

### Clinical Pharmacy Program Guidelines for Votrient

Program	Prior Authorization
Medication	Votrient® (pazopanib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

#### 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, Hürthle cell and papillary thyroid carcinomas; ovarian cancer; additional soft tissue sarcomas and uterine sarcoma.<sup>2</sup>

#### 2. Coverage Criteria:

<p><b>A. <u>Renal Cell Carcinoma (RCC)/Kidney Cancer</u></b></p> <p><b>1. <u>Initial Authorization</u></b></p> <p>a. <b>Votrient</b> will be approved based on <b>both</b> of the following criterion:</p> <p style="margin-left: 40px;">(1) Diagnosis of renal cell carcinoma (RCC)</p> <p style="text-align: center; margin-left: 80px;"><b>-AND-</b></p> <p style="margin-left: 40px;">(2) <b>One</b> of the following:</p> <p style="margin-left: 80px;">(a) Disease is relapsed</p> <p style="margin-left: 80px;">(b) Stage IV disease</p> <p style="margin-left: 40px;"><b>Authorization will be issued for 12 months.</b></p> <p><b>2. <u>Reauthorization</u></b></p> <p>a. <b>Votrient</b> will be approved based on the following criterion:</p>
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- (1) Patient does not show evidence of progressive disease while on Votrient therapy

**Authorization will be issued for 12 months.**

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

**1. Initial Authorization**

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

- (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 or progressive
- (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

**-OR-**

- (2) **Both** of the following:

- (a) Diagnosis of progressive gastrointestinal stromal tumors (GIST)

**-AND-**

- (b) History of failure, contraindication, or intolerance to **all** of the following:

- i. Gleevec (imatinib)
- ii. Sutent (sunitinib)
- iii. Stivarga (regorafenib)

**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. 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. Hürthle cell 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.**

**D. Uterine Sarcoma**

**1. Initial Authorization**

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

- (1) Diagnosis of uterine sarcoma

**-AND-**

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

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

**-AND-**

(3) Disease has progressed following previous cytotoxic chemotherapy (e.g., doxorubicin, docetaxel/gemcitabine, etc.)

**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. 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.**

**F. NCCN Recommended Regimens**

**1. Initial Authorization**

a. **Votrient** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

**Authorization will be issued for 12 months.**

**2. Reauthorization**

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

(1) Documentation of positive clinical response to **Votrient** therapy

**Authorization will be issued for 12 months.**

**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 limits may be in place

**4. References:**

1. **Votrient** [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at [www.nccn.org](http://www.nccn.org). Accessed October 5, 2020.

Program	Prior Authorization –Votrient (pazopanib)
<b>Change Control</b>	
Date	Change
9/2014	New guideline
7/2016	Updated clinical criteria to align with Employer and Individual notification policy and updated policy to new template
7/2017	Annual review with no changes to coverage criteria. Updated references.

11/2017	Updated criteria to align with NCCN recommendation for recurrent or persistent ovarian cancer. Removed criteria for dermatofibrosarcoma protuberans since it is no longer NCCN recommended. Updated references.
11/2018	Updated criteria to align with NCCN recommendations for renal cell carcinoma. Added NCCN Recommended Regimen review criteria. Updated background and references.
11/2019	Annual review. Updated criteria to align with NCCN recommendations for soft tissue sarcomas, ovarian cancer, and uterine cancer. Updated background and references.
11/2020	Annual review. Updated criteria to align with NCCN recommendations for soft tissue sarcoma and thyroid carcinoma. Added Additional Clinical Rules section. Updated background and references.