



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1113-12
Program	Prior Authorization/Notification
Medication	Votrient® (pazopanib)
P&T Approval Date	1/12/2010, 9/2010, 12/2010, 3/2011, 5/2012, 8/2012, 7/2013, 8/2014, 8/2015, 7/2016, 7/2017, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, 11/2022, 11/2023
Effective Date	2/1/2024

1. Background:

Votrient (pazopanib) is a kinase inhibitor indicated for the treatment of advanced renal cell carcinoma and advanced soft tissue sarcoma in patients who have received prior chemotherapy. Additionally, the National Comprehensive Cancer Network (NCCN) recommends use of Votrient in treatment of medullary, follicular, oncocytic, and papillary thyroid carcinomas; ovarian cancer; additional soft tissue sarcomas, chondrosarcoma, uterine sarcoma, merkel cell carcinoma, and gastrointestinal stromal tumors (GIST).

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria^a:

A. Patients less than 19 years of age

1. **Votrient** will be approved based on the following criterion:

- a. Patient is less than 19 years of age

Authorization will be issued for 12 months.

B. Renal cell carcinoma (RCC)/Kidney cancer

1. **Initial Authorization**

a. **Votrient** will be approved based on **one** of the following criteria:

(1) **Both** of the following:

- (a) Diagnosis of renal cell carcinoma (RCC)

-AND-

(b) **One** of the following:

- i. Disease has relapsed
- ii. Stage IV disease
- iii. Disease is advanced

-OR-

(2) Diagnosis of von Hippel-Lindau (VHL)-associated renal cell carcinoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Votrient** therapy

Authorization will be issued for 12 months.

C. **Soft Tissue Sarcoma (STS)**

1. **Initial Authorization**

a. **Votrient** will be approved based on the following criterion:

(1) Diagnosis of **one** of the following:

- (a) Angiosarcoma
- (b) Alveolar soft part sarcoma
- (c) Pleomorphic rhabdomyosarcoma
- (d) Retroperitoneal/Intra-abdominal disease that is unresectable, stage IV, or postoperative treatment for residual disease
- (e) Soft Tissue Sarcoma of the Extremity/Superficial Trunk or Head/Neck with disease that is stage IV or recurrent and has disseminated metastases
- (f) Solitary fibrous tumor/hemangiopericytoma
- (g) Desmoid tumors (aggressive fibromatosis)
- (h) Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation
- (i) Dedifferentiated Chordoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Votrient** therapy

Authorization will be issued for 12 months.

D. Thyroid Carcinoma

1. Initial Authorization

a. **Votrient** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of **one** of the following:

- i. Follicular carcinoma
- ii. Oncocytic carcinoma
- iii. Papillary carcinoma

-AND-

(b) **One** of the following:

- i. Unresectable locoregional recurrent disease
- ii. Persistent disease
- iii. Metastatic disease

-AND-

(c) **One** of the following:

- i. Patient has symptomatic disease
- ii. Patient has progressive disease

-AND-

(d) **One** of the following:

- i. Disease is refractory to radioactive iodine treatment
- ii. Distant metastatic disease not amenable to radioactive iodine treatment

-OR-

(2) **All** of the following:

(a) Diagnosis of medullary carcinoma

-AND-

(b) **One** of the following:

- i. Disease is progressive
- ii. Disease is symptomatic with distant metastases

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following:

- i. Caprelsa (vandetanib)
- ii. Cometriq (cabozantinib)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on **Votrient** therapy

Authorization will be issued for 12 months.

E. **Uterine Sarcoma**

1. **Initial Authorization**

a. **Votrient** will be approved based on **both** of the following criteria:

- (1) Diagnosis of uterine sarcoma

-AND-

(2) **One** of the following:

- (a) Disease is advanced
- (b) Disease is recurrent/metastatic
- (c) Disease is inoperable

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on **Votrient** therapy

Authorization will be issued for 12 months.

F. **Ovarian Cancer**

1. **Initial Authorization**

a. **Votrient** will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

- (a) Epithelial Ovarian Cancer
- (b) Fallopian Tube Cancer
- (c) Primary Peritoneal Cancer

-AND-

(2) **One** of the following:

- (a) Disease is persistent
- (b) Disease is recurrent

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

G. Chondrosarcoma

1. **Initial Authorization**

a. **Votrient** will be approved based on **both** of the following criteria:

- (1) Diagnosis of chondrosarcoma

-AND-

- (2) Disease is metastatic and widespread

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

H. Gastrointestinal Stromal Tumors (GIST)

1. **Initial Authorization**

a. **Votrient** will be approved based on **all** the following criteria:

(1) Diagnosis of GIST

-AND-

(2) Disease is unresectable, progressive, or metastatic

-AND-

(3) **One** of the following:

(a) Used as first-line therapy in SDH-deficient GIST

-OR-

(b) Used after progression on **all** of the following:

- i. Gleevec (imatinib)
- ii. Sutent (sunitinib)
- iii. Stivarga (regorafenib)
- iv. standard dose Qinlock (ripretinib)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Votrient** therapy

Authorization will be issued for 12 months.

I. **Merkel Cell Carcinoma**

1. **Initial Authorization**

a. **Votrient** will be approved based on **all** of the following criteria:

(1) Diagnosis of Merkel Cell Carcinoma

-AND-

(2) Disease is M1 disseminated

-AND-

(3) **One** of the following:

(a) Anti-PD-L1 or anti-PD-1 therapy is contraindicated

-OR-

(b) Disease has progressed on anti-PD-L1 or anti-PD-1 therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Votrient** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Votrient** therapy

Authorization will be issued for 12 months.

J. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limit may be in place.

4. References:

1. **Votrient** [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed September 18, 2023.

Program	Prior Authorization/Notification - Votrient (pazopanib)
Change Control	
8/2014	Annual review. Expanded disease description for RCC and reformatted thyroid carcinoma. Updated Background and References.
8/2015	Annual review. Updated criteria for soft tissue cancer and thyroid cancer. Added criteria for dermatofibrosarcoma protuberans and ovarian cancer. Updated background and references.

7/2016	Annual review. Revised renal cell carcinoma and soft tissue sarcoma criteria. Updated references.
7/2017	Annual review with no changes to coverage criteria. Updated references.
11/2017	Updated criteria to align with NCCN recommendations for recurrent or persistent ovarian cancer. Removed criteria for dermatofibrosarcoma protuberans (DFSP) as no longer recommended by NCCN. Updated reference.
11/2018	Annual review. Updated criteria to align with NCCN recommendations for renal cell carcinoma. Removed “off-label” from NCCN Compendium supported indications. Updated background and references.
11/2019	Annual review. Updated criteria to align with NCCN recommendations for soft tissue sarcomas, ovarian and uterine cancers. Added NCCN recommended regimens criteria. Updated background and references.
11/2020	Annual review. Updated criteria to align with NCCN recommendations for soft tissue sarcoma and thyroid carcinoma. Updated background and references.
11/2021	Annual review. Updated criteria to align with NCCN recommendations for soft tissue sarcoma. Added criteria for chondrosarcoma. Updated background and references.
11/2022	Annual review. Added state mandate and updated references.
11/2023	Annual review. Moved and updated criteria for GIST into its own section. Added Merkel Cell Carcinoma criteria per NCCN recommendations. Updated Soft Tissue Sarcoma criteria to align with NCCN. Updated Uterine Sarcoma criteria to align with NCCN. Updated Hürthle cell to oncocytic to align with NCCN nomenclature. Updated background to align with NCCN recommendations. Updated reference.