PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Votrient® (pazopanib tablets – GlaxoSmithKline)

DATE REVIEWED: 05/27/2020

OVERVIEW
Votrient, a multi-tyrosine kinase inhibitor, is indicated for the treatment of patients with advanced renal cell carcinoma (RCC), and for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy.[1] Limitation of Use. The efficacy of Votrient for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors (GIST) has not been demonstrated.

Guidelines
Votrient features prominently in the National Comprehensive Cancer Network (NCCN) guidelines for soft tissue sarcomas and kidney cancer and others. The indications listed in the FDA-approved and Other Uses with Supportive Evidence sections are supported by the prescribing information and/or the NCCN Compendium/Guidelines.

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Votrient. All approvals are provided for 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Votrient is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Renal Cell Carcinoma** (Clear Cell or Non-Clear Cell Histology). Approve for 3 years for relapsed or Stage IV disease.

2. **Soft Tissue Sarcoma (STS).** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   - **A)** The soft tissue sarcoma is advanced or metastatic; AND
   - **B)** The patient has ONE of the following (i, ii, iii, iv, v, or vi):[3]
     - **i.** Angiosarcoma; OR
     - **ii.** Pleomorphic rhabdomyosarcoma; OR
     - **iii.** Retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive; OR
     - **iv.** Soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma; OR
     - **v.** Solitary fibrous tumor/hemangiopericytoma; OR
     - **vi.** Alveolar soft part sarcoma; OR
   - **C)** The patient does not have gastrointestinal stromal tumor (GIST) [see Criterion 4].

Other Uses with Supportive Evidence

3. **Differentiated (i.e., papillary, follicular, and Hürthle cell) Thyroid Carcinoma.** Approve for 3 years if refractory to radioactive iodine therapy.

4. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   A) Patient has previously tried imatinib (Gleevec® tablets, generics); AND
   B) Patient has previously tried Sutent® (sunitinib capsules); AND
   C) Patient has previously tried Stivarga® (regorafinib tablets).

5. **Medullary Thyroid Carcinoma.** Approve for 3 years if the patient has tried Caprelsa® (vandetanib tablets) or Cometriq® (cabozantinib capsules).

6. **Ovarian Cancer (i.e., Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer).** Approve for 3 years if the patient has persistent or recurrent disease.

7. **Uterine Sarcoma (e.g., endometrial stromal sarcoma, undifferentiated uterine sarcoma, uterine leiomyosarcomas).** Approve for 3 years in patients with recurrent, advanced, or metastatic disease.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Votrient has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Votrient® tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; May 2017.
2. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 25, 2020. Search term: pazopanib.