Clinical Policy: Dabrafenib (Tafinlar)

Reference Number: CP.PHAR.239
Effective Date: 11.16.16
Last Review Date: 05.25
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Dabrafenib (Tafinlar®) is a kinase inhibitor.

FDA Approved Indication(s)

Tafinlar is indicated:

- As a single agent for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test
- In combination with trametinib (Mekinist®):
  - 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, as detected by an FDA-approved test, 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:

- Tafinlar is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition.
- Tafinlar is not indicated for treatment of patients with wild-type BRAF solid tumors.

** 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 Tafinlar 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. Prescribed as one of the following (a or b):
   a. In combination with Mekinist*;
   b. As a single agent for unresectable or metastatic disease with BRAF V600E mutation;
   **Prior authorization may be required for Mekinist*
6. For Tafinlar requests, member must use generic dabrafenib, 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. 300 mg per day;
      ii. 4 capsules 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 Mekinist*, unless the combination is not tolerated;
   **Prior authorization may be required for Mekinist*
6. For Tafinlar requests, member must use generic dabrafenib, 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. 300 mg per day;
      ii. 4 capsules 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 BRAF V600E mutation;
5. Prescribed in combination with Mekinist*;
   **Prior authorization may be required for Mekinist*
6. For Tafinlar requests, member must use generic dabrafenib, 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. 300 mg per day;
      ii. 4 capsules 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 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 meets both of the following (i and ii):
      i. Disease is unresectable or metastatic;
      ii. 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-xi):
      i. Ampullary adenocarcinoma, as subsequent therapy;
      ii. Salivary gland tumor;
      iii. Pancreatic adenocarcinoma;
      iv. One of the following thyroid carcinomas in unresectable, recurrent, persistent, or metastatic disease (a, b, or c):
         a) Papillary;
         b) Follicular;
         c) Oncocytic (Hürthle cell);
      v. Biliary tract cancers (e.g. cholangiocarcinoma and gallbladder cancer), as subsequent treatment in unresectable, resected gross residual (R2)[†], or metastatic disease;
      vi. One of the following central nervous system cancers (a-h):
         a) Adult pilocytic astrocytoma;

b) Adult ganglioglioma/neuroglioma/glioneuronal tumor;
c) Adult pleomorphic xanthoastrocytoma (WHO grade 2);
d) Recurrent or progressive circumscribed glioma;
e) Recurrent or progressive adult glioblastoma;
f) Recurrent or progressive adult high-grade gliomas;
g) Brain metastases;
h) 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 1p19q codeleted or astrocytoma IDH-mutant);

vii. Recurrent ovarian cancer, fallopian tube cancer, or peritoneal cancers (e.g., previous treatment with regimen containing carboplatin, cisplatin, or oxaliplatin), including any of the following (a-e):
a) Carcinosarcoma (malignant mixed Mullerian tumors) of the ovary;
b) Clear cell carcinoma of the ovary;
c) Grade 1 endometrioid carcinoma;
d) Mucinous neoplasms of ovary;
e) Low-grade serous carcinoma;

viii. Extrapulmonary poorly differentiated neuroendocrine carcinoma, large or small cell carcinoma, or mixed neuroendocrine-non-neuroendocrine neoplasms;

ix. Gastrointestinal stromal tumors in resectable†, resected gross residual (R2)†, unresectable primary disease, tumor rupture, recurrent, or metastatic disease;

x. Gastric, esophageal, or esophagogastric cancer as subsequent therapy in unresectable locally advanced, recurrent, or metastatic disease;

xi. Advanced or metastatic small bowel adenocarcinoma;

†Off-label

5. For thyroid carcinoma: Disease is not amenable to radioactive iodine therapy;
6. Prescribed in combination with Mekinist*;
   **Prior authorization may be required for Mekinist*
7. For Tafinlar requests, member must use generic dabrafenib, 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) 300 mg per day;
         b) 4 capsules 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 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

