Votrient (pazopanib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Votrient (pazopanib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Votrient (pazopanib) may be approved if the following criteria are met:

Individual has a diagnosis of one of the following:

I. Advanced renal cell carcinoma (kidney cancer);

OR

II. Von Hippel-Lindau (VHL)-associated renal cell carcinoma (NCCN 2A);

OR

III. Soft tissue sarcoma (including extremity/body wall, head/neck or retroperitoneal/Intra-abdominal, angiosarcoma, alveolar soft part, dermatofibrosarcoma protuberans (DFSP with fibrosarcomatous transformation, solitary fibrous tumor, rhabdomyosarcoma, epithelioid hemangioendothelioma, extraskeletal myxoid chondrosarcoma, desmoid tumors) (Label, NCCN 2A);

OR

IV. Gastrointestinal Stromal Tumors (GIST) – for the following:
A. Gross residual disease, tumor rupture, unresectable, recurrent, or metastatic disease after failure on approved therapies (such as imatinib, sunitinib, regorafenib, and ripretinib) (NCCN 2A); **OR**

OR

V. Succinate-dehydrogenase (SDH)- deficient unresectable gastrointestinal stromal tumor (GIST), as a single agent (NCCN 2A);

OR

VI. Uterine sarcoma – as second-line or subsequent therapy for inoperable, advanced, recurrent or metastatic disease (NCCN 2A);

OR

VII. Thyroid carcinomas (NCCN 2A);
A. For Follicular, Papillary, or Oncocytic Cell thyroid carcinomas if clinical

trials or other systemic therapies are not available or appropriate for treatment of progressive and/or symptomatic iodine-refractory disease; **OR**

B. For Medullary carcinomas in the treatment of progressive disease or symptomatic distant metastases if clinical trials or systemic therapy options are not available or appropriate, OR if there is progression on systemic therapy options;

OR

VI. Chondrosarcoma – for the treatment of metastatic disease or systemic recurrence (NCCN 2A).

Requests for **brand** Votrient must also meet the following criteria, in addition to the above Prior Authorization criteria:

I. Individual has failed an adequate trial of one chemically equivalent generic pazopanib agent. Medication samples/coupons/discount cards are

II. excluded from consideration as a trial.;
AND

A. Generic pazopanib had inadequate response; **OR**
B. Generic pazopanib caused adverse outcome; **OR**
C. The individual has a genuine allergic reaction to an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Votrient (pazopanib) may not be approved for the following:

I. For the treatment of adipocytic Soft Tissue Sarcoma (NCCN 2A).

Note:
Votrient (pazopanib) has a black box warning for hepatotoxicity. Severe and fatal hepatotoxicity has occurred in clinical trials. Hepatic function should be monitored and therapy interrupted, reduced, or discontinued as recommended.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Ganjoo KN, Villalobos VM, Kamaya A, et al. A multicenter phase II study of pazopanib in patients with advanced GIST following failure of at least imatinib and sunitinib. Ann Oncol 2014;25(1):236-40.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 15, 2024.
    a. Bone cancer. V2.2024. Revised March 12, 2024.
    b. Merkel Cell Carcinoma. V1.2024. Revised November 22, 2023.
    c. Thyroid Carcinoma. V3.2024. Revised June 18, 2024.
    d. Ovarian Cancer. V3.2024. Revised July 15, 2024.
    e. Kidney Cancer. V1.2025. Revised July 1, 2024.
    f. Uterine Neoplasms. V2.2024. Revised March 6, 2024.
    g. Soft Tissue Sarcoma. V1.2024. Revised April 26, 2024.
    h. Gastrointestinal Stromal Tumors (GISTs) V1.2024. Revised March 8, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.