

Genetic testing: oncology - cytogenetic testing

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is required for:

- FOLR1 Protein Analysis
- NTRK Fusion Analysis
- RET Gene Rearrangement Tests (FISH)
- Bladder Cancer Diagnostic and Recurrence FISH Tests
- Testing that is associated with a procedure code listed in "Box A", below.

Prior authorization is not required for:

- Tumor Specific ALK Gene Rearrangement (Qualitative FISH and PCR) Tests
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis
- Tumor Specific ERBB2 (HER2) Deletion/Duplication (FISH and CISH)
- Tumor Specific PD-L1 Protein Analysis Fusion
- Multiple Myeloma FISH Panel Analysis
- Tumor Specific PML/RARA Gene Rearrangement (Qualitative FISH and PCR)
- Tumor Specific ROS1 Gene Rearrangement

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

Please see Related Content for any genetic testing codes that do not require prior authorization.

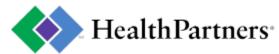
Refer to the list in Related Content to find out whether prior authorization is required for a specific indication. Prior authorization requirements are based on both the procedure code (CPT) and primary diagnosis code (ICD-10-CM) associated with the genetic testing.

Box A: Genetic testing procedure codes that require prior authorization			
Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479)			
Unlisted multianalyte assays (CPT 81599)			
Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test			

Policy Reference Table

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes
Tumor Specific ALK Gene Rearrangement (Qualitative FISH and PCR) Tests	ALK FISH, Non-Small cell Lung Cancer (Labcorp)	88271, 88274	C34, C73
Bladder Cancer Diagnostic and Recurrence FISH Tests	UroVysion Bladder Kit (Quest Diagnostics)	88120, 88121	C67, R31.9, Z85, Z85.5
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis	FISH for Chronic Lymphocytic Leukemia (Cleveland Clinic Laboratories)	88271, 88274, 88275, 88291	C91, C94, C95, Z85.6
	FISH, B-Cell Chronic Lymphocytic Leukemia Panel (Quest Diagnostics)		
Tumor Specific <i>ERBB2</i> (<i>HER2</i>) Deletion/Duplication (FISH and CISH)	ERBB2 (HER2/neu) Gene Amplification by FISH with Reflex, Tissue (ARUP Laboratories)	88360, 88377	C08, C15, C16, C18, C19, C20, C50



Multiple Myeloma FISH Panel Analysis	Oncology FISH Analysis - Multiple Myeloma FISH Panel (Baylor Genetics, LLC)	88271, 88237, 88275, 88291	C90
	Multiple Myeloma (MM) Profile, FISH (Labcorp)		
NTRK Fusion Analysis Panel	NTRK NGS Fusion Panel (NeoGenomics Laboratories)	81191, 81192, 81193, 81194	C15, C16, C18, C34, C49.9, C50, C51, C53, C54, C73, C80.1, C91
Tumor Specific <i>PD-L1</i> Protein Analysis	PD-L1, IHC with Interpretation (Quest Diagnostics)	88341, 88342, 88360, 88361	C11, C15, C16, C34, C50, C51, C53, C67
Tumor Specific FOLR1 Protein Analysis	FOLR1 Immunohistochemistry Analysis (Labcorp)	88360	C56
Tumor Specific <i>PML/RARA</i> Gene Rearrangement (Qualitative FISH and PCR)	FISH, APL, PML/RARA, Translocation 15, 17 (Quest Diagnostics)	81315, 81316, 88271, 88274, 88275, 88291	C91-C95
	PML/RARA t(15;17) (NeoGenomics Laboratories)		
Tumor Specific RET Gene Rearrangement (FISH)	RET FISH (NeoGenomics Laboratories)	88271, 88275, 88291, 88374, 88377	C34, C53, C73
	Oncology FISH Analysis - RET Rearrangement (Baylor Genetics)		
Tumor Specific ROS1 Gene Rearrangement	FISH ROS1 Rearrangement (Johns Hopkins Medical Institutions-Pathology Laboratory)	88271, 88274	C34

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Coverage

Tumor Specific ALK Gene Rearrangement (Qualitative FISH and PCR) Tests

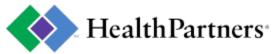
- Somatic ALK rearrangement analysis in solid tumors is considered **medically necessary** when:
 - A. The member has a diagnosis of or is in the initial work up stage for:
 - i. Stage 1B or higher lung adenocarcinoma, or
 - ii. Stage 1B or higher large cell lung carcinoma, **or**
 - iii. Stage 1B or higher squamous cell lung carcinoma, or
 - iv. Stage 1B or higher non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **or**
 - v. Anaplastic thyroid carcinoma, **or**
 - vi. Locally recurrent, advanced and/or metastatic papillary thyroid carcinoma, or
 - vii. Locally recurrent, advanced, and/or metastatic follicular thyroid cancer
 - viii. Locally advanced/metastatic ampullary adenocarcinoma, or
 - ix. Langerhans cell histiocytosis, or
 - x. Erdheim-Chester disease, or
 - xi. Resectable, borderline resectable or locally advanced or metastatic pancreatic adenocarcinoma, **or**

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xii. Pediatric (diagnosed age 18 or younger) diffuse high grade glioma.

