



An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/1/2016
LAST REVIEW DATE: 11/18/2021
LAST CRITERIA REVISION DATE: 11/18/2021
ARCHIVE DATE:

VOTRIENT® (pazopanib)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the [request form](#) in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**



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Criteria:

- **Criteria for initial therapy:** Votrient (pazopanib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
 1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual is 18 years of age or older
 3. A confirmed diagnosis of **ONE** of the following:
 - a. Advanced renal cell carcinoma (RCC) that has relapsed **or** is Stage IV and unresectable
 - b. Advanced soft tissue sarcoma (STS) in an individual who has received prior chemotherapy
 - c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2
 4. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
 - a. Electrocardiogram
 - b. Left ventricular ejection fraction
 - c. Evaluation of blood pressure, and if needed is adequately controlled with medication
 - d. Thyroid function tests
 - e. Urinalysis
 - f. Negative pregnancy test in a woman of childbearing potential
 - g. Eastern Cooperative Oncology Group (ECOG) performance status 0-1
 5. Will not be used in an individual with moderate or severe hepatic impairment (Child-Pugh Class B or C)
 6. There are no significant interacting drugs

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Votrient (pazopanib) is considered *medically necessary* and will be approved when **ALL** of the following criteria are met:
 1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
 2. Individual's condition has not worsened while on therapy
 - a. Worsening is defined as:
 - i. Disease progression
 - ii. There is no evidence of efficacy, disease stability and/or improvement



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3. Individual has been adherent with the medication
4. Individual has not developed any significant adverse drug effects that may exclude continued use:
 - a. Significant adverse effect such as:
 - i. Hepatic impairment
 - ii. QT prolongation
 - iii. Torsades de pointes
 - iv. Cardiac failure
 - v. Hemorrhage
 - vi. Arterial thromboembolic events
 - vii. Venous thromboembolic events
 - viii. Posterior Reversible Encephalopathy Syndrome
 - ix. Hypertensive Crisis and Hypertension despite dose reduction and use of antihypertensive medication
 - x. Proteinuria, repeated episodes of a 24-hour urine protein of ≥ 3 grams
 - xi. Nephrotic syndrome
 - xii. Gastrointestinal perforation or fistula
 - xiii. Interstitial lung disease/pneumonitis
 - xiv. Thrombotic microangiopathy (TMA), hemolytic uremia syndrome (HUS), and thrombocytopenic purpura (TTP)
5. Individual has not had more than two dose reductions because of adverse effects
6. Will not be used in an individual with moderate or severe hepatic impairment (Child-Pugh Class B or C)
7. There are no significant interacting drugs

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:
1. **Off-Label Use of a Non-cancer Medications**
 2. **Off-Label Use of a Cancer Medication for the Treatment of Cancer without a Specific Coverage Guideline**

Description:

Votrient (pazopanib) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) and it is indicated for the treatment of patients with advanced soft tissue sarcoma (STS) who have received prior chemotherapy. The efficacy of Votrient (pazopanib) for the treatment of patients with adipocytic STS or gastrointestinal stromal tumors (GIST) has not been demonstrated.



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Votrient (pazopanib) is a multi-tyrosine kinase inhibitor of vascular endothelial growth factor receptor (VEGFR)-1, VEGFR-2, VEGFR-3, platelet-derived growth factor receptor (PDGFR)- α and - β , fibroblast growth factor receptor (FGFR)-1 and -3, cytokine receptor (Kit), interleukin-2 receptor-inducible T-cell kinase (Itk), leukocyte-specific protein tyrosine kinase (Lck), and transmembrane glycoprotein receptor tyrosine kinase (c-Fms). In vitro, pazopanib inhibited ligand-induced autophosphorylation of VEGFR-2, Kit, and PDGFR- β receptors. In vivo, pazopanib inhibited VEGF-induced VEGFR-2 phosphorylation in mouse lungs, angiogenesis in a mouse model, and the growth of some human tumor xenografts in mice.

Resources:

Votrient (pazopanib) product information, revised by Novartis Pharmaceuticals Corporation 08-2020. Available at DailyMed <http://dailymed.nlm.nih.gov>. Accessed September 04, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 1.2022 – July 1, 2021. Available at <https://www.nccn.org>. Accessed September 4, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Soft Tissue Sarcoma Version 2.2021 – April 28, 2021. Available at; <https://www.nccn.org>. Accessed September 04, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.
