

Clinical Policy: Oncology Cytogenetic Testing

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[Coding Implications](#)

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Description

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).

Below is a list of higher volume tests and the associated laboratories for each criteria section.

This list is not all inclusive

CPT® Codes	Example Tests (Labs)	Criteria Section	Common ICD Codes
88271, 88274, 88275, 88291	ALK Rearrangement, FISH	ALK Rearrangement Analysis	C34, C73
88271, 88274, 88275, 88291	BCR-ABL FISH	BCR/ABL Rearrangement Analysis	C91.00-C91.02, D45, D47.1, D47.3
88120, 88121	UroVysion®, Abbott Molecular	Bladder Cancer Diagnostic and Recurrence FISH Tests	C67.0-C67.9, D09.0, D49.4, R31.9, Z85.51
88271, 88274, 88275, 88291	FISH CLL Panel, Blood (Johns Hopkins Medical Institutions - Pathology Laboratory)	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis	C91, C94, C95, Z85.6
88271, 88274, 88275, 88291	Chronic Lymphocytic Leukemia (CLL) Profile, FISH (LabCorp)	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis	C91, C94, C95, Z85.6
88271, 88274, 88275, 88291	Chronic Lymphocytic Leukemia (CLL) Prognostic Panel,	Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) FISH Panel Analysis	C91, C94, C95, Z85.6

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CPT® Codes	Example Tests (Labs)	Criteria Section	Common ICD Codes
	Comprehensive (Quest Diagnostics)		
88341, 88342, 88360, 88361	ERBB2 FISH (or CISH) Analysis	ERBB2 (HER2) Amplification Analysis	C08, C15, C16, C18, C19, C20, C50
88271, 88274, 88275, 88291	Myeloma, FISH, Fixed Cells (Mayo Medical Laboratories) Multiple Myeloma (MM) Profile, FISH (LabCorp) Multiple Myeloma Panel by FISH (ARUP Laboratories) FISH Profile Multiple Myeloma, Blood (Johns Hopkins Medical Institutions - Pathology Laboratory)	Multiple Myeloma FISH Panel Analysis	C90
88271, 88274, 88275, 88291, 88341, 88342, 88360, 88361, 88373, 88374, 88377	NTRK1/2/3 FISH Analysis	NTRK Fusion Analysis	C00-D49
88341, 88342, 88360, 88361	PD-L1 IHC Analysis	PD-L1 Protein Expression Analysis	C00-D49
88271, 88274, 88275, 88291	PML/RARA Rearrangement Analysis	PML/RARA Rearrangement Analysis	C91-C95
88271, 88274, 88275, 88291, 88373, 88374, 88377	ROS1 FISH Analysis	ROS1 Rearrangement Analysis	C34

This policy document provides criteria for Oncology: Cytogenetic Testing. Please refer to:

- **CP.MP.241 Oncology: Molecular Analysis of Solid Tumors and Hematologic Malignancies** for criteria related to DNA testing of a solid tumor or a blood cancer.

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- **CP.MP.225 Genetic Testing: Hereditary Cancer Susceptibility Syndromes** for criteria related to genetic testing for hereditary cancer predisposition syndromes.
- **CP.MP.238 Oncology: Cancer Screening** for criteria related to the use of non-invasive fecal, urine, or blood tests for screening for cancer.
- **CP.MP.239 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.
- **CP.MP.237 Oncology: Algorithmic Testing** for criteria related to gene expression profiling and tumor biomarker tests with algorithmic analyses.
- **CP.MP.219 Genetic Testing: Exome and Genome Sequencing for the Diagnosis of Genetic Disorders** for criteria related to whole genome and whole exome sequencing in rare genetic syndromes.
- **CP.MP.222 Genetic Testing: General Approach to Genetic Testing** for criteria related to cytogenetic testing in oncology that is not specifically discussed in this or another non-general policy.

