# Clinical Policy: Trametinib (Mekinist)

Reference Number: CP.PHAR.240
Effective Date: 07.01.16
Last Review Date: 05.23
Line of Business: Commercial, HIM, Medicaid Revision Log

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

## Description

Trametinib (Mekinist®) is a kinase inhibitor.

## FDA Approved Indication(s)

Mekinist is indicated:

- As a single agent for the treatment of BRAF-inhibitor treatment-naïve patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
- In combination with dabrafenib (Tafinlar®):
  - For the treatment of patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutations as detected by an FDA-approved test
  - For the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations, as detected by an FDA-approved test, and involvement of lymph node(s), following complete resection
  - For the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with BRAF V600E mutation as detected by an FDA-approved test
  - For the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options
  - For the treatment of adult and pediatric patients 1 year of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.*
  - For the treatment of pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy

Limitation(s) of use: Mekinist is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.

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** This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).*

## 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 Mekinist is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Melanoma** (must meet all)**:**

1. Diagnosis of melanoma with BRAF V600E or V600K mutation;
2. Disease meets one of the following (a or b):
   a. Unresectable, limited resectable, or metastatic;
   b. Presence of lymph node(s) involvement following complete resection;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 2 mg per day;
      ii. 1 tablet per day;
   b. 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 –** 12 months or duration of request, whichever is less

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

1. Diagnosis of advanced, metastatic, or recurrent NSCLC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is positive for a BRAF V600E mutation;
5. Prescribed in combination with Tafinlar;
6. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 2 mg per day;
      ii. 1 tablet per day;
   b. 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** – 12 months or duration of request, whichever is less

**C. Anaplastic Thyroid Cancer** (must meet all)**:**

1. Diagnosis of advanced or metastatic ATC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Disease is positive for a BRAF V600E mutation;
5. Prescribed in combination with Tafinlar;
6. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 2 mg per day;
      ii. 1 tablet per day;
   b. 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** – 12 months or duration of request, whichever is less

**D. BRAF V600E Mutation-Positive Solid Tumor** (must meet all):
1. Diagnosis of unresectable or metastatic solid tumor that is positive for a BRAF V600E mutation (*see Appendix D for examples*);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 1 year;
4. Request meets one of the following (a or b):
   a. Disease has progressed on prior treatment, and no satisfactory alternative treatment options are available;
   b. Prescribed for one of the following NCCN 2A or higher supported indications (i-vii):
      i. Ampullary adenocarcinoma, as subsequent therapy;
      ii. Salivary gland tumor;
      iii. Pancreatic adenocarcinoma;
      iv. One of the following thyroid carcinomas, as subsequent treatment in unresectable, recurrent, persistent, or metastatic disease (a, b, or c):
         a) Papillary;
         b) Follicular;
         c) Hürthle cell;
      iv. One of the following hepatobiliary cancers, as subsequent treatment in unresectable or metastatic disease (a, b, or c):
         a) Extrahepatic cholangiocarcinoma;
         b) Intrahepatic cholangiocarcinoma;
         c) Gallbladder cancer;
      v. One of the following central nervous system cancers (a - f):
         a) Adult low-grade (World Health Organization [WHO] grade 1) glioma;
         b) Recurrent adult isocitrate dehydrogenase (IDH) mutant oligodendroglioma (1p19q codeleted, WHO grade 2 or 3);
         c) Recurrent adult IDH mutant astrocytoma (WHO grade 2, 3, or 4);
         d) Recurrent adult glioblastoma;
         e) Brain metastases;

f) Pediatric diffuse high-grade gliomas, as adjuvant treatment (except for diffuse midline glioma, H3 K27-altered or pontine location), or treatment for recurrent or progressive disease (except for oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant);

vi. One of the following for ovarian cancer, fallopian tube cancer, or peritoneal cancers (a-e):
a) Carcinosarcoma (malignant mixed Müllerian tumors) of the ovary;
b) Clear cell carcinoma of the ovary;
c) Grade 1 endometrioid carcinoma;
d) Mucinous carcinoma of ovary;
e) Low-grade serous carcinoma;

vii. Metastatic uveal melanoma;

5. For ovarian cancer, fallopian tube cancer, or peritoneal cancer: Request is for recurrence therapy (e.g., previous treatment with a regimen containing carboplatin, cisplatin, or oxaliplatin);
6. Request meets one of the following (a or b):
   a. For metastatic uveal melanoma, prescribed as a single agent;
   b. For all other indications, prescribed in combination with Tafinlar;
7. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
8. For pediatric members, documentation of member's current body weight (in kg);
9. Request meets one of the following (a or b):
   a. Dose does not exceed one of the following (i or ii):
      i. Adults: both of the following (a and b):
         a) 2 mg per day;
         b) 1 tablet per day;
      ii. Pediatric members: FDA approved maximum recommended dose (*see Section V*);
   b. Dose is supported by practice guidelines or peer-reviewed literature for 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** – 12 months or duration of request, whichever is less

