PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/1/2016
LAST REVIEW DATE: 11/19/2020
LAST CRITERIA REVISION DATE: 11/19/2020
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.

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.**

VOTRIENT® (pazopanib)

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. Any of the following advanced soft tissue sarcoma (STS) in an individual who has received prior chemotherapy
        i. Alveolar soft part sarcoma as a preferred single-agent therapy

        ii. Angiosarcoma as Single-agent therapy

        iii. Extremity/Superficial Trunk, Head/Neck as first-line advanced/metastatic therapy as a single agent in patients ineligible for IV chemotherapy **or** as preferred single agent palliative treatment for non-adipocytic sarcoma as subsequent line of therapy for advanced/metastatic disease with disseminated metastases

        iv. Gastrointestinal stromal tumors as fourth-line therapy after single-agent therapy with imatinib, sunitinib and regorafenib

        v. Retroperitoneal/Intra-Abdominal as first-line advanced/metastatic therapy as a single agent in patients ineligible for IV chemotherapy **or** as preferred single agent palliative treatment for non-adipocytic sarcoma as subsequent line of therapy for recurrent unresectable or stage IV disease

        vi. Rhabdomyosarcoma as preferred as palliative, subsequent lines of therapy

        vii. Solitary Fibrous Tumor as a preferred single-agent therapy

        viii. Undifferentiated Pleomorphic Sarcoma (UPS) as a preferred single-agent therapy

     c. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer that is persistent or recurred

     d. 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. Comprehensive metabolic panel
b. Electrocardiogram
c. Left ventricular ejection fraction
d. Evaluation of blood pressure, and if needed is adequately controlled with medication
e. Thyroid function tests
f. Urinalysis
g. Negative pregnancy test in a woman of child bearing potential
h. 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)

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 progressed while on Votrient
        ii. There is no evidence of efficacy, disease stability and/or improvement

3. Individual has been adherent with the medication

4. Individual has not developed any significant level 4 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. Posterior Reversible Encephalopathy Syndrome
        viii. Hypertension and Hypertensive Crisis
        ix. Proteinuria, repeated episodes of a 24-hour urine protein of $\geq$ 3 grams
        x. Nephrotic syndrome
        xi. Gastrointestinal perforation
        xii. Interstitial lung disease
        xiii. Thrombotic microangiopathy (TMA), hemolytic uremia syndrome (HUS), and thrombocytopenic purpura (TTP)

5. Will not be used in an individual with moderate or severe hepatic impairment (Child-Pugh Class B or C)

VOTRIENT® (pazopanib)

6. There are no significant interacting drugs

Renewal duration: 12 months

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.

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 manufacturer 08-2020, at DailyMed http://dailymed.nlm.nih.gov accessed September 4, 2020

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 1.2021 – July 15, 2020; https://www.nccn.org. Accessed September 4, 2020

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Soft Tissue Sarcoma Version 2.2020 – May 28, 2020; https://www.nccn.org. Accessed September 4, 2020

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Ovarian Cancer Version 1.2020 – March 11, 2020; https://www.nccn.org. Accessed September 4, 2020

Atkins MB. Overview of the treatment of renal cell carcinoma. In: UpToDate, Richie JP, Shah S (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 4, 2020

Atkins MB. Antiangiogenic and molecularly targeted therapy for advanced or metastatic clear cell renal carcinoma. In: UpToDate, Richie JP, Shah S (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 4, 2020

Choueiri TK, Pal SK. The treatment of advanced non-clear cell renal carcinoma. In: UpToDate, Atkins MB, Shah S (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 4, 2020

VOTRIENT® (pazopanib)

George D, Jonasch E. Systemic therapy of advanced clear cell renal carcinoa. In: UpToDate, Atkins MB, Shah S (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 4, 2020

George S. Systemic treatment of metastatic soft tissue sarcoma. In: UpToDate, Maki R, Shah S (Eds), UpToDate, Waltham MA.: UpToDate Inc. http://uptodate.com. Accessed on September 4, 2020

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.