Policy/Criteria

ALK Rearrangement Analysis

- I. It is the policy of health plans affiliated with Centene Corporation® that 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 any of the following:
 1. Advanced or metastatic lung adenocarcinoma,
 2. Advanced or metastatic large cell lung carcinoma,
 3. Advanced or metastatic squamous cell lung carcinoma,
 4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS),
 5. Anaplastic thyroid carcinoma.

BCR/ABL Rearrangement Analysis

- I. It is the policy of health plans affiliated with Centene Corporation® that somatic *BCR/ABL1* rearrangement analysis via fluorescent in situ hybridization (FISH) (88271, 88274, 88275, 88291) in peripheral blood or bone marrow is considered **medically necessary** when meeting either of the following:

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- A. The member/enrollee is suspected to have a myeloproliferative neoplasm (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, chronic myeloid leukemia),
- B. The member/enrollee is undergoing diagnostic workup for any of the following:
 - 1. Acute lymphoblastic leukemia (ALL),
 - 2. Acute myeloid leukemia (AML),
 - 3. Chronic myelogenous leukemia (CML),
 - 4. Lymphoblastic leukemia,
 - 5. Gastrointestinal stromal tumor (GIST).

Bladder Cancer Diagnostic and Recurrence FISH Tests

- I. It is the policy of health plans affiliated with Centene Corporation[®] that current evidence does not support bladder cancer diagnostic and recurrence FISH tests (e.g., Urovysion) (88120, 88121) for the screening, diagnosis of, and monitoring for bladder cancer.

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

- I. It is the policy of health plans affiliated with Centene Corporation[®] that 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 meeting both of the following:
 - A. The panel includes analysis for +12, del(11q), del(13q), and del(17p),
 - B. The member/enrollee is undergoing initial diagnostic workup for chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL).

ERBB2 (HER2) Amplification Analysis

- I. It is the policy of health plans affiliated with Centene Corporation[®] that somatic ERBB2 (HER2) amplification analysis via in situ hybridization (ISH) (i.e., FISH or CISH) (88341, 88342, 88360, 88361) in solid tumors is considered **medically necessary** when:
 - A. The member/enrollee has any of the following:
 - 1. Recurrent or newly diagnosed stage I-IV invasive breast cancer,
 - 2. Suspected or proven metastatic gastric cancer,
 - 3. Suspected or proven metastatic, synchronous or metachronous colorectal cancer or documented metachronous metastases by CT, MRI and/or biopsy,

4. Suspected or proven metastatic esophageal and/or esophagogastric junction adenocarcinoma,
5. Metastatic salivary gland tumors with distant metastases.

Multiple Myeloma FISH Panel Analysis

- I. It is the policy of health plans affiliated with Centene Corporation® that multiple myeloma FISH panel analysis (88271, 88274, 88275, 88291) in bone marrow is considered **medically necessary** when meeting both of the following:
 - 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),
 - B. The member/enrollee is undergoing initial diagnostic workup for multiple myeloma.

NTRK Fusion Analysis

- I. It is the policy of health plans affiliated with Centene Corporation® that somatic NTRK 1/2/3 fusion analysis (88271, 88274, 88275, 88291, 88341, 88342, 88360, 88361, 88373, 88374, 88377) 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 any of the following:
 1. Advanced or metastatic lung adenocarcinoma,
 2. Advanced or metastatic large cell lung carcinoma,
 3. Advanced or metastatic squamous cell lung carcinoma,
 4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS),
 5. Unknown primary cancers,
 6. Advanced or metastatic colorectal cancer,
 7. Recurrent, progressive or metastatic cervical cancer,
 8. Recurrent, progressive or metastatic vulvar cancer,
 9. Recurrent or metastatic uterine cancer or a diagnosis of uterine sarcoma,
 10. Recurrent or stage IV invasive breast cancer,
 11. Locally advanced, recurrent or metastatic gastric cancer,
 12. Locally advanced, recurrent or metastatic esophageal cancer,

13. Anaplastic thyroid carcinoma or locally recurrent, advanced and/or metastatic papillary, follicular or Hurthle cell thyroid carcinoma,
14. Pediatric acute lymphoblastic leukemia (ALL),
15. Soft tissue sarcoma and previous tumor testing was negative for *KIT* and *PDGFRA* somatic mutations.

