

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Pazopanib Prior Authorization Policy

Votrient[®] (pazopanib tablets – Novartis; generic)

REVIEW DATE: 06/18/2025

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Pazopanib, a multi-tyrosine kinase inhibitor, is indicated in adults for the following uses:

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

Guidelines

Pazopanib is discussed in guidelines from the National Comprehensive Cancer Network (NCCN)²:

 Bone Cancer: NCCN guidelines (version 2.2025 – February 28, 2025) recommend pazopanib as a systemic therapy agent as "other recommended" regimens for chondrosarcoma for metastatic and widespread disease (category 2A).³

- **Gastrointestinal Stromal Tumor (GIST)**: NCCN guidelines (version 1.2025 April 17, 2025) recommend pazopanib as an additional option after failure on approved therapies as "useful in certain circumstances" (category 2A).⁴ The first line therapy is imatinib; second-line therapy is sunitinib; third-line therapy is Stivarga® (regorafenib tablets); and fourth-line therapy is Qinlock® (ripretinib tablets). The guidelines also state in a footnote that for unresectable disease, sunitinib, Stivarga, and pazopanib are special considerations for succinate dehydrogenase (SDH)-deficient GIST (category 2A).⁴
- **Kidney Cancer**: NCCN guidelines (version 3.2025 January 9, 2025) recommend pazopanib as first-line and subsequent therapy for relapsed or stage IV disease for clear cell histology (category 2A).⁵ Pazopanib 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 2.2025 May 23, 2024) recommend pazopanib (category 2B) as single-agent therapy for persistent disease or recurrence.⁶
- **Soft Tissue Sarcoma**: NCCN guidelines (version 1.2025 May 2, 2025) recommend pazopanib as single agent therapy for alveolar soft part sarcoma, angiosarcoma, desmoid tumors (aggressive fibromatosis), extraskeletal myxoid chondrosarcoma, epithelioid hemangioendothelioma, and solitary fibrous tumor/hemangiopericytoma. Pazopanib 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 pazopanib 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 or in combination with gemcitabine (category 2A).
- Thyroid Carcinoma: NCCN guidelines (version 1.2025 March 27, 2025) for differentiated thyroid carcinoma recommend pazopanib (category 2A) for progressive and/or symptomatic disease for unresectable locoregional recurrent or persistent disease not amenable to radioactive iodine therapy (for papillary and follicular types) 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. A majority of oncocytic carcinoma are non-iodineavid. Pazopanib 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 3.2025 March 7, 2025) recommend pazopanib 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 pazopanib. All approvals are provided for the duration noted below.

• Votrient® (pazopanib tablets - Novartis; generic) 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 BOTH of the following (A <u>and</u> 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 ALL of the following (A, B, C, <u>and</u> D):
 - **A)** Patient is \geq 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, vii, viii, ix, x, or xi):
 - i. Alveolar soft part sarcoma; OR
 - ii. Angiosarcoma; OR
 - iii. Dedifferentiated chordoma; OR
 - iv. Dedifferentiated liposarcoma; OR
 - v. Desmoid tumors (aggressive fibromatosis); OR
 - **vi.** Dermatofibrosarcoma protuberans with fibrosarcomatous transformation; OR
 - vii. Epithelioid hemangioendothelioma; OR
 - viii. Extraskeletal myxoid chondrosarcoma
 - ix. Non-adipocytic sarcoma; OR
 - x. Pleomorphic rhabdomyosarcoma; OR
 - **xi.** Solitary fibrous tumor/hemangiopericytoma.

Other Uses with Supportive Evidence

3. Bone Cancer. Approve for 1 year if the patient meets ALL of the following (A, B, and C):

- **A)** Patient is \geq 18 years of age; AND
- **B)** Patient has chondrosarcoma; AND
- **C)** Patient meets BOTH of 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 BOTH of the following (A <u>and</u> B):
 - **A)** Patient is ≥ 18 years of age; AND
 - **B)** Patient meets ONE of the following (i or ii):
 - i. Patient has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor; OR
 - ii. Patient has tried ALL of the following (a, b, c, and d):
 - a) imatinib; AND
 - b) sunitinib; 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 BOTH of the following (A <u>and</u> B):
 - **A)** Patient is \geq 18 years of age; AND
 - **B)** Patient has persistent or recurrent disease.
- **6. Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets BOTH of the following (A, and B):

<u>Note</u>: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma).

- **A)** Patient is \geq 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
 - i. Patient meets BOTH of the following (a and b):
 - a) Patient has papillary or follicular thyroid carcinoma; AND
 - **b)** The disease is refractory to radioactive iodine therapy; OR
 - ii. Patient has oncocytic (formerly Hürthle cell) carcinoma.
- **7. Thyroid Carcinoma, Medullary.** Approve for 1 year if the patient meets BOTH of the following (A <u>and</u> B):
 - **A)** Patient is \geq 18 years of age; AND
 - **B)** Patient has tried at least one systemic therapy.

<u>Note</u>: 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 ALL of the following (A, B, and C):

<u>Note</u>: Examples of uterine sarcoma include endometrial stromal sarcoma, undifferentiated uterine sarcoma, or uterine leiomyosarcomas.

- **A)** Patient is \geq 18 years of age; AND
- B) Patient has recurrent or metastatic disease; AND

C) Patient has tried at least one systemic regimen.
<u>Note</u>: 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 - Novartis; generic) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

- 1. Votrient® tablets [prescribing information]. East Hanover, NJ: Novartis; January 2024.
- 2. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 10, 2025. Search term: pazopanib.
- 3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2025 February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 10, 2025.
- 4. The NCCN Gastrointestinal Stromal Tumors Clinical Practice Guidelines in Oncology (version 1.2025 April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 10, 2025.
- 5. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2025 January 9, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 10, 2025.
- 6. The NCCN Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Clinical Practice Guidelines in Oncology (version 2.2025 May 23, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 10, 2025.
- 7. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 May 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 10, 2025.
- 8. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 March 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 11, 2025.
- The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 3.2025 March 7, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 11, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	Generic Votrient is available. Changed filename from Votrient Prior Authorization Policy to Pazopanib Prior Authorization Policy. Also changed Votrient to pazopanib throughout the policy. No criteria changes.	06/26/2024
Annual Revision	Soft Tissue Sarcoma: Added dedifferentiated chordoma and liposarcoma, epithelioid hemangioendothelioma, and extraskeletal myxoid chondrosarcoma to the list of approvable subtypes.	06/18/2025

Gastrointestinal Stromal Tumor: Deleted Ayvakit and Sprycel as therapy options from criteria.

Thyroid Carcinoma, Differentiated: Moved Note listing the different types of differentiate thyroid carcinoma to be under the indication. Separated criteria such that radioactive iodine-refractory disease is applicable to only follicular or papillary carcinoma and not for oncocytic carcinoma.

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