Reference number
2009-A

SPECIALTY GUIDELINE MANAGEMENT

VOTRIENT (pazopanib)
pazopanib

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Treatment of adults with advanced renal cell carcinoma (RCC)
2. Treatment of adults with advanced soft tissue sarcoma (STS) who have received prior chemotherapy

Limitations of Use: The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors has not been demonstrated.

B. Compendial Uses
1. Relapsed or stage IV renal cell carcinoma
2. Uterine sarcoma
3. Gastrointestinal stromal tumors (GIST)
4. Soft tissue sarcoma that is not an adipocytic sarcoma
5. Medullary, papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma
6. Bone cancer of one of the following subtypes:
   a. Chordoma
   b. Chondrosarcoma
   c. Osteosarcoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma

Authorization of 12 months may be granted when either the following criteria are met:
1. The requested medication will be used as a single agent for treatment of advanced, relapsed, or stage IV renal cell carcinoma.
2. The requested medication will be used as a single agent for treatment of von Hippel-Lindau (VHL)-associated renal cell carcinoma.

B. Gastrointestinal Stromal Tumors

Authorization of 12 months may be granted for treatment of GIST when any of the following criteria are met:
1. The requested medication will be used as a single agent for treatment of residual, unresectable, recurrent, or metastatic/tumor rupture GIST after the member has failed at least four FDA-approved therapies (e.g., imatinib, sunitinib, regorafenib and ripretinib).

2. The requested medication will be used for treatment of residual, unresectable, tumor rupture or recurrent/metastatic succinate dehydrogenase (SDH)-deficient GIST as a single agent.

C. Soft Tissue Sarcoma

Authorization of 12 months may be granted for treatment of soft tissue sarcoma, excluding adipocytic sarcoma and GIST (see specific criteria for GIST) when either of the following criteria are met:

1. The requested medication will be used as a single agent
2. The requested medication will be used for treatment of angiosarcoma or dedifferentiated chordoma and the requested medication will be used in combination with gemcitabine

D. Uterine Sarcoma

Authorization of 12 months may be granted as a single agent for subsequent treatment of advanced, recurrent/metastatic or inoperable uterine sarcoma.

E. Papillary, Oncocytic/Hürthle Cell, or Follicular Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of progressive and/or symptomatic papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma not amenable to radioactive iodine (RAI) therapy.

F. Medullary Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of recurrent or metastatic medullary thyroid carcinoma when either of the following criteria are met:

1. Member has an intolerance or contraindication to FDA approved systemic therapy options (e.g., cabozantinib [Cometriq], vandetanib [Caprelsa]); OR
2. Member has disease progression while on FDA approved systemic therapy options (e.g., cabozantinib [Cometriq], vandetanib [Caprelsa]).

G. Bone cancer

Authorization of 12 months may be granted for treatment of one of the following subtypes of bone cancer:

1. Chordoma
2. Chondrosarcoma
3. Osteosarcoma

III. CONTINUATION OF THERAPY

A. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of GIST when there is no evidence of unacceptable toxicity while on the current regimen.

B. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Votrient [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; January 2024.
2. Pazopanib [package insert]. Parsippany, NJ: Teva Pharmaceuticals; April 2023.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 3, 2024.
4. Ganjoo KN, Villalobos VM, Kamaya A, et al. A multicenter phase II study of pazopanib in patients with advanced gastrointestinal stromal tumors (GIST) following failure of at least imatinib and sunitinib. *Ann Oncol* 2014;25(1):236-40.

5. van der Graaf WT, Blay JY, Chawla SP, et al. Pazopanib for metastatic soft-tissue sarcoma (PALETTE): a randomised, double blind, placebo-controlled phase 3 trial. *Lancet*. 2012;379(9829):1879-1886.
6. Nakano K, Motoi N, Inagaki L, et al. Differences in the responses to pazopanib and the prognoses of soft tissue sarcomas by their histological eligibility for the PALETTE study. *Jpn J Clin Oncol.* 2015;45(5):449-455.
7. Lipplaa A, Dijkstra S, Gelderblom H. Efficacy of pazopanib and sunitinib in advanced axial chordoma: a single reference centre case series. *Clin Sarcoma Res*. 2016;6:19.
8. Jones RL, Katz D, Loggers ET, et al. Clinical benefit of antiangiogenic therapy in advanced and metastatic chondrosarcoma. *Med Oncol*. 2017;34:167.
9. Safwat A, Boysen A, Lücke A, et al. Pazopanib in metastatic osteosarcoma: Significant clinical response in three consecutive patients. *Acta Oncol.* 2014;53(10):1451-1454.
10. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Thyroid Carcinoma. Version 2.2024. Accessed May 2, 2024.