CONCERT GENETICS ONCOLOGY: CYTOGENETIC TESTING

See Important Reminder at the end of this policy for important regulatory and legal information.

OVERVIEW

Cytogenetic analysis of solid tumors and hematologic malignancies aims to both classify the type of tumor or cancer present and also to identify somatic oncogenic mutations in cancer. These mutations, often called “driver” mutations, are becoming increasingly useful for targeted therapy selection, and may give insight into prognosis and treatment response in a subset of cancers. In addition, molecular analysis of solid tumors and hematologic malignancies, in particular, can also aid in making a diagnosis of a specific type of malignancy. For solid tumors, molecular analysis can be performed via direct testing of the tumor (which is addressed in this policy) or via circulating tumor DNA or circulating tumor cells (CTCs) (see Other Related Policies). For hematologic malignancies, molecular analysis can be performed on blood samples or bone marrow biopsy samples (skin or buccal cells/saliva is occasionally used in patients who have received a hematopoietic stem cell transplant).

POLICY REFERENCE TABLE

Below is a list of higher volume tests and the associated laboratories for each coverage criteria section. This list is not all inclusive.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2022, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage.

Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes	Ref
Tumor Specific *ALK* Gene Rearrangement (Qualitative FISH and PCR) Tests	*ALK* Gene Rearrangements (LabCorp)	88271, 88274, 88275, 88291	C34, C73	1, 4
Tumor Specific BCR/ABL Gene Rearrangement (Qualitative FISH and PCR) Tests	Detection by FISH of t(9;22) BCR/ABL (CGC Genetics) BCR/ABL t(9;22) (NeoGenomics Laboratories) BCR ABL Qualitative (Cincinnati Children's Hospital)	81479, 88271, 88274, 88275, 88291	C91.00 through C91.02, C92.0 through C92.12, D45, D47.1, D47.3, D69.3	7, 8, 9, 10, 11
Bladder Cancer Diagnostic and Recurrence FISH Tests	UroVysion® FISH (ARUP Laboratories)	88120, 88121	C67, D09.0, D49.4, R31.9, Z85.51	16, 18
Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis	FISH CLL Panel, Blood (Johns Hopkins Medical Institutions - Pathology Laboratory) FISH, B-Cell Chronic Lymphocytic Leukemia Panel (Quest Diagnostics)	88271, 88274, 88275, 88291	C91, C94, C95, Z85.6	12
Tumor Specific *ERBB2* (*HER2*) 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	2, 5, 6, 13, 14
Multiple Myeloma FISH Panel Analysis	Multiple Myeloma Panel by FISH (ARUP Laboratories)	88271, 88274, 88275, 88291	C90	15

	FISH Profile Multiple Myeloma, Bone Marrow (Johns Hopkins Medical Institutions - Pathology Laboratory)			
NTRK Fusion Analysis Panel	NTRK NGS Fusion Panel (NeoGenomics)	81191, 81192, 81193, 81194	C15, C16, C18, C34, C49.9, C50, C51, C53, C54, C73, C80.1, C91	2, 3, 4, 5, 6, 10, 11, 13, 17, 19, 20, 21
Tumor Specific *PD-L1* Protein Analysis Fusion	PD-L1, IHC with Interpretation (Quest Diagnostics)	88341, 88342, 88360, 88361	C11, C15, C16, C34, C50, C51, C53, C67	1, 3, 5, 6, 13, 14, 16, 17
Tumor Specific *PML*/*RARA* Gene Rearrangement (Qualitative FISH and PCR)	FISH, AML M3, PML/RARA, Translocation 15, 17 (Quest Diagnostics)	88271, 88274, 88275, 88291	C91 through C95	7
Tumor Specific *ROS1* Gene Rearrangement	FISH ROS1 Rearrangement (Johns Hopkins Medical Institutions-Pathology Laboratory)	88271, 88274	C34	1

OTHER RELATED POLICIES

This policy document provides coverage criteria for ONCOLOGY: CYTOGENETIC TESTING. Please refer to:

- ***Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies*** for criteria related to DNA testing of a solid tumor or a blood cancer.
- ***Genetic Testing: Hereditary Cancer Susceptibility Syndromes*** for coverage criteria related to genetic testing for hereditary cancer predisposition syndromes.
- ***Oncology: Cancer Screening*** for coverage criteria related to the use of non-invasive fecal, urine, or blood tests for screening for cancer.

