Clinical Policy: Atezolizumab (Tecentriq), Atezolizumab-Hyaluronidase (Tecentriq Hybreza)

Reference Number: CP.PHAR.235
Effective Date: 06.01.16
Last Review Date: 02.24
Line of Business: Commercial, HIM, Medicaid

Coding Implications
Revision Log

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

Description

- Atezolizumab (Tecentriq®) is a programmed death-ligand 1 (PD-L1) blocking antibody.
- Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza™) is a combination of atezolizumab and hyaluronidase, and endoglycosidase.

FDA Approved Indication(s)

Tecentriq and Tecentriq Hybreza are indicated:

- **Non-small cell lung cancer (NSCLC)**
  - As adjuvant treatment following resection and platinum-based chemotherapy for adult patients with stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.
  - For the first-line treatment of adult patients with metastatic NSCLC whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
  - In combination with bevacizumab, paclitaxel, and carboplatin, for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - In combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous NSCLC with no EGFR or ALK genomic tumor aberrations.
  - For the treatment of adult patients with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations prior to receiving Tecentriq.
- **Small cell lung cancer (SCLC)**
  - In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC).
- **Heptatocellular carcinoma (HCC)**
  - In combination with bevacizumab for the treatment of patients with unresectable or metastatic HCC who have not received prior systemic therapy.
- **Melanoma**
  - In combination with cobimetinib and vemurafenib for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

- **Alveolar soft part sarcoma (ASPS)**
  - Tecentriq is used for the treatment of adult and pediatric patients 2 years of age and older with unresectable or metastatic ASPS.
  - Tecentriq Hybreza is only used for the treatment of adult with unresectable or metastatic ASPS.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Tecentriq and Tecentriq Hybreza are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Non-Small Cell Lung Cancer (must meet all)**:**

1. Diagnosis of NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Member meets one of the following (a, b, or c):
   a. For stage II to III NSCLC, prescribed as a single agent and meets one of the following (i or ii):
      i. Member has had previous resection;
      ii. Member has all the following (1, 2 and 3):
         1) High-risk stage IIA or stage IIIB NSCLC (*see Appendix D*);
         2) PD-L1 expression ≥ 1%;
         3) Previously received platinum-containing chemotherapy *(see Appendix B)*;
   b. For member with both a negative or unknown EGFR or ALK mutation status AND recurrent, advanced, or metastatic NSCLC: Member meets one of the following (i, ii, iii, or iv):
      i. Request is for use as a single agent as first-line therapy for tumors that have high PD-L1 expression (PD-L1 ≥ 50% [TC ≥ 50%] or tumor-infiltrating IC covering ≥ 10% of the tumor area [IC ≥ 10%]);
      ii. Disease is non-squamous, and Tecentriq is prescribed in combination with one of the following (1 or 2):
         1) Bevacizumab, paclitaxel, and carboplatin;
         2) Paclitaxel protein-bound (Abraxane®) and carboplatin;
      iii. Member has previously received platinum-containing chemotherapy *(see Appendix B)*;
      iv. If no prior progression on a PD-1/PD-L1 inhibitor (i.e., Tecentriq as well as nivolumab, pembrolizumab, durvalumab), request is for single agent as subsequent therapy;
   c. For member with a positive EGFR or ALK mutation status AND recurrent, advanced, or metastatic NSCLC: Member has a history of disease progression during or following an NCCN-recommended therapy for the specific mutation *(see Appendix B)*;

5. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: dose does not exceed 1,875 mg every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

B. Small Cell Lung Cancer (must meet all)**:**
1. Diagnosis of extensive-stage SCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with carboplatin and etoposide;
5. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: Dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: dose does not exceed 1,875 mg every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

C. Hepatocellular Carcinoma (must meet all):
1. Diagnosis of HCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as first-line systemic therapy;
5. Confirmation of Child-Pugh class A or B status;
6. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: dose does not exceeded 1,875 mg every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

D. Melanoma (must meet all):
1. Diagnosis of melanoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with cobimetinib and vemurafenib;

5. One of the following (a or b):
   a. For member with *BRAF V600* mutation AND unresectable or metastatic melanoma;
   b. Request is for use as re-induction therapy;
6. Request meets one of the following (a, b, or c):*
   a. For Tecentriq: dose does not exceed 1,680 mg every 4 weeks;
   b. For Tecentriq Hybreza: dose does not exceed 1,875 mg every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

E. Alveolar Soft Part Sarcoma (must meet all):
1. Diagnosis of ASPS;
2. Disease is unresectable or metastatic;
3. Prescribed by or in consultation with an oncologist;
4. Member meets one of the following (a or b):
   a. Tecentriq: age ≥ 2 years;
   b. Tecentriq Hybreza: age ≥ 18 years;
5. Prescribed as a single-agent therapy;
6. Request meets one of the following (a, b, or c):*
   a. For Tecentriq, dose does not exceed one of the following (i or ii):
      i. For adults: 1,680 mg every 4 weeks;
      ii. For pediatrics: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks;
   b. For Tecentriq Hybreza: 1,875 mg every 3 weeks;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

