UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1113-14
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, 11/2024, 11/2025
Effective Date	2/1/2026

1. Background:

Votrient (pazopanib) is a kinase inhibitor indicated for the treatment of adults with 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. <u>Patients less than 19 years of age</u>

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. <u>Renal cell carcinoma (RCC)/Kidney cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Votrient** will be approved based on **<u>one</u>** of the following criteria:

      (1) **<u>Both</u>** 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) Alveolar soft part sarcoma
(b) Angiosarcoma
(c) Dedifferentiated chordoma
(d) Dedifferentiated liposarcoma with or without concurrent well-differentiated liposarcoma
(e) Dermatofibrosarcoma Protuberans (DFSP) with Fibrosarcomatous Transformation
(f) Desmoid tumors (aggressive fibromatosis)
(g) Epithelioid hemangioendothelioma
(h) Extraskeletal myxoid chondrosarcoma
(i) Soft tissue sarcoma of the extremity/superficial trunk or head/neck with disease that is stage IV or recurrent and has disseminated metastases
(j) Retroperitoneal/Intra-abdominal disease that is unresectable, stage IV, or postoperative treatment for residual disease
(k) Pleomorphic rhabdomyosarcoma
(l) Solitary fibrous tumor/hemangiopericytoma

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. 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 oncocytic 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

-OR-

(3) **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. 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 residual, 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. imatinib
            ii. 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 **both** of the following criteria:

(1) Diagnosis of Merkel Cell Carcinoma

-AND-

(2) **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; January 2024.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed October 13, 2025.

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.
11/2024	Annual review. Added epithelioid hemangioendothelioma and extraskeletal myxoid chondrosarcoma to Soft Tissue Sarcoma criteria to align with NCCN. Updated references.
11/2025	Annual review. Added additional soft tissue sarcomas to align with NCCN and reformatted soft tissue sarcoma criteria. Updated oncocytic carcinoma criteria to remove radioactive iodine criteria. Removed staging system criteria for Merkel Cell Carcinoma. Updated references.