Maryland
DEPARTMENT OF HEALTH

Molecular Pathology Procedure - Level 2 Clinical Criteria (81401)

CPT Code 81401 is a Molecular Pathology Level 2 code. There are many different specific analyte/genes that can be tested. The Maryland Medicaid policy will mirror CMS National Coverage Determination for coverage for only those specific analyte/gene(s) tested that have been identified by CMS as having clinical significance.

Molecular Pathology Procedure 81401 - Level 2 Requires ***Prior Authorization***
(When used to identity any of the following specific analyte/gene)

- CBFB-MYH11,
- E2A/PBX1,
- EML4-ALK,
- ETV6-RUNX1,
- EWSR1/ERG,
- EWSR1/FLI1,
- EWSR1/WT1,
- F11 Coagulation factor XI,
- FIP1L1-PDGFR,
- FOXO1/PAX3,
- FOXO1/PAX7,
- MUTYH (mutY homolog [E.coli]),
- NPM/ALK,
- PAX8/PPARG,
- RUNX1/RUNX1T1

I. Criteria for Initial Approval

CPT Code 81401 will be considered for coverage when **ALL** of the criteria below are met, confirmed with supporting medical documentation.

- Approved for all age ranges.
- Test is ordered by or in collaboration with a medical geneticist or certified genetic counselor.
- The medical record from the ordering provider must clearly indicate all tests that are to be performed.

- Documentation of the suspected diagnosis, indications for testing, medical/treatment history to date.

- Provider attestation as to why the test will likely impact therapeutic decision-making, directly impact treatment, outcome and/or clinical management.

II. Exclusions from Coverage

The use of CPT Code 81401 for indications other than those listed above is considered experimental, investigational, or unproven.

CPT Code 81401 is considered **Non Covered** for the following Indications:

- Tests considered screening in the absence of clinical signs and symptoms of disease.
- Tests performed to determine carrier screening
- Tests performed for screening hereditary cancer syndromes
- Prenatal diagnostic testing
- Tests performed on patients without signs or symptoms to determine risk for developing a disease or condition
- Tests without diagnosis specific indications

CPT Code 81401 is considered **Non Covered** for the following **Code/Gene Combinations:**

- ADRB2,
- APOE,
- ATN1,
- CFH/ARMS2,
- DEK/NUP214,
- FGFR3,
- GALT (galactose-1-phosphate uridylyltransferase),
- H19, KCNQ10T1 (KCNQ1 overlapping transcript 1),
- MEG3/DLK1,
- MLL/AFF,
- MT-ATP6,
- MT-ND4,
- MT-ND6,
- MT-ND5 mitochondrially encoded tRNA leucine 1 [UUA/G] mitochondrially encoded NADH dehydrogenase 5),
- MT-RNR1 (mitochondrially encoded 12S RNA),

- MT-TK (mitochondrially encoded tRNA lysine),
- MT-TL1,
- MT-TS1,
- PRSS1 (protease, serine, 1 [trypsin 1])

III. Length of Authorization For initial therapy

CPT 81401 will be authorized for coverage for 3 months from when criteria for initial approval are met.

IV. Billing Code/Information

CPT Code 81401 - Molecular Pathology Level 2 code

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 10/30/2023
Last Reviewed Date: 10/30/2023