Bladder Cancer Diagnostic and Recurrence FISH Tests

- 1. Bladder cancer diagnostic and recurrence FISH tests for diagnosing and monitoring bladder cancer are considered **medically necessary** when:
 - A. The member has hematuria, and
 - . Diagnostic studies have failed to identify the etiology of the hematuria, and
 - ii. A bladder cancer diagnostic and recurrence FISH test has not been ordered more than 1 time in the past 12 months, **or**
 - B. The member has been treated for bladder cancer, and
 - i. The bladder cancer diagnostic and recurrence FISH tests are ordered with the following frequency:



- a) No more than 4 bladder tumor marker studies per year for years 1-2 after diagnosis
- b) No more than 3 bladder tumor marker studies per year for year 3 after diagnosis
- c) No more than 2 bladder tumor marker studies for year 4 after diagnosis
- d) No more than 1 bladder tumor marker studies annually for up to 15 years after diagnosis.
- 2. Bladder cancer diagnostic and recurrence FISH tests for screening of members with hematuria are considered **investigational**.
- 3. Bladder cancer diagnostic and recurrence FISH tests for diagnosing and monitoring bladder cancer are considered **investigational** for all other indications.

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Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis

- 1. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) FISH panel analysis in peripheral blood or bone marrow is considered **medically necessary** when:
 - A. The panel includes analysis for +12, del(11q), del(13q), and del(17p), and
 - B. The member is undergoing initial diagnostic workup for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).

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Tumor Specific ERBB2 (HER2) Deletion/Duplication (FISH and CISH)

- 1. Tumor specific ERBB2 (HER2) amplification analysis via in situ hybridization (ISH) (i.e., FISH or CISH) or immunohistochemistry (IHC) in solid tumors is considered **medically necessary** when:
 - A. The member has any of the following:
 - i. Recurrent or newly diagnosed stage I-IV invasive breast cancer, or
 - ii. Inoperable locally advanced, recurrent or metastatic gastric cancer
 - iii. Suspected or proven metastatic colorectal cancer or appendiceal adenocarcinoma, **or**
 - iv. Inoperable locally advanced, recurrent or metastatic esophageal and/or esophagogastric junction
 - adenocarcinoma, or
 - v. Recurrent, unresectable, or metastatic salivary gland tumors, or
 - vi. Recurrent, advanced, or metastatic cervical carcinoma, or
 - vii. Serous endometrial carcinoma, or
 - viii. Endometrial carcinosarcoma, or
 - ix. p53 abnormal endometrial carcinoma, or
 - x. Resectable, borderline resectable, or locally advanced/metastatic pancreatic adenocarcinoma, **or**
 - xi. Recurrent ovarian/fallopian tube/primary peritoneal cancer, or
 - xii. Recurrent or metastatic vaginal cancer, or
 - xiii. Stage IIIB or higher muscle invasive bladder cancer, or
 - xiv. Metastatic small bowel adenocarcinoma.

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Multiple Myeloma FISH Panel Analysis

- 1. Multiple myeloma FISH panel analysis of bone marrow is considered **medically necessary** when:
 - A. The panel includes analysis for del (13), del(17p13), t(4;14), t(11;14), t(14;16), t(14;20), 1q21 gain/amplification, del(1p), **and**
 - B. The member is undergoing initial diagnostic workup for multiple myeloma.

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NTRK Fusion Analysis Panel

- 1. NTRK 1/2/3 fusion analysis panel via fluorescent in situ hybridization (FISH) or immunohistochemistry (IHC) in solid tumors is considered **medically necessary** when:
 - A. The member is undergoing initial diagnostic workup for or has a diagnosis of:
 - i. Advanced
 - ii. U,progressive, or metastatic solid tumor **or**
 - iii. Cancer for which surgical resection is not possible, or
 - iv. Unknown primary cancers, or
 - v. The member has a diagnosis of any of the following cancers at any stage:
 - a) Cervical sarcoma, or
 - b) Anaplastic thyroid carcinoma, **or**
 - c) Acute lymphoblastic leukemia (ALL), or
 - d) Pediatric (diagnosed age 18 years or younger) diffuse high grade glioma