**E. Pediatric Low-Grade Glioma** (must meet all):
1. Diagnosis of LGG (WHO grade 1 or 2);
2. Prescribed by or in consultation with an oncologist;
3. Age is between 1 to < 18 years;
4. Disease is positive for a BRAF V600E mutation;
5. Prescribed in combination with Tafinlar;
6. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Documentation of member's current body weight (in kg);

8. Request meets one of the following (a or b):*
   a. Dose does not exceed the FDA approved maximum recommended dose (*see Section V*);
   b. 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** – 12 months or duration of request, whichever is less

**F. Off-Label NCCN Compendium Recommended Indication(s)** (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Histiocytic neoplasms that are positive for a MAP kinase pathway mutation or have no detectable mutation, unless testing is not available (i, ii, or iii):
      i. Erdheim-Chester disease;
      ii. Langerhans Cell histiocytosis;
      iii. Rosai Dorfman disease;
   b. Recurrent low-grade serous carcinoma that is platinum-sensitive or platinum-resistant;
2. Prescribed by or in consultation with one of the following (a or b):
   a. Histiocytic neoplasms: a hematologist or oncologist;
   b. Low-grade serous carcinoma: oncologist;
3. Age ≥ 18 years;
4. Disease is;
5. Prescribed as a single agent;
6. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed both of the following (i and ii):
      i. 2 mg per day;
      ii. 1 tablet per day;
   b. 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** – 12 months or duration of request, whichever is less

**G. 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 Mekinist for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Mekinist requests, member must use generic trametinib, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. For pediatric members, documentation of member's current body weight (in kg);
5. 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, ii or iii):
      i. BRAF V600E mutation-positive solid tumor (a or b):
         a) Adults: both of the following (1 and 2):
            1) 2 mg per day;
            2) 1 tablet per day;
         b) Pediatric members: FDA approved maximum (*see Section V*);
      ii. Pediatric LGG: FDA approved maximum (*see Section V*);
      iii. All other indications: both of the following (a and b):
         a) 2 mg per day;
         b) 1 tablet per day;
   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** – 12 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 policies – 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*

ATC: anaplastic thyroid cancer
BRAF: B-Raf proto-oncogene serine/threonine kinase
FDA: Food and Drug Administration
IDH: isocitrate dehydrogenase
MAP: mitogen-activated protein
NSCLC: non-small cell lung cancer
WHO: World Health Organization

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Boxed Warnings*

None reported

*Appendix D: General Information*

- According to NCCN, Mekinist has category 2A recommendation for combination treatment with Tafinlar for brain metastases if active against primary tumor (melanoma) for recurrent disease.
- Examples of solid tumors that may be BRAF V600E mutation-positive include, but are not limited to, the following: biliary tract cancer, high grade glioma (glioblastoma, anaplastic pleomorphic xanthoastrocytoma, anaplastic astrocytoma, astroblastoma, anaplastic ganglioglioma, and anaplastic oligodendroglioma), low grade glioma (astrocytoma, ganglioglioma, pleomorphic xanthoastrocytoma, pilocytic astrocytoma, choroid plexus papilloma, gangliocytoma/ganglioglioma), adenocarcinoma of small intestine, pancreas, or anus, mixed ductal/adenoneuroendocrine carcinoma, neuroendocrine carcinoma of colon, ameloblastoma of mandible, combined small cell-squamous carcinoma of lung, mucinous-papillary serous adenocarcinoma of peritoneum, gastrointestinal stromal tumor.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Melanoma, NSCLC, ATC | 2 mg (1 tablet) PO QD<br><br>The recommended duration of treatment in the adjuvant melanoma setting is until disease recurrence or unacceptable toxicity for up to 1 year. The recommended duration of treatment for all other indications is until disease progression or unacceptable toxicity. | 2 mg/day |
| BRAF V600E mutation-positive solid tumors | Adults: 2 mg (1 tablet) PO QD<br><br>Pediatric patients:<br>*Tablets*:<br>• 26-37 kg: 1 mg (two 0.5 mg tablets) PO QD<br>• 38-50 kg: 1.5 mg (three 0.5 mg tablets) PO QD<br>• ≥ 51 kg: 2 mg (one 2 mg tablet) PO QD<br>*Oral solution*:<br>• 8 kg: 0.3 mg (6 mL) PO QD<br>• 9 and 10 kg: 0.35 mg (7 mL) PO QD<br>• 11 kg: 0.4 mg (8 mL) PO QD<br>• 12 to 13 kg: 0.45 mg (9 mL) PO QD<br>• 14 to 17 kg: 0.55 mg (11 mL) PO QD<br>• 18 to 21 kg: 0.7 mg (14 mL) PO QD<br>• 22 to 25 kg: 0.85 mg (17 mL) PO QD<br>• 26 to 29 kg: 0.9 mg (18 mL) PO QD<br>• 30 to 33 kg: 1 mg (20 mL) PO QD<br>• 34 to 37 kg: 1.15 mg (23 mL) PO QD<br>• 38 to 41 kg: 1.25 (25 mL) PO QD<br>• 42 to 45 kg: 1.4 mg (28 mL) PO QD<br>• 46 to 50 kg: 1.6 mg (32 mL) PO QD<br>• ≥ 51 kg: 2 mg (40 mL) PO QD<br><br>The recommended duration of treatment is until disease progression or unacceptable toxicity. | 2 mg/day |
| Pediatric LGG | Tablets:<br>• 26-37 kg: 1 mg (two 0.5 mg tablets) PO QD<br>• 38-50 kg: 1.5 mg (three 0.5 mg tablets) PO QD<br>• ≥ 51 kg: 2 mg (one 2 mg tablet) PO QD<br><br>Oral solution:<br>• 8 kg: 0.3 mg (6 mL) PO QD<br>• 9 and 10 kg: 0.35 mg (7 mL) PO QD<br>• 11 kg: 0.4 mg (8 mL) PO QD<br>• 12 to 13 kg: 0.45 mg (9 mL) PO QD<br>• 14 to 17 kg: 0.55 mg (11 mL) PO QD | See dosing regimen |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| | • 18 to 21 kg: 0.7 mg (14 mL) PO QD<br>• 22 to 25 kg: 0.85 mg (17 mL) PO QD<br>• 26 to 29 kg: 0.9 mg (18 mL) PO QD<br>• 30 to 33 kg: 1 mg (20 mL) PO QD<br>• 34 to 37 kg: 1.15 mg (23 mL) PO QD<br>• 38 to 41 kg: 1.25 (25 mL) PO QD<br>• 42 to 45 kg: 1.4 mg (28 mL) PO QD<br>• 46 to 50 kg: 1.6 mg (32 mL) PO QD<br>• ≥ 51 kg: 2 mg (40 mL) PO QD<br><br>The recommended duration of treatment is until disease progression or unacceptable toxicity. | |

