Clinical Policy: Pembrolizumab (Keytruda)

Reference Number: CP.PHAR.322
Effective Date: 03.01.17
Last Review Date: 11.18
Line of Business: Commercial, Medicaid, HIM-Medical Benefit Revision Log

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

Description

Pembrolizumab (Keytruda®) is a programmed cell death receptor-1 (PD-1)-blocking antibody.

FDA Approved Indication(s)

Keytruda is indicated for the treatment of:

- **Melanoma**
  - For the treatment of patients with unresectable or metastatic melanoma.
- **Non-Small Cell Lung Cancer (NSCLC)**
  - As a single agent for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression [(Tumor Proportion Score (TPS) ≥ 50%)] as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.
  - As a single agent for the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS ≥ 1%) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving Keytruda.
  - In combination with pemetrexed and carboplatin, as first-line treatment of patients with metastatic nonsquamous NSCLC.^
- **Head and Neck Squamous Cell Cancer (HNSCC)**
  - For the treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy.*
- **Classical Hodgkin Lymphoma (cHL)**
  - For the treatment of adult and pediatric patients with refractory cHL, or who have relapsed after 3 or more prior lines of therapy.*
- **Urothelial Carcinoma**
  - For the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (Combined Positive Score [CPS] ≥ 10), or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.*
  - For the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
- **Microsatellite Instability-High Cancer**
  - For the treatment of adult and pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient*

    - Solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, or
    - Colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.
  - Limitation(s) of use: The safety and effectiveness of Keytruda in pediatric patients with MSI-H central nervous system cancers have not been established.
- **Gastric Cancer**
  - For the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, human epidermal growth factor receptor 2 (HER2)/neu-targeted therapy.*
- **Cervical Cancer**
  - For the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy whose tumors express PD-L1 (CPS ≥ 1) as determined by an FDA-approved test.*
- **Primary Mediastinal Large B-Cell Lymphoma (PMBCL)**
  - For the treatment of adult and pediatric patients with refractory PMBCL, or who have relapsed after 2 or more prior lines of therapy.*
  - Limitation(s) of Use: Keytruda is not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy.

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* This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

^ This indication is approved under accelerated approval based on tumor response rate and progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

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 Keytruda is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Cervical Cancer (must meet all)**:**

1. Diagnosis of recurrent or metastatic cervical cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Tumors express PD-L1 [CPS ≥ 1];
5. Disease has progressed on or after at least one chemotherapy regimen (e.g., single-agent cisplatin, carboplatin, paclitaxel, or combination regimens containing these agents);

6. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

B. Classical Hodgkin Lymphoma (must meet all)**:**
1. Diagnosis of cHL;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Age ≥ 2 years;
4. Disease is refractory or member has relapsed after three or more lines of therapy;
5. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Gastric Cancer (must meet all)**:**
1. Diagnosis of recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Tumors express PD-L1 [CPS ≥1];
5. Disease has progressed on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

D. Head and Neck Squamous Cell Carcinoma (must meet all)**:**
1. Diagnosis of HNSCC (*see Appendix D* for subtypes by location);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease has progressed on or after platinum-containing chemotherapy (e.g., cisplatin, carboplatin, oxaliplatin);
5. Request meets one of the following (a or b):

a. Dose does not exceed 200 mg every 3 weeks;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Melanoma (must meet all)**:**
1. Diagnosis of unresectable or metastatic melanoma (including uveal melanoma [off-label]);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 2 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

F. Merkel Cell Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of Merkel cell carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

G. Microsatellite Instability-High Cancer (must meet all)**:**
1. Diagnosis of MSI-H or defective mismatch repair (dMMR) cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 2 years;
4. Disease is unresectable or metastatic;
5. Meets one of the following (a, b, or c):
   a. Colorectal cancer (*colon cancer, rectal cancer, or both*);
   b. Other solid tumors (*see Appendix E for examples*): Disease progressed following prior treatment;
   c. Hepatobiliary cancer (gallbladder, intra/extra-hepatic cholangiocarcinoma) [off-label];
6. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;