- ***Oncology: Circulating Tumor DNA and Circulating Tumor Cells (Liquid Biopsy)*** for criteria related to circulating tumor DNA (ctDNA) or circulating tumor cell testing performed on peripheral blood for cancer diagnosis, management, and surveillance.
- ***Oncology: Algorithmic Testing*** for coverage criteria related to gene expression profiling and tumor biomarker tests with algorithmic analyses.
- ***Genetic Testing: Exome and Genome Sequencing for the Diagnosis of Genetic Disorders*** for coverage criteria related to whole genome and whole exome sequencing in rare genetic syndromes.
- ***Genetic Testing: General Approach to Genetic Testing*** for coverage criteria related to cytogenetic testing in oncology that is not specifically discussed in this or another non-general policy.

CRITERIA

It is the policy of health plans affiliated with Centene Corporation® that the specific genetic testing noted below is **medically necessary** when meeting the related criteria:

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

I. Somatic *ALK* rearrangement analysis (88271, 88274, 88275, 88291) in solid tumors is considered **medically necessary** when:

A. The member/enrollee has a diagnosis of or is in the initial work up stage for:

1. Advanced or metastatic lung adenocarcinoma, **OR**
2. Advanced or metastatic large cell lung carcinoma, **OR**
3. Advanced or metastatic squamous cell lung carcinoma, **OR**
4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **OR**
5. Anaplastic thyroid carcinoma.

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Tumor Specific *BCR/ABL* Gene Rearrangement (Qualitative FISH and PCR) Tests

I. Somatic *BCR/ABL1* rearrangement analysis via fluorescent in situ hybridization (FISH) (88271, 88274, 88275, 88291) or PCR (81479) in peripheral blood or bone marrow is considered **medically necessary** when:

   A. The member/enrollee is suspected to have a myeloproliferative neoplasm (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, or chronic myeloid leukemia), **OR**

   B. The member/enrollee is undergoing diagnostic workup for:

      1. Acute lymphoblastic leukemia (ALL), **OR**
      2. Acute myeloid leukemia (AML), **OR**
      3. Chronic myelogenous leukemia (CML)

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Bladder Cancer Diagnostic and Recurrence FISH Tests

I. Bladder cancer diagnostic and recurrence FISH tests (88120, 88121) for the screening, diagnosis of, and monitoring for bladder cancer are considered **investigational**.

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

I. Chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) FISH panel analysis (88271, 88274, 88275, 88291) 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/enrollee 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)

I. Somatic *ERBB2 (HER2*) amplification analysis via in situ hybridization (ISH) (i.e., FISH or CISH) (88360, 88377) in solid tumors is considered **medically necessary** when:

A. The member/enrollee has any of the following:

1. Recurrent or newly diagnosed stage I through IV invasive breast cancer, **OR**
2. Inoperable locally advanced, recurrent, or metastatic gastric cancer and trastuzumab (or FDA-approved equivalent medication) is being considered for treatment, **OR**
3. Suspected or proven metastatic synchronous colorectal cancer or documented metachronous metastases by CT, MRI, and/or biopsy, **OR**
4. Suspected or proven metastatic esophageal and/or esophagogastric junction adenocarcinoma, **OR**
5. Recurrent, unresectable, or metastatic salivary gland tumors.

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Multiple Myeloma FISH Panel Analysis

I. Multiple myeloma FISH panel analysis (88271, 88274, 88275, 88291) 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/enrollee is undergoing initial diagnostic workup for multiple myeloma.

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NTRK Fusion Analysis Panel

I. Somatic *NTRK 1/2/3* fusion analysis (81191, 81192, 81193, 81194) via fluorescent in situ hybridization (FISH) or immunohistochemistry (IHC) in solid tumors is considered **medically necessary** when:

A. The member/enrollee is undergoing initial diagnostic workup for or has a diagnosis of:

1. Advanced or metastatic lung adenocarcinoma, **OR**
2. Advanced or metastatic large cell lung carcinoma, **OR**
3. Advanced or metastatic squamous cell lung carcinoma, **OR**
4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **OR**
5. Unknown primary cancers, **OR**
6. Advanced or metastatic colorectal cancer, **OR**
7. Cervical sarcoma, **OR**
8. Recurrent, progressive, or metastatic vulvar cancer, **OR**
9. Recurrent or metastatic endometrial carcinoma or a diagnosis of uterine sarcoma, **OR**
10. Recurrent unresectable or stage IV invasive breast cancer, **OR**
11. Unresectable locally advanced, recurrent, or metastatic gastric cancer, **OR**
12. Unresectable locally advanced, recurrent, or metastatic esophageal cancer, **OR**
13. Anaplastic thyroid carcinoma or locally recurrent, advanced,and/or metastatic papillary, follicular, or Hurthle cell thyroid carcinoma, **OR**
14. Acute lymphoblastic leukemia (ALL), **OR**
15. Soft tissue sarcoma.