## VI. Product Availability

- Tablets: 0.5 mg, 2 mg
- Oral solution: 4.7 mg per bottle

## VII. References

1. Mekinist Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2023. Available at: www.pharma.us.novartis.com/product/pi/pdf/mekinist.pdf. Accessed September 14, 2023.
2. Trametinib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium. Accessed September 14, 2023.
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4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed September 14, 2023.
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7. National Comprehensive Cancer Network. Uveal Melanoma Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf. January 27, 2023.
8. National Comprehensive Cancer Network. Ovarian Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed January 27, 2023.
9. National Comprehensive Cancer Network. Ampullary Adenocarcinoma Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf. Accessed January 27, 2023.

10. National Comprehensive Cancer Network. Pediatric Central Nervous System Cancers Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_cns.pdf. Accessed September 14, 2023.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| 2Q 2019 annual review: no significant changes; references reviewed and updated. | 02.26.19 | 05.19 |
| 2Q 2020 annual review: added NCCN supported off-label uses in ovarian, colon, and rectal cancers; added NCCN supported off-label dosing verbiage; for uveal melanoma removed unresectable disease to align with NCCN Compendium; for NSCLC added advanced disease; references reviewed and updated. | 02.10.20 | 05.20 |
| 2Q 2021 annual review: removed colorectal cancer off-label use as it is no longer included in the NCCN Compendium; oral oncology generic redirection language added; revised reference to HIM off-label use policy from HIM.PHAR.21 to HIM.PA.154; references reviewed and updated. | 01.12.21 | 05.21 |
| 2Q 2022 annual review: added "limited resectable" melanoma classification per NCCN; clarified thyroid cancer should be advanced or metastatic per NCCN; added indications of central nervous system cancers, hepatobiliary cancers, and histiocytic neoplasms per NCCN; Commercial approval duration revised from "Length of Benefit" to "12 months or duration of request, whichever is less"; references reviewed and updated. | 02.21.22 | 05.22 |
| RT4: revised criteria to include new FDA-approved indication of BRAF V600E mutation-positive solid tumors. | 07.11.22 | |
| Template changes applied to other diagnoses/indications. | 10.10.22 | |
| 2Q 2023 annual review: moved the following indications: hepatobiliary cancers, CNS cancer, ovarian, fallopian, and peritoneal cancers, and metastatic uveal melanoma from off-label criteria and added ampullary adenocarcinoma, pancreatic adenocarcinoma, salivary gland tumor, thyroid carcinoma (papillary, follicular, Hürthle) to solid tumor criteria (per NCCN 2A recommendation), as they are classified as solid tumors; for NSCLC updated oral oncology generic redirection language to align with other indications in policy; RT4: added newly FDA approved indication of pediatric LGG and updated dosing (including additional requirement for documentation of body weight for all pediatric requests)/product availability to include oral solution; references reviewed and updated. | 04.05.23 | 05.23 |
| RT4: for V600E mutation positive unresectable or metastatic solid tumors indication, updated FDA approved indication section and criteria to reflect pediatric expansion from patients aged 6 years of age and older to patients aged 1 year of age and older. | 09.21.23 | |

**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.