PD-L1 Protein Expression Analysis

- I. It is the policy of health plans affiliated with Centene Corporation[®] that 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 any of the following:
 1. Advanced or metastatic lung adenocarcinoma,
 2. Advanced or metastatic large cell lung carcinoma,
 3. Advanced or metastatic squamous cell lung carcinoma,
 4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS),
 5. Locally advanced or metastatic bladder cancer,
 6. Recurrent, progressive, or metastatic cervical cancer,
 7. Recurrent or stage IV triple negative breast cancer,
 8. Suspected or proven metastatic esophageal and/or esophagogastric junction adenocarcinoma,
 9. Suspected or proven metastatic gastric cancer,
 10. Recurrent, unresectable, or metastatic nasopharyngeal cancer,
 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

PML/RARA Rearrangement Analysis

- I. It is the policy of health plans affiliated with Centene Corporation[®] that 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 leukemia.

ROS1 Rearrangement Analysis

- I. It is the policy of health plans affiliated with Centene Corporation® that somatic ROS1 rearrangement analysis via fluorescent in situ hybridization (FISH) (88271, 88274, 88275, 88291, 88373, 88374, 88377) in solid tumors is considered **medically necessary** when:
 - A. The member/enrollee has a diagnosis of any of the following:
 1. Advanced or metastatic lung adenocarcinoma,
 2. Advanced or metastatic large cell lung carcinoma,
 3. Advanced or metastatic squamous cell lung carcinoma,
 4. Advanced or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS)

Background

American Society of Clinical Oncology (ASCO)

Lung Cancer

The American Society of Clinical Oncology (2018) endorsed the College of American Pathologists/International Association for the Study of Lung cancer/Association of Molecular Pathology Clinical Practice Guideline Update for Molecular Testing for the Selection of Patients with Lung Cancer for Treatment with Targeted Tyrosine Kinase Inhibitors which recommends that physicians should use molecular testing for the appropriate genetic targets on either primary or metastatic lung lesions to guide initial therapy selection. They further recommend that multiplexed genetic sequencing panels are preferred where available over multiple single gene tests to identify other treatment options beyond *EGFR*, *ALK*, *BRAF*, and *ROS1*. The panel recommends that *EGFR*, *ALK*, *ROS1* and *BRAF* testing should be performed on all patients with advanced lung adenocarcinoma. They went on to state that *RET*, *HER2*, *KRAS*, and *MET* molecular testing are not indicated as stand alone tests but are appropriate to include as part of a larger testing panel

Multiple Myeloma

ASCO and Cancer Care Ontario (CCO) published a joint clinical practice guideline for the treatment of multiple myeloma (2019) that included the following:

- Recommendation 3.5. There is insufficient evidence to make modifications to maintenance therapy based on depth of response, including minimal residual disease (MRD) status (Type: informal consensus/evidence based; Evidence quality: low/intermediate, benefit outweighs harm; Strength of recommendation: moderate).
- Recommendation 4.2. The goal of initial therapy for transplant-eligible patients should be achievement of the best depth of remission. MRD-negative status has been associated with improved outcomes, but it should not be used to guide treatment goals outside the

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context of a clinical trial (Type: evidence based; Evidence quality: high, benefit outweighs harm; Strength of recommendation: moderate).

- Recommendation 8.2. Repeat risk assessment at the time of relapse should be performed and should include bone marrow with fluorescence in situ hybridization for myeloma abnormalities seen with progression, including 17p and 1q abnormalities. Fluorescence in situ hybridization for primary abnormalities (translocations and trisomies), if seen in the initial diagnostic marrow, does not need to be repeated (Type: evidence based; Evidence quality: high, benefit outweighs harm; Strength of recommendation: strong).