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 Mekinist*;
   **Prior authorization may be required for Mekinist*
6. For Tafinlar requests, member must use generic dabrafenib, if available, unless contraindicated or clinically significant adverse effects are experienced;
7. Documentation of member's current body weight (in kg);
8. Requests 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 neoplasm (i or ii):
      i. Erdheim-Chester disease positive for BRAF V600E mutation;
      ii. Langerhans Cell histiocytosis positive for BRAF V600E mutation;
   b. Hairy cell leukemia not previously treated with BRAF inhibitor;
2. Prescribed by or in consultation with a hematologist or oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. For histiocytic neoplasms, prescribed as a single agent;
   b. For hairy cell leukemia, prescribed in combination with Mekinist*;
      **Prior authorization may be required for Mekinist*
5. For Tafinlar requests, member must use generic dabrafenib, 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. 300 mg per day;
      ii. 4 capsules 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 Tafinlar for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For Tafinlar requests, member must use generic dabrafenib, 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: one of the following (1 or 2):
         1) Adults: both of the following (a and b):
            a) 300 mg per day;
            b) 4 capsules per day;
         2) 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 (1 and 2):
         1) 300 mg per day;
         2) 4 capsules 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
GIST: gastrointestinal stromal tumor
IDH: isocitrate dehydrogenase
LGG: low grade glioma
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

- Nearly half of patients with melanoma have a BRAF mutation gene. The most common forms of the BRAF mutation are V600E (80-90%) and V600K (10-20%).
- Tafinlar can potentiate the activity of the mitogen-activated protein kinases (MAPK) pathway in cells with wild-type BRAF (mutation-negative) and could accelerate the growth of some tumors with wild-type BRAF (mutation-negative).
- 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	150 mg (two 75 mg capsules) PO BID 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.	300 mg/day
BRAF V600E mutation-positive solid tumors	Adults: 150 mg (two 75 mg capsules) PO BID Pediatric patients: *Capsules:* • 26-37 kg: 75 mg (one 75 mg capsule) PO BID • 38-50 kg: 100 mg (two 50 mg capsules) PO BID • ≥ 51 kg: 150 mg (two 75 mg capsules) PO BID *Tablets for oral suspension*: • 8 to 9 kg: 20 mg (two 10 mg tablets) PO BID • 10 to 13 kg: 30 mg (three 10 mg tablets) PO BID • 14 to 17 kg: 40 mg (four 10 mg tablets) PO BID • 18 to 21 kg: 50 mg (five 10 mg tablets) PO BID • 22 to 25 kg: 60 mg (six 10 mg tablets) PO BID • 26 to 29 kg: 70 mg (seven 10 mg tablets) PO BID • 30 to 33 kg: 80 mg (eight 10 mg tablets) PO BID • 34 to 37 kg: 90 mg (nine 10 mg tablets) PO BID • 38 to 41 kg: 100 mg (ten 10 mg tablets) PO BID • 42 to 45 kg: 110 mg (eleven 10 mg tablets) PO BID • 46 to 50 kg: 130 mg (thirteen 10 mg tablets) PO BID • ≥ 51 kg: 150 mg (fifteen 10 mg tablets) PO BID The recommended duration of treatment is until disease progression or unacceptable toxicity.	300 mg/day
Pediatric LGG	Capsules: • 26-37 kg: 75 mg (one 75 mg capsule) PO BID • 38-50 kg: 100 mg (two 50 mg capsules) PO BID • ≥ 51 kg: 150 mg (two 75 mg capsules) PO BID	See dosing regimen

Indication	Dosing Regimen	Maximum Dose
	Tablets for oral suspension: • 8 to 9 kg: 20 mg (two 10 mg tablets) PO BID • 10 to 13 kg: 30 mg (three 10 mg tablets) PO BID • 14 to 17 kg: 40 mg (four 10 mg tablets) PO BID • 18 to 21 kg: 50 mg (five 10 mg tablets) PO BID • 22 to 25 kg: 60 mg (six 10 mg tablets) PO BID • 26 to 29 kg: 70 mg (seven 10 mg tablets) PO BID • 30 to 33 kg: 80 mg (eight 10 mg tablets) PO BID • 34 to 37 kg: 90 mg (nine 10 mg tablets) PO BID • 38 to 41 kg: 100 mg (ten 10 mg tablets) PO BID • 42 to 45 kg: 110 mg (eleven 10 mg tablets) PO BID • 46 to 50 kg: 130 mg (thirteen 10 mg tablets) PO BID • ≥ 51 kg: 150 mg (fifteen 10 mg tablets) PO BID The recommended duration of treatment is until disease progression or unacceptable toxicity.	