b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

H. 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. Disease is recurrent or metastatic;
5. Meets one of the following (a or b):
   a. First-line therapy (i or ii):
      i. Disease is non-squamous and Keytruda is prescribed in combination with pemetrexed and either carboplatin or cisplatin;
      ii. Tumor PD-L1 expression ≥ 50% (TPS), and EGFR, ALK, ROS1 and BRAF mutation status negative or unknown;
   b. Subsequent therapy (i and ii):
      i. Tumor PD-L1 expression ≥ 1% (TPS);
      ii. Disease has progressed on or after one of the following (a, b, c, d, or e):
         a) Platinum-containing chemotherapy if EGFR, ALK, ROS1 and BRAF mutation status is negative or unknown;
         b) FDA-approved therapy for EGFR mutation positive disease (e.g., Tarceva®, Gilotrif®, Iressa®, Tagrisso®);
         c) FDA-approved therapy for ALK mutation positive disease (e.g., Xalkori®, Zykadia®, Alecensa®, Alunbrig®);
         d) FDA-approved or NCCN-supported therapy for ROS1 mutation positive disease (e.g., Xalkori, Zykadia);
         e) FDA-approved therapy for BRAF V600E mutation positive disease (e.g., Tafinlar® with Mekinist®);

      **Prior authorization is (or may be) required for Alecensa, Alunbrig, Gilotrif, Iressa, Mekinist, Tafinlar, Tarceva, Tagrisso, Xalkori, Zykadia*
6. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

I. Urothelial Carcinoma (must meet all)**:**
1. Diagnosis of urothelial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Meets one of the following (a or b):

a. Member is not eligible for platinum-containing chemotherapy;
b. Disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy;

5. Request meets one of the following (a or b):
   a. Dose does not exceed 200 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration:
Medicaid/HIM – 6 months
Commercial – 6 months or to the member's renewal date, whichever is longer

J. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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 Keytruda 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 200 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*).

Approval duration:
Medicaid/HIM – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 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.PHAR.21 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
cHL: classical Hodgkin lymphoma
CPS: combined positive score
dMMR: mismatch repair deficient
EGFR: epidermal growth factor receptor
EPOCH-R: etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin + rituximab
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HNSCC: head and neck squamous cell carcinoma
ICE: ifosfamide, carboplatin, etoposide
MSI-H: microsatellite instability-high
NCCN: National Comprehensive Cancer Network
NSCLC: non-small cell lung cancer
PD-1: programmed cell death protein 1
PD-L1/2: programmed death-ligand 1/2
RCHOP: rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone
ROS1: ROS proto-oncogene 1, receptor tyrosine kinase
TPS: tumor proportion score

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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Various chemotherapy regimens	PMBCL first-line therapy: EPOCH-R, RCHOP, RCHOP followed by ICE PMBCL – intend to proceed to high-dose therapy: • DHAP (dexamethasone, cisplatin, cytarabine) ± R • ESHAP (etoposide (Toposar®), methylprednisolone, cytarabine, cisplatin) ± R • GDP (gemcitabine (Gemzar®), dexamethasone, cisplatin/carboplatin) ± R • GemOx (gemcitabine (Gemzar), oxaliplatin_± R • ICE (ifosfamide (Ifex®), carboplatin, etoposide (Toposar)) ± R • MINE (mesna (Mesnex®), ifosfamide (Ifex), mitoxantrone, etoposide (Toposar)) ± R PMBCL – non-candidates for high-dose therapy: • Bendamustine ± R • CEPP (cyclophosphamide, etoposide (Toposar), prednisone, Matulane® (procarbazine)) ± R	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	• CEOP (cyclophosphamide, etoposide (Toposar), vincristine (Vincasar®), prednisone) ± R • DA-EPOCH ± R • GDP ± R • GemOx ± R	
cisplatin, carboplatin, paclitaxel, or combination regimens containing these agents	Cervical Cancer: Varies	Varies
Xalkori (crizotinib)	NSCLC: 250 mg PO BID	500 mg/day
Zykadia (ceritinib)	NSCLC: 450 mg PO QD	450 mg/day
Tafinlar (dabrafenib) with Mekinist (trametinib)	NSCLC: Tafinlar: 150 mg PO BID Mekinist: 2 mg PO QD	Tafinlar: 300 mg/day Mekinist: 2 mg/day
Alecensa (alectinib)	NSCLC: 600 mg PO BID	1200 mg/day
Alunbrig (brigatinib)	NSCLC: 90 mg PO QD for 7 days, if tolerated increase to 180 mg PO QD	180 mg/day
Tarceva (erlotinib)	NSCLC: 150 mg PO QD	150 mg/day
Gilotrif (afatinib)	NSCLC: 40 mg PO QD	40 mg/day
Iressa (gefitinib)	NSCLC: 250 mg PO QD	250 mg/day
Tagrisso (osimertinib)	NSCLC: 80 mg PO QD	80 mg/day

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.
R = Rituxan® (rituximab)