National Comprehensive Cancer Network (NCCN):

ALK Rearrangement Analysis

The NCCN (1.2021) guidelines on thyroid carcinoma recommend molecular diagnostic testing for evaluating FNA results that are suspicious for follicular cell neoplasms or AUS/FLUS and somatic RET testing in all individuals with newly diagnosed medullary thyroid carcinoma. Additionally they comment that molecular testing has shown to be beneficial when making targeted therapy decisions. The guideline also comments that individuals with anaplastic thyroid cancer and/or metastatic disease should undergo molecular testing including BRAF, NTRK, ALK, RET, MSI, dMMR, and tumor mutational burden if not previously done.

NCCN guidelines on non-small cell lung cancer (v.5.2021) recommend ALK rearrangement testing in patients with Advanced or metastatic disease: Adenocarcinoma, Large Cell, Squamous cell, and NSCLC not otherwise specified (NOS).

BCR/ABL Rearrangement Analysis

NCCN guidelines for acute lymphoblastic leukemia (v.1.2021) recommend BCR/ABL rearrangement analysis for patients for the diagnosis/workup of ALL.

NCCN guidelines for acute myeloid leukemia (v3.2021) recommend BCR/ABL rearrangement analysis for patients for the evaluation of acute leukemia.

NCCN guidelines for pediatric acute lymphoblastic leukemia (v.2.2021) recommend BCR/ABL rearrangement analysis for patients for the diagnosis/work-up of ALL.

NCCN guidelines for chronic myeloid leukemia (v.1.2022) recommend BCR/ABL rearrangement analysis for patients for the diagnosis/work-up of CML.

NCCN guidelines for myeloproliferative neoplasms (v.1.2021) recommend BCR/ABL rearrangement analysis for patients during the workup of suspected MPN.

Bladder Cancer Diagnostic and Recurrence FISH Tests

NCCN guidelines for bladder cancer (v.3.2021) do not currently recommend the use of bladder cancer diagnostic and recurrence FISH tests (e.g., Urovysion).

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

NCCN guidelines for CLL/SLL (v.1.2022) recommend consideration of FISH testing for the rearrangements specified (at a minimum) during the diagnostic workup for CLL/SLL.

ERBB2 (HER2) Amplification Analysis

NCCN guidelines for esophageal and esophagogastric junction cancers (v.4.2021) recommend ERBB2 testing during the workup of documented or suspected metastatic adenocarcinoma.

NCCN guidelines for head and neck cancers (v.3.2021) recommend ERBB2 testing for therapeutic options for individuals diagnosed with recurrent, unresectable or metastatic salivary gland tumor.

NCCN guidelines for colon cancer (v.2.2021) recommend ERBB2 testing during the workup for suspected or proven metastatic, synchronous or metachronous colorectal cancer or documented metachronous metastases by CT, MRI and/or biopsy

NCCN guidelines for gastric cancer (v.3.2021) recommend ERBB2 testing during the workup of documented or suspected metastatic adenocarcinoma.

NCCN guidelines for breast cancer (v.5.2021) recommend ERBB2 testing during the workup of recurrent or newly diagnosed stage I-IV invasive breast cancer.

Multiple Myeloma FISH Panel Analysis

NCCN guidelines for multiple myeloma (v.1.2022) recommend FISH testing during the initial workup of multiple myeloma for prognostic purposes.

NTRK Fusion Analysis

The NCCN (1.2021) guidelines on thyroid carcinoma recommend molecular diagnostic testing for evaluating FNA results that are suspicious for follicular cell neoplasms or AUS/FLUS and somatic RET testing in all individuals with newly diagnosed medullary thyroid carcinoma. Additionally they comment that molecular testing has shown to be beneficial when making targeted therapy decisions. The guideline also comments that individuals with anaplastic thyroid cancer and/or metastatic disease should undergo molecular testing including BRAF, NTRK, ALK, RET, MSI, dMMR, and tumor mutational burden if not previously done.

The NCCN guideline for colon cancer (v.2.2021) recommends NTRK fusion analysis for patients with advanced or metastatic colorectal cancer.