VI. Product Availability

- Capsules: 50 mg, 75 mg
- Tablet for oral suspension: 10 mg

VII. References

1. Tafinlar Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2025. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/202806s036,217514s010lbl.pdf Accessed February 12, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium. Accessed February 12, 2025.
3. National Comprehensive Cancer Network. Melanoma: Cutaneous Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf. Accessed February 12, 2025.
4. National Comprehensive Cancer Network. Central Nervous System Cancers Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed February 12, 2025.
5. National Comprehensive Cancer Network Guidelines. Non-Small Cell Lung Cancer Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed February 12, 2025.
6. National Comprehensive Cancer Network. Pediatric Central Nervous System Cancers Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ped_cns.pdf. Accessed February 12, 2025.

7. National Comprehensive Cancer Network Guidelines. Thyroid Carcinoma Version 5.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed February 12, 2025.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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: Per NCCN added "limited resectable" melanoma classification, added allowance for therapy without Tafinlar for NSCLC, clarified thyroid cancer should be advanced or metastatic, clarified specific BRAF V600E mutation is a criterion for only ATC of thyroid cancers, added radioactive iodine therapy criterion for follicular, papillary, and Hürthle cell carcinomas, and added indications of central nervous system cancers, hepatobiliary cancers, and histiocytic neoplasms; 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.	07.08.22	
Template changes applied to other diagnoses/indications.	10.10.22	
2Q 2023 annual review: moved the following indications: hepatobiliary cancers, CNS cancers, ovarian, fallopian and peritoneal cancers 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; 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 tablet for oral solution; references reviewed and updated.	04.04.23	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	
2Q 2024 annual review: for thyroid cancer, revised section to specify only ATC per PI (other thyroid carcinomas are covered in solid tumor section); for BRAF V600E mutation-positive solid tumor per NCCN, revised criteria to include off-label indications for resectable disease, removed "as subsequent treatment" from thyroid carcinomas to allow first-line treatment, specified adult low-grade glioma to adult pilocytic astrocytoma, ganglioglioma, and pleomorphic	02.07.24	05.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
xanthoastrocytoma (grade 2), removed recurrent adult IDH-mutant oligodendroglioma and IDH-mutant astrocytoma, added that thyroid carcinoma must not be amenable to radioactive iodine therapy, added the following indications: off-label resected gross residual hepatobiliary cancer, recurrent or progressive circumscribed glioma, progressive adult glioblastoma, poorly differentiated mixed neuroendocrine carcinomas, gastrointestinal stromal tumors, gastric and esophageal adenocarcinoma, esophageal and esophagogastric squamous cell carcinoma, and small bowel adenocarcinoma; for off-label NCCN compendium recommendations added indication of hairy cell leukemia; referenced reviewed and updated.		
2Q 2025 annual review: for BRAF V600E mutation-positive solid tumor per NCCN, consolidated types of biliary tract cancers, added neuroglioma and glioneuronal tumor, added recurrent or progressive adult high-grade gliomas, clarified listed types of ovarian cancer are acceptable diagnoses in addition to ovarian cancer, fallopian tube cancer, and peritoneal cancer; consolidated criterion for recurrent ovarian cancer, fallopian tube cancer, and peritoneal cancer; consolidated gastric, esophageal, or esophagogastric cancers; references reviewed and updated. RT4: for ATC, updated FDA-approved indication to include detection by an FDA approved test.	02.12.25	05.25

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.