative.

Per 42 Code of Federal Regulations (CFR) section 410.32 (a) the following requirements must be met for coverage: All diagnostic x-rays tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see §411.15(k)(1)). Also, see Medicare Benefit Policy Manual (100-02), Chapter 15, Section 80.6 for related physician order instructions.

Laboratory services must meet all applicable requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as set forth at 42 CFR part 493. Section 1862(a)(1)(A) of the Act provides that Medicare payment may not be made for services that are not reasonable and necessary. Clinical laboratory services must be ordered and used promptly by the physician who is treating the beneficiary as described in 42 CFR 410.32(a), or by a qualified nonphysician practitioner, as described in 42 CFR 410.32(a)(3).

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This LCD gives general guidance to the medically reasonable and necessary applications of the Molecular Pathology Procedures and Genomic Sequencing Procedures, described in Current Procedural Terminology (CPT).

Indications:
Molecular pathology procedures (Tier1 and Tier 2) may be eligible for coverage when ALL of the following criteria are met:

- Alternative laboratory or clinical tests to definitively diagnose the disorder/identify the condition are unavailable or results are clearly equivocal; AND
- Availability of a clinically valid test, based on published peer reviewed medical literature; AND
- Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) of analytical validity and clinical utility; AND
- Results of the testing must directly impact treatment or management of the Medicare beneficiary; AND
- For testing panels, including but not limited to, multiple genes or multiple conditions, and in cases where a tiered approach/method is clinically available, testing would be covered ONLY for the number of genes or test that are reasonable and necessary to obtain necessary information for therapeutic decision making; AND
- Individual has not previously received genetic testing for the disease/condition. (In general, diagnostic genetic testing for a disease should be performed once in a lifetime.) Exceptions include clinical scenarios whereby repeat testing of somatically-acquired mutations (for example, pre- and post- therapy) may be required to inform appropriate therapeutic decision-making.

Limitations:

- Any procedures required prior to cell lysis (e.g., microdissection [CPT codes 88380 and 88381]) should be reported separately and utilization must be clearly supported based on the application and clinical utility. Such claims may be subject to prepayment medical review.
- HCPCS code G0452 describes the medically necessary interpretation and report of a molecular pathology test, written by a pathologist, which is above and beyond the report of standard laboratory results. Non- physician practitioners (e.g., PhD, scientists etc.) are not eligible to report this code; only physicians may use/bill this code.
- Testing for quality assurance [component of the service is not separately billable per CMS National Correct Coding Initiative (NCCI)].

CPT Code 81270
JAK2 V617F genotyping is considered medically necessary in the initial diagnostic work-up of BCR-ABL negative, JAK2-negative adults with clinical, laboratory, or pathological findings suggesting myeloproliferative neoplasm (MPN) (polycythemia vera (PV), essential thrombocythemia (ET) or primary myelofibrosis (PMF)) or a myelodysplastic syndrome (MDS). Note: JAK2 (exons 12 and 13) (reported with 81403) is medically necessary in individuals for whom PV is a strong consideration.

CPT Code 81338 MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), common variants (eg, W515A, W515K, W515L, W515R) is considered medically necessary in the initial work-up of BCR-ABL negative, JAK2 negative, and CALR negative adults with clinical, laboratory, or pathological findings suggesting thrombocytosis, essential thrombocythemia (ET), or primary myelofibrosis (PMF).

CPT Code 81339 MPL (myeloproliferative leukemia virus oncogene, thrombopoietin receptor, TPOR) (eg, myeloproliferative disorder), exon 10 sequence is considered medically necessary in the initial work-up of BCR-ABL negative, JAK2 negative, and CALR negative adults with clinical, laboratory, or pathological findings suggesting thrombocytosis, essential thrombocythemia (ET), or primary myelofibrosis (PMF).

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Please refer to the Limitations or Utilization Guidelines section on previous page(s) for frequency information.

The ICD10 codes listed below are the top diagnosis codes currently utilized by ordering physicians for the limited coverage test highlighted above that are also listed as medically supportive under Medicare's limited coverage policy. **If you are ordering this test for diagnostic reasons that are not covered under Medicare policy, an Advance Beneficiary Notice form is required.**

Code	Description
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D72.829	Elevated white blood cell count, unspecified
D75.1	Secondary polycythemia

Visit **QuestDiagnostics.com/MLCP** to view current limited coverage tests, reference guides, and policy information.

To view the complete policy and the full list of medically supportive codes, please refer to the CMS website reference www.cms.gov ▶

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