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Tumor Specific *PD-L1* Protein Analysis Fusion

I. *PD-L1* protein expression analysis via immunohistochemistry (IHC) (88341, 88342, 88360, 88361) in solid tumors is considered **medically necessary** when:

A. The member/enrollee has a diagnosis of or is in the initial work up stage for:

1. Advanced or metastatic lung adenocarcinoma, **OR**
2. Advanced or metastatic large cell lung carcinoma, **OR**
3. Advanced or metastatic squamous cell lung carcinoma, **OR**
4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **OR**
5. Locally advanced or metastatic bladder cancer, **OR**
6. Recurrent, progressive, or metastatic cervical cancer (squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma), **OR**
7. Recurrent or stage IV triple negative breast cancer, **OR**
8. Suspected or proven metastatic esophageal and/or esophagogastric junction adenocarcinoma, **OR**
9. Suspected or proven metastatic gastric adenocarcinoma, **OR**
10. Recurrent, unresectable, oligometastatic, or metastatic nasopharyngeal cancer, **OR**
11. Recurrent, progressive or metastatic vulvar 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 *PML/RARA* Gene Rearrangement (Qualitative FISH and PCR)

I. *PML/RARA* rearrangement analysis via fluorescent in situ hybridization (FISH) (88271, 88274, 88275, 88291) in peripheral blood or bone marrow is considered **medically necessary** when:

A. The member/enrollee is undergoing initial diagnostic work up for acute myeloid leukemia (AML).

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Tumor Specific *ROS1* Gene Rearrangement

I. Somatic *ROS1* rearrangement analysis via fluorescent in situ hybridization (FISH) (88271, 88274) in solid tumors is considered **medically necessary** when:

A. The member/enrollee has a diagnosis of:

1. Advanced or metastatic lung adenocarcinoma, **OR**
2. Advanced or metastatic large cell lung carcinoma, **OR**
3. Advanced or metastatic squamous cell lung carcinoma, **OR**
4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS).

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NOTES AND DEFINITIONS

Advanced cancer is 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.

BACKGROUND AND RATIONALE

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

National Comprehensive Cancer Network (NCCN)

The NCCN Thyroid Carcinoma guidelines (3.2022) recommend that individuals with anaplastic thyroid cancer should undergo molecular testing including *BRAF, NTRK, ALK, RET*, MSI, dMMR, and tumor mutational burden if not previously done (p. ANAP-1).

NCCN Non-Small Cell Lung Cancer guidelines (2.2023) recommend *ALK* rearrangement testing in patients with advanced or metastatic disease of lung Adenocarcinoma, Large Cell, Squamous cell, or NSCLC not otherwise specified (NOS). (p. NSCL-18)

Tumor Specific *BCR/ABL* Gene Rearrangement (Qualitative FISH and PCR) Tests

National Comprehensive Cancer Network (NCCN)

NCCN Acute Lymphoblastic Leukemia guidelines (1.2022) recommend *BCR/ABL* rearrangement analysis for patients for the diagnosis/workup of ALL. (p. ALL-1)

NCCN Acute Myeloid Leukemia guidelines (3.2022) recommend *BCR/ABL* rearrangement analysis for patients to stratify risk for AML. (p. AML-A 1 of 4)

NCCN Pediatric Acute Lymphoblastic Leukemia guidelines (1.2023) recommend *BCR/ABL* rearrangement analysis for patients for the diagnosis/work-up of ALL. (p. PEDALL-1)

NCCN Chronic Myeloid Leukemia guidelines (1.2023) recommend *BCR/ABL* rearrangement analysis for patients for the diagnosis/work-up of CML. (p. CML-1)

NCCN Myeloproliferative Neoplasms guidelines (3.2022) recommend *BCR/ABL* rearrangement analysis for patients during the workup of suspected MPN. (p. MPN-1)

Bladder Cancer Diagnostic and Recurrence FISH Tests

National Comprehensive Cancer Network (NCCN)

NCCN Bladder Cancer guidelines (1.2023) do not currently mention a recommendation for the use of bladder cancer diagnostic and recurrence FISH tests. (e.g., Urovysion)