F. Peritoneal Mesothelioma (off-label) (must meet all):
1. Diagnosis of peritoneal mesothelioma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in combination with bevacizumab as subsequent systemic therapy;
5. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

G. Urothelial Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of urothelial carcinoma (UC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Member is ineligible for cisplatin-containing chemotherapy, and the tumor expresses PD-L1;
   b. Member is ineligible for any platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin) regardless of PD-L1 status;
5. Prescribed as a single agent;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

H. Cervical Cancer (off-label) (must meet all)
1. Diagnosis of small cell neuroendocrine carcinoma of the cervix;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is persistent, recurrent, or metastatic;
5. Prescribed in combination with cisplatin/carboplatin and etoposide;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).**

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or duration of request, whichever is less

I. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line

of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Tecentriq for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed one of the following (i or ii):
      i. For pediatric ASPS: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks;
      ii. All other indications (1 or 2):
         1) For Tecentriq: 1,680 mg every 4 weeks;
         2) For Tecentriq Hybreza: 1,875 mg every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or duration of request, whichever is less

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ALK: anaplastic lymphoma kinase
ASPS: alveolar soft part sarcoma
EGFR: epidermal growth factor receptor
ES-SCLC: extensive-stage small cell lung cancer
FDA: Food and Drug Administration
HCC: hepatocellular carcinoma
IC: immune cells
NSCLC: non-small cell lung cancer
PD-L1: programmed death-ligand 1
SCLC: small cell lung cancer
TC: tumor cells
UC: urothelial carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
cisplatin-, oxaliplatin- (Eloxatin®) or carboplatin-containing chemotherapy	UC: Varies	Varies
cisplatin-, or carboplatin-containing chemotherapy	NSCLC: Varies	Varies
Xalkori® (crizotinib) Alecensa® (alectinib) Zykadia® (ceritinib)	NSCLC with ALK tumor aberration: Varies	Varies
erlotinib (Tarceva®) Gilotrif® (afatinib) gefitinib (Iressa®)	NSCLC with EGFR tumor aberration: Varies	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- NSCLC examples of high-risk factors: may include poorly differentiated tumors (including lung neuroendocrine tumors [excluding well-differentiated neuroendocrine tumors]), vascular invasion, wedge resection, visceral pleural involvement, and unknown lymph node status (Nx). These factors independently may or may not be an indication and may be considered when determining treatment with adjuvant chemotherapy.
- SCLC consists of two stages: limited-stage and extensive-stage. Extensive-stage is defined as stage IV (T any, N any M 1a/b) or T3-4 due to multiple lung nodules that are too extensive or have tumor/nodal volume that is too large to be encompassed in a tolerable radiation plan.
- On December 2, 2022, following consultation with the FDA, Roche withdrew Tecentriq's use for any form of UC. The withdrawal was based on data from the IMVigor130 study, which tested Tecentriq with chemotherapy against chemotherapy alone and failed to meet the co-primary endpoint of overall survival. Patients given Tecentriq chemo combination

lived a median of 16 months after treatment, compared with 13.4 months for those receiving just chemo, a difference that wasn't statistically significant.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
NSCLC	In the adjuvant setting: administer Tecentriq following resection and up to 4 cycles of platinum-based chemotherapy as 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks for up to 1 year OR Administer Tecentriq Hybeza 1,875 mg subcutaneously every 3 weeks In the metastatic setting: administer Tecentriq as 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks OR Administer Tecentriq Hybeza 1,875 mg subcutaneously every 3 weeks When administering with chemotherapy with or without bevacizumab, administer Tecentriq or Tecentriq Hybreza prior to chemotherapy and bevavizumab when given on the same day	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
SCLC	Tecentriq: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks. OR Tecentriq Hybreza: administer 1,875 mg subcutaneously every 3 weeks When administering with carboplatin and etoposide, administer Tecentriq or Tecentriq Hybreza prior to chemotherapy when given on the same day.	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
HCC	Tecentriq: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks. OR	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks

Indication	Dosing Regimen	Maximum Dose
	Tecentriq Hybreza: administer 1,875 mg subcutaneously every 3 weeks Administer Tecentriq or Tecentriq Hybreza prior to bevacizumab when given on the same day. Bevacizumab is administered at 15 mg/kg every 3 weeks.	
Melanoma	Following completion of a 28 day cycle of cobimetinib and vemurafenib, administer Tecentriq 840 mg IV every 2 weeks, 1,200 mg every 3 weeks, or 1680 mg every 4 weeks or Tecentriq Hybreza subcutaneously 1,875 mg every 3 weeks with cobimetinib 60 mg PO QD (21 days on/7 days off) and vemurafenib 720 mg PO BID	Tecentriq: 1,680 mg/4 weeks Tecentriq Hybreza; 1,875 mg/3 weeks
ASPS	Tecentriq: Adults: 840 mg IV every 2 weeks, 1,200 mg IV every 3 weeks, or 1,680 mg IV every 4 weeks Pediatrics: 15 mg/kg (up to a maximum of 1,200 mg) every 3 weeks OR Tecentriq Hybreza (adults only): administer 1,875 mg subcutaneously every 3 weeks	Tecentriq: Adults: 1,680 mg/4 weeks Tecntriq: Pediatrics: 1,200 mg/3 weeks Tecentriq Hybreza (adults only); 1,875 mg/3 weeks

VI. Product Availability

- Tecentriq: Single-dose vials: 840 mg/14 mL, 1,200 mg/20 mL
- Tecentriq Hybreza: Single-dose vial: 1,875 mg atezolizumab/30,000 units hyaluronidase/15 mL

VII. References

1. Tecentriq Hybreza Prescribing Information. South San Francisco, CA: Genentech, Inc.; September 2024. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761347s000lbl.pdf. Accessed November 04, 2024.
2. Tecentriq Prescribing Information. South San Francisco, CA: Genentech, Inc.; May 2023. Available at: https://www.tecentriq.com. Accessed October 16, 2023.
3. Atezolizumab In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 15, 2023.
4. Atezolizumab and hyaluronidase-tqjs In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: nccn.org. Accessed November 04, 2024.

Coding Implications
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.

HCPCS Codes	Description
J9022	Injection, atezolizumab, 10 mg
C9399, J9999	Unclassified drugs or biologicals; not otherwise classified, antineoplastic drugs (for Tecentriq Hybreza)

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria added for new FDA indication: first-line treatment of metastatic non-squamous NSCLC; added specialist involvement in care for all indications; added off-label criteria for SCLC; references reviewed and updated.	01.08.19	02.19
Criteria added for new FDA indication: triple-negative breast cancer in combination with paclitaxel protein-bound; off-label designation removed for SCLC as it is now FDA-approved; references reviewed and updated.	04.16.19	05.19
1Q 2020 annual review: criteria added for new FDA indication: metastatic non-squamous NSCLC in combination with paclitaxel protein-bound and carboplatin; for NSCLC, added indication as subsequent therapy if no progression on other PD-1/PD-L1 inhibitors; references reviewed and updated.	01.14.20	02.20
RT4 policy update to add criteria for newly FDA-approved indications: 1) first-line therapy for metastatic NSCLC with high PD-L1 expression, and 2) first-line therapy for HCC in combination with bevacizumab; references reviewed and updated.	06.08.20	
Added Commercial line of business; RT4 policy update to add criteria for newly FDA-approved indication for melanoma in combination with cobimetinib and vemurafenib; references reviewed and updated.	08.15.20	
1Q 2021 annual review: for HCC, unresectable or metastatic removed to accommodate local disease per NCCN; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.15.20	02.21
RT4 policy update to remove the indication, previously approved under accelerated approval, for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy.	05.12.21	
1Q 2022 annual review: RT4: removed breast cancer indication and added NSCLC stage II to IIIA treatment indication per updated label;	01.18.22	02.22

Reviews, Revisions, and Approvals	Date	P&T Approval Date
added criterion for use as single-agent therapy for urothelial carcinoma per NCCN; added criterion for Child-Pugh class A status in HCC per NCCN; references reviewed and updated.		
Template changes applied to other diagnoses/indications and continued therapy section.	10.07.22	
1Q 2023 annual review: added criterion for malignant peritoneal mesothelioma per NCCN; adjusted dose to not exceed 1,680 mg every 4 weeks for melanoma per PI; section V updated per PI; revised commercial approval duration to the current standard for injectables of "6 months or to member's renewal date, whichever is longer"; references reviewed and updated. RT4: for urothelial carcinoma, removed FDA approved accelerated indication per updated PI and changed to off-label as still supported by NCCN; added ASPS indication per updated PI.	01.09.23	02.23
1Q 2024 annual review: for NSCLC, added option for stage IIIB NSCLC; for HCC, added option for Child-Pugh Class B per NCCN; for melanoma, added option for usage as re-induction therapy per NCCN; for ASPS, added prescribed as single-agent therapy per NCCN; added criterion for cervical cancer per NCCN; updated generic availability for Tarceva and Iressa in Appendix B; references reviewed and updated.	10.16.23	02.24
RT4: added newly approved Hybreza formulation.	11.04.24	

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

Note:
For Medicaid members, 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.