PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/29/2022

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 2.2022 – October 8, 2021) recommend Votrient as a systemic therapy agent as other recommended regimens for chondrosarcoma for metastatic and widespread disease (category 2A).[3]
- **Gastrointestinal Stromal Tumor**: NCCN guidelines (version 1.2022 – January 21, 2022) recommend Votrient as an additional option after failure on approved therapies, useful in certain circumstances (category 2A).[4] The first line therapies are imatinib or Ayvakit™ (avapritinib tablets; for patients with *PDGFRA* exon 18 mutation, including the *PDGFRA* D842V mutation); second-line therapy is Sutent® (sunitinib capsules) or Sprycel® (dasatinib tablets; for *PDGFRA* exon 18 mutations that are insensitive to imatinib [including the *PDGFRA D842V* mutation]);; third-line therapy is Stivarga® (regorafenib tablets); fourth-line therapy is Qinlock® (ripretinib tablets). The guidelines also state in a footnote that for unresectable disease, Sutent, Stivarga, and Votrient are special considerations for succinate dehydrogenase (SDH)-deficient GIST (category 2A).[4]
- **Kidney Cancer**: NCCN guidelines (version 1.2023 – June 17, 2022) 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] Votrient is also recommended as a single-agent therapy for von Hippel-Lindau-associated renal cell carcinoma as useful in certain circumstances (category 2A).
- **Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer**: NCCN guidelines (version 1.2022 – January 18, 2022) recommend Votrient (category 2B) as single-agent therapy for persistent disease or recurrence.[6]
- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2022 – May 17, 2022) recommend Votrient as single agent therapy for alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis), and solitary fibrous tumor/hemangiopericytoma.[7] Votrient is also recommended for dermatofibrosarcoma protuberans with fibrosarcomatous transformation for patients who are ineligible for intravenous systemic therapy or patients who are not candidates for anthracyclines-based regimens. 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 or patients who are not candidates for anthracyclines-based regimens and as a subsequent line of therapy for advanced or metastatic disease as palliative therapy as a single-agent (category 2A) or in combination with gemcitabine (category 2B).
- **Thyroid Carcinoma**: NCCN guidelines (version 2.2022 – May 5, 2022) 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 1.2022 – November 4, 2021) recommend Votrient for as a systemic therapy option for uterine sarcoma as other recommended regimen for patients with recurrent or metastatic disease that have progressed on prior cytotoxic chemotherapy (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Votrient. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Votrient is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Renal Cell Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets one of the following (i or ii):
     - **i.** Patient has relapsed or advanced disease; OR
     - **ii.** Patient has von Hippel-Lindau disease.

2. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient does not have gastrointestinal stromal tumor; AND
     Note: If patient has gastrointestinal stromal tumor, see criteria 4 for gastrointestinal stromal tumor.
   - **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.** Dermatofibrosarcoma protuberans with fibrosarcomatous transformation; OR
     - **v.** Non-adipocytic sarcoma; OR
     - **vi.** Pleomorphic rhabdomyosarcoma; OR
     - **vii.** Solitary fibrous tumor/hemangiopericytoma.

Other Uses with Supportive Evidence

3. **Bone Cancer.** Approve for 1 year 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.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets one of the following criteria (i or ii):
      i. Patient has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor; OR
      ii. Patient has tried each of the following (a, b, c, and d):
         a) One of imatinib or Ayvakit (avapritinib tablets); AND
         b) One of Sutent (sunitinib capsules) or Sprycel (dasatinib tablets); AND
         c) Stivarga (regorafinib tablets); AND
         d) Qinlock (ripretinib tablets).

5. **Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer.** Approve for 1 year 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 1 year 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 1 year 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 (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

8. **Uterine Sarcoma.** Approve for 1 year if the patient meets the following (A, B, and C):
   Note: Examples of uterine sarcoma include endometrial stromal sarcoma, undifferentiated uterine sarcoma, or uterine leiomyosarcomas.
   A) Patient is ≥ 18 years of age; AND
   B) Patient has recurrent or metastatic disease; AND
   C) Patient has tried at least one systemic regimen.
   Note: Examples of a systemic regimen include one or more of the following: doxorubicin, docetaxel, gemcitabine, ifosfamide, dacarbazine, epirubicin, or vinorelbine.

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; December 2021.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. . Accessed on June 27, 2022. Search term: pazopanib.

3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 27, 2022
4. The NCCN Gastrointestinal Stromal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – January 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 27, 2022.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – June 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 27, 2022.
6. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – January 18, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 27, 2022.
7. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 27, 2022.
8. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 27, 2022.
9. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 1.2022 – November 4, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 27, 2022.