The NCCN guideline for non-small cell lung cancer (v.5.2021) recommends NTRK fusion analysis for patients with Advanced or metastatic disease: Adenocarcinoma, Large Cell, Squamous cell, and NSCLC not otherwise specified (NOS)

The NCCN guideline for occult primary (v.1.2022) recommends NTRK fusion analysis for cancer of unknown primary.

The NCCN guideline for cervical cancer (v.1.2021) recommends NTRK fusion analysis for recurrent, progressive or metastatic cervical cancer.

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The NCCN guideline for vulvar (v.3.2021) recommends NTRK fusion analysis for recurrent, progressive or metastatic vulvar cancer.

The NCCN guideline for uterine neoplasms (v.3.2021) recommends NTRK fusion analysis for recurrent or metastatic uterine cancer or a diagnosis of uterine sarcoma.

The NCCN guideline for breast cancer (v.5.2021) recommends NTRK fusion analysis for recurrent or stage IV invasive breast cancer.

The NCCN guideline for gastric cancer (v.3.2021) recommends NTRK fusion analysis for locally advanced, recurrent or metastatic gastric cancer.

The NCCN guideline for esophageal and esophagogastric junction cancer (v.4.2021) recommends NTRK fusion analysis for locally advanced, recurrent or metastatic esophageal cancer.

The NCCN guideline for pediatric acute lymphoblastic leukemia (v.2.2021) recommends NTRK fusion analysis for pediatric acute lymphoblastic leukemia (ALL).

The NCCN guideline for soft tissue sarcomas (v.2.2021) recommends NTRK fusion analysis for soft tissue sarcoma when previous tumor testing was negative for *KIT* and *PDGFRA* somatic mutations.

PD-L1 Protein Expression Analysis

The NCCN guideline for gastric cancer (v.3.2021) recommends PD-L1 testing during the workup for documented or suspected metastatic adenocarcinoma.

The NCCN guideline for head and neck cancers (v.3.2021) recommends PD-L1 testing during the workup phase for cancer of the nasopharynx.

NCCN guidelines for bladder cancer (v.3.2021) recommend PD-L1 testing in individuals with locally advanced or metastatic (stage IV) bladder cancer.

The NCCN guideline for vulvar cancer (v.3.2021) recommends PD-L1 testing for individuals with recurrent, progressive, or metastatic vulvar cancer.

The NCCN guideline for Esophageal and Esophagogastric Junction Cancers (v.4.2021) recommends PD-L1 testing for individuals during the workup phase for documented or suspected metastatic esophageal and esophagogastric junction cancers.

The NCCN guideline for cervical cancer (v.1.2021) recommends PD-L1 testing for individuals with recurrent, progressive, or metastatic cervical cancer.

NCCN guidelines for non-small cell lung cancer (v.5.2021) recommend PD-L1 testing in patients with Advanced or metastatic disease: Adenocarcinoma, Large Cell, Squamous cell, and NSCLC not otherwise specified (NOS).

The NCCN guideline for breast cancer (v.5.2021) recommends PD-L1 testing for individuals with recurrent or stage IV triple negative breast cancer.

PML/RARA Rearrangement Analysis

NCCN guidelines for acute lymphoblastic leukemia (v.1.2021) recommend PML/RARA rearrangement analysis for patients for the evaluation of acute leukemia.

ROS1 Rearrangement Analysis

NCCN guidelines on non-small cell lung cancer (v.5.2021) recommend ROS1 rearrangement testing in patients with Advanced or metastatic disease: Adenocarcinoma, Large Cell, Squamous cell, and NSCLC not otherwise specified (NOS).

The 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 NMIBC.”
- “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.”
- “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.”

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 2021, 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.

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed.	02/22	02/22

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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.

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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 member/enrollees. This clinical policy is not intended to recommend treatment for member/enrollees. Member/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, member/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, member/enrollees and their representatives agree to be bound by such terms and conditions by providing services to member/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid member/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 member/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.

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