Prior Authorization Approval Criteria

Votrient (pazopanib)

Generic name: pazopanib

Brand name: Votrient

Medication class: Tyrosine Kinase Inhibitor

FDA-approved uses: Advanced renal cell carcinoma
Advanced soft tissue sarcoma who have received prior chemotherapy

Criteria for use (bullet points below are all inclusive unless otherwise noted):

- Must be prescribed by an oncologist
- Clinically documented advanced renal cell carcinoma.
- OR
- Clinically documented advanced soft tissue sarcoma and previous treatment with at least one prior chemotherapy agent, such as:
    - Doxorubicin
    - Epirubicin
    - Ifosfamide
    - Gemcitabine
    - Paclitaxel

Criteria for continuation of therapy:

- Patient's therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient's condition at this time.
- Patient is tolerating treatment Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient's condition)

Monitoring:

- Votrient is associated with increases in liver enzymes: therefore, monitoring of liver function is recommended prior to initiation of therapy, every 4 weeks for at least the first 4 months of treatment, and periodically thereafter.

Approval Duration:

- Initial: 6 months
- Renewal: 12 months

Benefit Type:

- Pharmacy

** **Off-label Use:**

Fallon may authorize coverage of the requested medication for use in other cancer diagnoses with submitted documentation that the drug is recognized as a "Medically Accepted Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

If the requested off-label use is not acknowledged by the NCCN Drugs and Biologics Compendium, Fallon will abide by the Centers for Medicare and Medicaid Services (CMS) guidance or Massachusetts regulations[1] accepting documentation of recommended off-label use of the requested medication in any one of the following:

1. One of the following standard reference compendia:
   - American Hospital Formulary Service – Drug information (AHFS-DI)
   - Thomson Micromedex DrugDex
   - Clinical Pharmacology (Gold Standard)
   - Wolters Kluwer Lexi-Drugs

2. Peer-reviewed published medical literature indicating that sufficient evidence exists to support use.

[1]Reference: https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXXII/Chapter175/Section47K accessed 7/7/2017

Adopted: 03/10/10
Revised: 03/13/2013, 12/17/13, 9/13/17: removed documentation requirement, removed specialist, updated continuation of therapy, added approval duration and benefit type.
Reviewed: 11/28/17 – for peer reviewed literature, replaced “determined by Fallon” with “indicating”