PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/14/2023

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CIGNA NATIONAL FORMULARY COVERAGE:

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)[2]:

- **Bone Cancer**: NCCN guidelines (version 3.2023 – April 4, 2023) 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 1.2023 – March 13, 2023) recommend Votrient as an additional option after failure on approved therapies as "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 sunitinib 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, sunitinib, Stivarga, and Votrient are special considerations for succinate dehydrogenase (SDH)-deficient GIST (category 2A).[4]

- **Kidney Cancer**: NCCN guidelines (version 4.2023 – January 18, 2023) 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 as "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 2.2023 – June 2, 2023) recommend Votrient (category 2B) as single-agent therapy for persistent disease or recurrence.[6]
- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2023 – April 25, 2023) 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 2.2023 – May 18, 2023) 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] For differentiated thyroid cancer subtypes, the guidelines have changed the naming of Hürthle cell neoplasm to oncocytic carcinoma. 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 2.2023 – April 28, 2023) 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).[9]

POLICY STATEMENT

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

- **Votrient® (pazopanib tablets (GlaxoSmithKline)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 criteria (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 criteria (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 criteria (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 sunitinib or Sprycel (dasatinib tablets); AND
   c) Stivarga (regorafenib 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 criteria (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 oncocytic carcinoma (formerly Hürthle cell carcinoma).
   C) Patient is refractory to radioactive iodine therapy.

7. **Thyroid Carcinoma, Medullary.** 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 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 COVERED

- **Votrient® (pazopanib tablets (GlaxoSmithKline)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Votrient® tablets [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; December 2021.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 13, 2023. Search term: pazopanib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 4, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 13, 2023.
4. The NCCN Gastrointestinal Stromal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – March 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 13, 2023.
5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – January 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 13, 2023.
6. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 2.2023 – June 2, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 13, 2023.
7. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 13, 2023.
8. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2023 – May 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. . Accessed June 13, 2023.
9. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2023 – April 28, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 13, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Renal Cell Cancer:** An option was added for patients who have Von Hippel-Lindau disease. **Soft Tissue Sarcoma:** The following soft tissue sarcomas were added to the criteria, "Dermatofibrosarcoma Protuberans with Fibrosarcomatous Transformation" and "Non-adipocytic sarcoma" and the following soft tissue sarcomas were removed from the criteria, "Retroperitoneal/intra-abdominal soft tissue sarcoma that is unresectable or progressive and "soft tissue sarcoma of the extremity/superficial trunk or head/neck, including synovial sarcoma." **Gastrointestinal Stromal Tumors:** An option of trial of Sprycel (dasatinib tablets) was added to trial of Sutent (sunitinib capsules). An option for a patient who has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor was added to the criteria. **Ovarian Cancer, Fallopian Tube, or Primary Peritoneal Cancer):** The following were removed from the condition of approval "i.e." and "epithelial ovarian." **Uterine Sarcoma**: The following "endometrial stromal sarcoma, undifferentiated uterine sarcoma, or uterine leiomyosarcomas," was removed from the condition of approval and added as a note of examples of uterine sarcoma. The requirement of "advanced" disease was removed. The requirement that the patient has tried at least one systemic regimen was added with a Note with examples.	06/29/2022
Annual Revision	**Thyroid Carcinoma, Differentiated:** For examples of thyroid carcinoma, changed Hürthle cell carcinoma name to "oncocytic carcinoma (formerly Hürthle cell carcinoma)" based on guideline changes.	06/14/2023