BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

Pazopanib
VOTRIENT® (pazopanib)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Pazopanib or 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. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Advanced renal cell carcinoma (RCC)

    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. Individual does not have adipocytic soft tissue sarcoma or gastrointestinal stromal tumor

5. Individual has received and completed **ALL** the following **baseline tests** before initiation of treatment and with continued monitoring of the individual as clinically appropriate:
   a. Liver function tests
   b. Serum electrolytes with correction of potassium, magnesium, and calcium if abnormal
   c. Electrocardiogram if individual is at risk for cardiac dysfunction or QT prolongation
   d. Left ventricular ejection fraction in an individual at risk for cardiac dysfunction
   e. Blood pressure is within normal limits, if needed is adequately controlled with medication
   f. Thyroid function tests
   g. Urinalysis
   h. Negative pregnancy test in a woman of childbearing potential
   i. Eastern Cooperative Oncology Group (ECOG) performance status 0-1

6. **For brand Votrient:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic pazopanib** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Will not be used in an individual with severe hepatic impairment (Child-Pugh Class C)

8. Individual is not currently taking any other drugs which cause any significant drug interactions such as:
   a. Strong CYP3A4 inducers (e.g., carbamazepine, phenobarbital, phenytoin, primidone, rifampin, etc.)
   b. Inhibitors of p-gp (e.g., amiodarone, clarithromycin, cyclosporine, erythromycin, itraconazole, ketoconazole, quinidine, verapamil, etc.)
   c. Proton pump inhibitors(e.g., lansoprazole, omeprazole, pantoprazole, rabeprazole, esomeprazole, etc.)
   d. H2-receptor antagonists (e.g., cimetidine, famotidine, ranitidine)
   e. Drugs that increase QT-interval (e.g., amiodarone, sotalol, quinidine, etc.)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Pazopanib or Votrient (pazopanib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

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 responded while on therapy with response defined as there is evidence of efficacy, disease stability and/or improvement

3. Individual has been adherent with the medication

4. **For brand Votrient:** Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for **generic pazopanib** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
    a. Hepatic impairment or toxicity
    b. QT prolongation
    c. Torsades de pointes
    d. Cardiac failure
    e. Hemorrhage
    f. Arterial thromboembolic events
    g. Venous thromboembolic events
    h. Posterior Reversible Encephalopathy Syndrome
    i. Hypertensive Crisis and Hypertension despite dose reduction and use of antihypertensive medication
    j. Proteinuria, repeated episodes of a 24-hour urine protein of ≥ 3 grams
    k. Nephrotic syndrome
    l. Gastrointestinal perforation or fistula
    m. Interstitial lung disease/pneumonitis
    n. Thrombotic microangiopathy (TMA), hemolytic uremia syndrome (HUS), and thrombocytopenic purpura (TTP)

6. Individual does not have adipocytic soft tissue sarcoma or gastrointestinal stromal tumor

7. Individual has not had more than two dose reductions because of adverse effects

8. Will not be used in an individual with severe hepatic impairment (Child-Pugh Class C)

9. Individual is not currently taking any other drugs which cause any significant drug interactions such as:
    a. Strong CYP3A4 inducers such as carbamazepine, phenobarbital, phenytoin, primidone, rifampin, others
    b. Inhibitors of p-gp such as amiodarone, clarithromycin, cyclosporine, erythromycin, itraconazole, ketoconazole, quinidine, verapamil, others
    c. Proton pump inhibitors such as lansoprazole, omeprazole, pantoprazole, rabeprazole, esomeprazole, others
    d. H2-receptor antagonists such as cimetidine, famotidine
    e. Drugs that increase QT-interval such as amiodarone, sotalol, quinidine, others

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 Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

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VOTRIENT® (pazopanib)

Description:

Votrient (pazopanib) and generic pazopanib are 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.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Resources:

Pazopanib product information, revised by Novugen Pharma (USA), LLC. 04-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 22, 2024.

Votrient (pazopanib) product information, revised by Novartis Pharmaceuticals Corporation 01-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 22, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 2.2025 – Updated September 06, 2024. Available at https://www.nccn.org. Accessed October 22, 2024.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Soft Tissue Sarcoma Version 3.2024 – September 27, 2024. Available at; https://www.nccn.org. Accessed October 22, 2024.

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.

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