Prior Authorization DRUG Guidelines

Votrient™ (pazopanib)

Effective Date: 7/24/12
Date Developed: 7/17/12 by Albert Reeves MD
Last Approval Date: 1/26/16, 1/24/17, 1/23/18

Votrient is an Antineoplastic Agent, Tyrosine Kinase Inhibitor; Vascular Endothelial Growth Factor (VEGF) Inhibitor.

Pre-Approval Criteria:

VCHCP will authorize Votrient for FDA approved treatment of advanced renal cell cancer (RCC); and treatment of advanced soft tissue sarcoma (STS) in patients previously treated with chemotherapy.

Off-label use: treatment of thyroid cancer (advanced, differentiated). Note: off label uses are not covered except under certain strict circumstances. See the VCHCP policy on Coverage of Prescription Medication for Off-Label Use.

VCHCP requires that Votrient be prescribed by an Oncologist or Endocrinologist.

Dosing:

Renal cell cancer (RCC): Oral: 800 mg once daily (Sternberg, 2010)

Soft tissue sarcoma (STS), advanced refractory: Oral: 800 mg once daily (Van Der Graaf, 2011)

Thyroid cancer, advanced differentiated (unlabeled use): Oral: 800 mg once daily until disease progression or unacceptable toxicity (Bible, 2010)

Dosage Forms: U.S.

Tablet, oral: Votrient™: 200 mg

Warnings/Precautions

Boxed warnings:

• Hepatotoxicity: See “Concerns related to adverse effects” below.

Concerns related to adverse effects:

• Gastrointestinal perforation/fistula: Perforation and fistula (including fatal) have been
reported; monitor for symptoms of gastrointestinal perforation and fistula.
• Heart failure: May cause new-onset or worsening of existing heart failure.
• Hemorrhage: Hemorrhagic events (including fatal) have been reported. Use is not recommended in patients with a history of hemoptysis, cerebral hemorrhage or clinically significant gastrointestinal hemorrhage within 6 months.
• Hepatotoxicity: [U.S. Boxed Warning]: Severe and fatal hepatotoxicity (transaminase and bilirubin elevations) has been reported with use. Monitor hepatic function. May require dosage interruption, reduction, or discontinuation.
• Hypertension: May cause and/or worsen hypertension; hypertensive crisis has been observed.
• Infections: Serious, including fatal, infections have been reported; monitor for signs and symptoms of infection. Temporarily or permanently discontinue therapy for serious infections as clinically indicated.
• Proteinuria: Has been reported with use.
• QTc prolongation: QTc prolongation, including torsade de pointes, has been observed.
• Reversible posterior leukoencephalopathy syndrome (RPLS): Has been reported (rarely); may be fatal.
• Thromboembolic events: Venous and arterial thromboembolism have been reported.
• Thyroid disorders: Hypothyroidism has been reported with use; monitor thyroid function tests.
• Wound healing complications: Vascular endothelial growth factor (VEGF) receptor inhibitors are associated with impaired wound healing.

**Disease-related concerns:**

Renal impairment: Patients with mild-to-moderate renal impairment (Clcr ≥30 mL/minute) were included in trials. There are no pharmacokinetic data in patients with severe renal impairment undergoing dialysis (peritoneal and hemodialysis, however, renal impairment is not expected to significantly influence pazopanib pharmacokinetics or exposure.

**REFERENCES:**


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