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: Head and Neck Squamous Cell Cancers by Location[*5]
- Paranasal sinuses (ethmoid, maxillary)
- Larynx (glottis, supraglottis)
- Pharynx (nasopharynx, oropharynx, hypopharynx)
- Lip and oral cavity
- Major salivary glands (parotid, submandibular, sublingual)
- Occult primary

**Squamous cell carcinoma, or a variant, is the histologic type in more than 90% of head and neck cancers.*

Appendix E: Examples of Solid Tumors

- Adrenal gland tumors
- Cervical cancer
- Endometrial cancer
- Biliary cancer
- Gastric/gastroesophageal junction cancer
- Hepatobiliary cancer
- Ovarian, fallopian tube, primary peritoneal cancer
- Pancreatic cancer
- Penile cancer
- Small intestinal cancer
- Breast cancer
- Prostate cancer
- Vulvar cancer
- Bladder cancer
- Esophageal cancer
- Sarcoma
- Testicular cancer
- Thyroid cancer
- Rectal cancer
- Retroperitoneal adenocarcinoma
- Small cell lung cancer
- Renal cell carcinoma

Appendix F: General Information

- NCCN Compendium recommend Keytruda for the treatment of Merkel cell carcinoma for disseminated, clinical M1 disease with or without surgery and/or radiation therapy.
- NCCN Compendium recommend Keytruda for the treatment of unresectable or metastatic MSI-H or dMMR colorectal cancer for the following: disease progression following treatment with a fluoropyrimidine (e.g., fluorouracil, capecitabine), oxaliplatin, and irinotecan; following adjuvant therapy with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOx (capecitabine and oxaliplatin) within the past 12 months; as a single agent for members in which intensive therapy is not appropriate.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Cervical cancer, cHL, HNSCC, melanoma, MSI-H cancer, gastric cancer NSCLC, PMBCL, urothelial carcinoma	Adults: 200 mg IV every 3 weeks	200 mg every 3 weeks
cHL, melanoma, MSI-H cancer, PMBCL	Pediatrics: 2 mg/kg IV every 3 weeks	200 mg every 3 weeks

All regimens are an intravenous infusion over 30 minutes

VI. Product Availability

- Powder, single-dose vial: 50 mg
- Solution, single-dose vial: 100 mg/4 mL

VII. References

1. Keytruda Prescribing Information. Whitehouse Station, NJ: Merck and Co.; June 2018. Available at http://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf. Accessed June 19, 2018.

2. Pembrolizumab. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed June 19, 2018.
3. Melanoma (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 21, 2018.
4. Non-small cell lung cancer (Version 4.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 21, 2018.
5. Head and neck cancers (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 21, 2018.
6. Hodgkin lymphoma (Version 3.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 21, 2018.
7. Bladder cancer (Version 4.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 21, 2018.
8. Gastric Cancer (Version 2.2018). In: National Comprehensive Cancer Network Guidelines. Available at www.nccn.org. Accessed June 21, 2018.
9. National Comprehensive Cancer Network. Cervical Cancer Version 1.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf. Accessed June 19, 2018.
10. National Comprehensive Cancer Network. B-Cell Lymphomas Version 4.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed June 19, 2018.

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
J9271	Injection, pembrolizumab, 1 mg

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.182 Excellus Oncology. Non-small cell lung cancer: NCCN off-label recommendations added; "recurrent or" added to "metastatic disease" and "or unknown" added to "negative mutation status" to consolidate criteria of those FDA/NCCN uses that differed by the referenced terms. Head and neck cancers: NCCN off-label recommended uses added; subtypes by location outlined at Appendix B.	01.17	03.17
Created criteria for new FDA indications: cHL, urothelial carcinoma, and MSI-H cancer. Melanoma: modified max dose from 2 mg/kg to 200 mg per package insert. NSCLC: added criteria for updated FDA indication (non-squamous metastatic disease).	05.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
HNSCC: specified that recommended NCCN off-label uses pertain to non-nasopharyngeal cancer. All indications: added max dose requirement to both initial and re-auth criteria. Increased all approval durations from 3/6 months to 6/12 months. Removed reasons to discontinue. Added requirement for documentation of positive response to therapy.		
Created criteria for new FDA indications per PI and NCCN: Gastric Cancer	10.17	11.17
Criteria added for new FDA indications cervical cancer and primary mediastinal large B-cell lymphoma; urothelial carcinoma criteria updated for use in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status; added Commercial line of business; added age and specialist prescribing for all indications; applied oncology streamlining approach; added HIM-Medical Benefit line of business; reference reviewed and updated.	07.17.18	08.18
4Q 2018 annual review: no significant changes; references reviewed and updated.	07.26.18	11.18

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.

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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.