Tumor Specific PD-L1 Protein Analysis

- 1. PD-L1 protein expression analysis via immunohistochemistry (IHC) in solid tumors is considered **medically necessary** when:
 - A. The member has a diagnosis of or is in the initial work up stage for:
 - . Stage 1B or higher lung adenocarcinoma, or
 - ii. Stage 1B or higher large cell lung carcinoma, or
 - iii. Stage 1B or higher squamous cell lung carcinoma, or
 - iv. Stage 1B or higher non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **or**
 - v. Locally advanced or metastatic bladder cancer, or
 - vi. Recurrent, progressive, or metastatic cervical cancer (squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma), **or**
 - vii. Recurrent unresectable or stage IV triple negative breast cancer, or
 - viii. Locally advanced, recurrent or metastatic esophageal and/or esophagogastric junction adenocarcinoma, **or**
 - ix. Locally advanced, recurrent or metastatic gastric adenocarcinoma, or
 - x. Recurrent, unresectable, oligometastatic or metastatic nasopharyngeal cancer, **or**
 - xi. Recurrent, progressive, or metastatic squamous cell vulvar cancer, or
 - xii. Recurrent or metastatic vaginal cancer.

Note: PD-L1 protein expression analysis via IHC is often performed as an adjunct component of comprehensive molecular profiling panels for solid tumors

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Tumor Specific FOLR1 Protein Analysis

- 1. Tumor specific FOLR1 protein expression analysis via immunohistochemistry (IHC) analysis is considered **medically necessary** when:
 - A. The member has recurrent, platinum resistant epithelial ovarian, fallopian tube or primary peritoneal cancer, **and**
 - B. Elahere (mirvetuximab soravtansine) is being considered for treatment.

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Tumor Specific PML/RARA Gene Rearrangement (Qualitative FISH and PCR)

- 1. PML/RARA rearrangement analysis via fluorescent in situ hybridization (FISH) in peripheral blood or bone marrow is considered **medically necessary** when:
 - A. The member is undergoing initial diagnostic work up for acute myeloid leukemia (AML).

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Tumor Specific RET Gene Rearrangement Tests (FISH)

- 1. Tumor specific RET gene rearrangement testing via fluorescent in situ hybridization (FISH) in solid tumors is considered **medically necessary** when:
 - A. The member has a diagnosis of:
 - i. Recurrent or persistent locoregional or metastatic medullary thyroid cancer, and
 - a) Germline testing for RET mutations is negative or has not been done, or
 - B. Anaplastic thyroid carcinoma, **or**
 - C. Locally recurrent, advanced and/or metastatic papillary thyroid carcinoma, or
 - D. Locally recurrent, advanced and/or metastatic follicular thyroid carcinoma, or
 - E. Locally recurrent, advanced and/or metastatic oncocytic carcinoma (formerly called Hurthle cell carcinoma), **or**
 - F. Advanced or metastatic adenocarcinoma of the lung, or
 - G. Advanced or metastatic large cell cancer of the lung, or
 - H. Advanced or metastatic non small-cell cancer of the lung, not otherwise specified, or
 - I. Locally advanced or metastatic squamous cell carcinoma of the cervix, **or**,
 - J. Locally advanced or metastatic adenocarcinoma of the cervix, or
 - K. Locally advanced or metastatic adenosquamous carcinoma of the cervix, or
 - L. Recurrent unresectable or stage IV breast cancer, or
 - M. Suspected or confirmed metastatic colon cancer, or
 - N. Resectable, borderline resectable, locally advanced or metastatic pancreatic adenocarcinoma, **or**
 - O. Locally advanced, recurrent or metastatic esophageal or esophagogastric junction cancer,

or D

- P. Locally advanced, recurrent or metastatic gastric cancer, or
- Q. Recurrent or metastatic vaginal cancer.





Tumor Specific ROS1 Gene Rearrangement

- 1. Tumor specific ROS1 gene rearrangement analysis via fluorescent in situ hybridization (FISH) in solid tumors is considered **medically necessary** when:
 - A. The member has a diagnosis of:
 - Advanced or metastatic lung adenocarcinoma, or
 - ii. Advanced or metastatic large cell lung carcinoma, or
 - Advanced or metastatic squamous cell lung carcinoma, or
 - iv. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS). **or**
 - v. Locally advanced or metastatic ampullary adenocarcinoma, or
 - vi. Resectable or borderline resectable, or locally advanced, or metastatic pancreatic adenocarcinoma, **or**
 - vii. Pediatric (diagnosed age 18 years or younger) diffuse high-grade glioma.

Definitions

1. **Advanced cancer:** Cancer that is unlikely to be cured or controlled with treatment. The cancer may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body. Treatment may be given to help shrink the tumor, slow the growth of cancer cells, or relieve symptoms.

Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

Approved Medical Director Committee 6/17/2021; Revised 9/27/2023, 03/12/2024, 9/11/2024; Reviewed 12/2021, 7/2022, 1/2023, 7/2023, 1/2024, 7/2024, 1/2025

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