# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Votrient Prior Authorization Policy
- Votrient® (pazopanib tablets – GlaxoSmithKline)

**REVIEW DATE:** 06/23/2021

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## OVERVIEW

Votrient, a multi-tyrosine kinase inhibitor, is indicated in adults for the following uses:[1]

- **Renal cell carcinoma,** advanced.
- **Soft tissue sarcoma**, advanced, for patients who have received prior chemotherapy.

## Guidelines

Votrient is discussed in guidelines from The National Comprehensive Cancer Network (NCCN):

- **Bone Cancer**: NCCN guidelines (version 1.2021 – November 20, 2020) recommend Votrient as a systemic therapy agent as other recommended regimens for chondrosarcoma for metastatic and widespread disease.[3]
- **Gastrointestinal Stromal Tumor (GIST)**: NCCN guidelines (version 1.2021 – October 30, 2020) recommend Votrient (category 2A) as an additional option after failure on approved therapies, useful in certain circumstances.[4] The first line therapies are imatinib or Avyakit (avapritinib tablets; for GIST with *PDGFRA* exon 18 mutation, including the *PDGFRA* D842V mutation); second-line therapy is Sutent (sunitinib); third-line therapy is Stivarga (regorafenib); fourth-line therapy is Qinlock (ripretinib).
- **Kidney Cancer**: NCCN guidelines (version 4.2021 – April 19, 2021) recommend Votrient as first-line and subsequent therapy for relapsed or stage IV disease for clear cell histology and as systemic therapy for non-clear cell histology, useful in certain circumstances (category 2A).[5]
- **Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer**: NCCN guidelines (version 1.2021 – February 26, 2021) recommend Votrient (category 2B) as single-agent therapy for persistent disease or recurrence.[6]
- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2021 – April 28, 2021) recommend Votrient as single agent therapy for alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis), and solitary fibrous tumor/hemangiopericytoma.[7] For soft tissue sarcoma subtypes with non-specific histology, the guidelines recommend Votrient as first-line therapy for advanced and metastatic for patients who are ineligible for intravenous systemic therapy and as a subsequent line of therapy for advanced or metastatic disease as palliative therapy.
- **Thyroid Carcinoma**: NCCN guidelines (version 1.2021 – April 9, 2021) for differentiated thyroid carcinoma recommend Votrient (category 2A) for progressive and/or symptomatic disease for unresectable locoregional recurrent or persistent disease not amenable to radioactive iodine therapy or distant metastatic disease not amendable to radioactive iodine therapy.[8] Votrient can be considered for treatment of progressive or symptomatic medullary thyroid disease if clinical trials or preferred systemic therapy options are not available or appropriate, or if there is progression on preferred systemic therapy options.
- **Uterine Neoplasms**: NCCN guidelines (version 2.2021 – May 7, 2021) recommend Votrient (category 2A) for as a systemic therapy option for uterine sarcoma as other recommended regimen.

## 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 Cancer.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or advanced disease.

2. **Soft Tissue Sarcoma.** Approve for 3 years if the patient meets the following criteria (A, B, C and D):
   - **A)** Patient does not have gastrointestinal stromal tumor (GIST); AND
     Note: If patient has gastrointestinal stromal tumor (GIST), see criteria 4 for gastrointestinal stromal tumor.
   - **B)** Patient is ≥ 18 years of age; AND
   - **C)** Patient has advanced or metastatic disease; AND
   - **D)** Patient has ONE of the following (i, ii, iii, iv, v, vi or vii):
     - **i.** Alveolar soft part sarcoma; OR
     - **ii.** Angiosarcoma; OR
     - **iii.** Desmoid tumors (aggressive fibromatosis); OR
     - **iv.** Pleomorphic rhabdomyosarcoma; OR
     - **v.** Retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive; OR
     - **vi.** Soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma; OR
     - **vii.** Solitary fibrous tumor/hemangiopericytoma.

**Other Uses with Supportive Evidence**

3. **Bone Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has chondrosarcoma; AND
   - **C)** Patient meets the following (i and ii):
     - **i.** Patient has metastatic disease; AND
     - **ii.** According to the prescriber, patient has widespread disease.

4. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has tried each of the following (i, ii, iii, and iv):
     - **i.** Imatinib or Avyakit (avapritinib tablets); AND
     - **ii.** Sutent (sunitinib capsules); AND
     - **iii.** Stivarga (regorafinib tablets); AND
     - **iv.** Qinlock (ripretinib tablets).

5. **Ovarian Cancer (i.e., Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer).** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND

**B)** Patient has persistent or recurrent disease.

6. **Thyroid Carcinoma, Differentiated.** Approve for 3 years if the patient meets the following (A, B, and C):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** Patient has differentiated thyroid carcinoma; AND
   Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hürthle cell thyroid carcinoma.
   **C)** Patient is refractory to radioactive iodine therapy.

7. **Thyroid Carcinoma, Medullary.** Approve for 3 years if the patient meets the following (A and B):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** Patient has tried at least one systemic therapy.
   Note: Examples of systemic therapy include Caprelsa (vandetanib tablets), Cometriq (carbozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

8. **Uterine Sarcoma (e.g., endometrial stromal sarcoma, undifferentiated uterine sarcoma, uterine leiomyosarcomas).** Approve for 3 years if the patient meets the following (A and B):
   **A)** Patient is ≥ 18 years of age; AND
   **B)** Patient has recurrent, advanced, or metastatic disease.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Votrient is not recommended in the following situations:

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; August 2020.
2. The NCCN Drugs & Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed on May 28, 2021. Search term: pazopanib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 1.2021 – November 20, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed May 18, 2021
4. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2021 – October 30, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed May 18, 2021.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2021 – April 19, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed May 18, 2021.
6. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2021 – February 26, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed May 18, 2021.
7. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2021 – April 28, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed May 18, 2021.
8. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2021 – April 9, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed May 18, 2021.
9. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2021 – May 7, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.