American Urological Association and Society of Urologic Oncology

The American Urological Association and Society of Urologic Oncology (2016) addressed the diagnosis and treatment of non-muscle-invasive bladder cancer, based on a systematic review and includes the following statements on the use of urine markers after the diagnosis of bladder cancer:

- Urinary biomarker analysis should not replace cystoscopic evaluation in the surveillance of non-muscle invasive bladder cancer (NMIBC). (Strong Recommendation; Evidence Strength: Grade B)

- Urinary biomarker analysis or cytology should not routinely be used during surveillance in a patient with a history of low-risk cancer and a normal cystoscopy. (Expert Opinion)
- Urinary biomarker analysis may be used to assess response to intravesical BCG (UroVysion FISH) and adjudicate equivocal cytology (UroVysion FISH and ImmunoCyt) in a patient with NMIBC. (Expert Opinion) (p. 1024 and 1025)

Note: "Evidence Strength B" describes a recommendation of moderate certainty. "Expert Opinion" is defined in this guideline as "A statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge, and judgment for which there is no evidence." (p. 1022)

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

National Comprehensive Cancer Network (NCCN)

NCCN Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma guidelines (2.2023) recommend FISH testing for the rearrangements specified (at a minimum) during the diagnostic workup for CLL/SLL, including: +12, del(11q), del(13q), and del(17p). (p. CSLL-1)

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

National Comprehensive Cancer Network (NCCN)

NCCN Esophageal and Esophagogastric Junction Cancers guidelines (5.2022) recommend HER2/*ERBB2* testing during the workup of documented or suspected metastatic adenocarcinoma. (p. ESOPH-1)

NCCN Head and Neck Cancers guidelines (1.2023) recommend HER2/*ERBB2* testing for therapeutic options for individuals diagnosed with recurrent, unresectable, or metastatic salivary gland tumors. (p. SALI-B 1 of 2)

NCCN Colon Cancer guidelines (3.2022) recommend HER2/*ERBB2* testing during the workup for suspected or proven metastatic synchronous colorectal cancer (p. COL-4) or documented metachronous metastases by CT, MRI and/or biopsy. (p. COL-9)

NCCN Gastric Cancer guidelines (2.2022) recommend HER2/*ERBB2* testing for patients in the following clinical scenarios: locally advanced, recurrent, or metastatic adenocarcinoma of the stomach, for whom trastuzumab therapy (or FDA-approved equivalent medication) is being considered for treatment. (p. GAST-B 3 of 6).

NCCN Breast Cancer guidelines (2.2023) recommend HER2/*ERBB2* testing be performed on all patients with newly diagnosed primary or metastatic breast cancer. (p. BINV-A 1 of 2)

Multiple Myeloma FISH Panel Analysis

National Comprehensive Cancer Network (NCCN)

NCCN Multiple Myeloma guidelines (3.2023) recommend FISH testing during the initial workup of multiple myeloma for prognostic purposes. The recommended FISH testing includes: del(13), del (17p13), t(4;14), t(11;14), t(14;16), t(14:20), 1q21 gain/1q21 amplification, 1p deletion. (p. MYEL-1)

***NTRK* Fusion Analysis Panel**

National Comprehensive Cancer Network (NCCN)

The NCCN Thyroid Carcinoma guidelines (3.2022) recommend that individuals with anaplastic thyroid cancer or locally recurrent, advanced, and/or metastatic papillary, follicular, and Hurthle cell carcinoma should undergo molecular testing including *BRAF, NTRK, ALK, RET*, MSI, dMMR, and tumor mutational burden if not previously done. (p. ANAP-1, p. PAP-9, p. FOLL-8, p. HURT-8)

The NCCN Colon Cancer guidelines (3.2022) recommends *NTRK* fusion analysis for patients with advanced or metastatic colorectal cancer. (p. COL-B 5 of 8)

The NCCN Non-Small Cell Lung Cancer guidelines (2.2023) recommends *NTRK* fusion analysis for patients with advanced or metastatic disease of lung Adenocarcinoma, Large Cell, Squamous cell carcinoma, and NSCLC not otherwise specified (NOS). (p. NSCL-18)

The NCCN Occult Primary guidelines (3.2023) recommends *NTRK* fusion analysis for cancer of unknown primary. (p. OCC-A 1 of 5)

The NCCN Cervical Cancer guidelines (1.2023) recommends *NTRK* fusion analysis for patients with cervical sarcoma. (p. CERV-A 1 of 3).

The NCCN Vulvar Cancer guidelines (1.2023) recommends *NTRK* fusion analysis for recurrent, progressive, or metastatic vulvar cancer. (p. VULVA-A 1 of 3)

The NCCN Uterine Neoplasms guidelines (1.2023) recommends *NTRK* fusion analysis for recurrent or metastatic endometrial carcinoma (p. ENDO-A 2 of 4) or a diagnosis of uterine sarcoma. (p. UTSARC-A 1 of 8)

The NCCN Breast Cancer guidelines (2.2023) recommends *NTRK* fusion analysis for recurrent unresectable or stage IV invasive breast cancer. (p. BINV-R 1 of 3)

The NCCN Gastric Cancer guidelines (2.2022) recommends *NTRK* fusion analysis for unresectable locally advanced, recurrent, or metastatic gastric cancer. (p. GAST-B 5 of 6, p. GAST-F 4 of 16)

The NCCN Esophageal and Esophagogastric Junction Cancer guidelines (5.2022) recommends *NTRK* fusion analysis for unresectable, locally advanced, recurrent, or metastatic esophageal cancer. (p. ESOPH-B 5 of 6, p. ESOPH-F 4 of 17)

The NCCN Acute Lymphoblastic Leukemia guidelines (1.2022) and Pediatric Acute Lymphoblastic Leukemia guidelines (1.2023) recommend *NTRK* fusion analysis for acute lymphoblastic leukemia (ALL). (p. ALL-A 1 of 2; p. PEDALL-A)

The NCCN Soft Tissue Sarcoma guidelines (2.2022) recommends *NTRK* fusion analysis for soft tissue sarcoma to guide medical management. (p. SARC-F 1 of 11)

Tumor Specific *PD-L1* Protein Analysis Fusion

National Comprehensive Cancer Network (NCCN)

The NCCN Gastric Cancer guidelines (2.2022) recommends *PD-L1* testing during the workup for documented or suspected metastatic adenocarcinoma. (p. GAST-1)

The NCCN Head and Neck Cancers guidelines (1.2023) recommends *PD-L1* testing during the workup phase for recurrent, unresectable, oligometastatic, or metastatic cancer of the nasopharynx. (p. NASO-B 1 of 3)

NCCN Bladder Cancer guidelines (1.2023) recommend *PD-L1* testing in individuals with locally advanced or metastatic (stage IV) bladder cancer to guide medical management. (p. BL-G 2 of 7)

The NCCN Vulvar Cancer guidelines (1.2023) recommends *PD-L1* testing for individuals with recurrent, progressive, or metastatic vulvar cancer. (p. VULVA-A 1 of 3)

The NCCN Esophageal and Esophagogastric Junction Cancers guidelines (5.2022) recommends *PD-L1* testing for individuals during the workup phase for documented or suspected metastatic esophageal and esophagogastric junction cancers. (p. ESOPH-1)

The NCCN Cervical Cancer guidelines (1.2023) recommends *PD-L1* testing for individuals with recurrent, progressive, or metastatic cervical cancer of the following pathologies: squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma. (p. CERV-A 1 of 3)

NCCN Non-Small Cell Lung Cancer guidelines (2.2023) recommend *PD-L1* testing in patients with advanced or metastatic disease of the following lung cancer pathologies: Adenocarcinoma, Large Cell, Squamous cell, and NSCLC not otherwise specified (NOS). (p. NSCL-18)

The NCCN Breast Cancer guidelines (2.2023) recommends *PD-L1* testing for individuals with recurrent or stage IV triple negative breast cancer. (p. BINV-R 1 of 3)

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

National Comprehensive Cancer Network (NCCN)

NCCN Acute Myeloid Leukemia guidelines (3.2022) state that many different types of gene mutations are associated with specific prognoses, helping to guide medical management decisions, and/or may indicate that specific therapeutic agents are useful. Therefore, all patients with AML should be tested for these mutations. (p. EVAL-1A). The discussion section of this guideline states that PML-RAR alpha is included in this group of genetic markers that should be tested in all patients. (p. MS-3)

Tumor Specific *ROS1* Gene Rearrangement

National Comprehensive Cancer Network (NCCN)

NCCN Non-Small Cell Lung Cancer guidelines (2.2023) recommend *ROS1* rearrangement testing in patients with advanced or metastatic disease of the following lung cancer pathologies: Adenocarcinoma, Large Cell, Squamous Cell, and NSCLC not otherwise specified (NOS). (p. NSCL-18)

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Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed	03/23	03/23

REFERENCES

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage

decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.