Pharmacy Medical Necessity Guidelines: Votrient™ (pazopanib)

Effective: April 11, 2017 (All plans except Tufts Health RITogether)
Effective: June 1, 2017 (Tufts Health RITogether)

Prior authorization required ✓ Type of review – care management ✓
Not covered Type of review – clinical review
Pharmacy (RX) or medical (MED) benefit RX Department to review RXUM

This Pharmacy Medical Necessity Guideline applies to the following:
**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan – large group plans
- Tufts Health Freedom Plan – small group plans

**Fax Numbers:**
RXUM: 617.673.0988

**Note:** For Tufts Health Plan Medicare Preferred Members, refer to the Tufts Health Plan Medicare Preferred step therapy criteria. Background, applicable product and disclaimer information can be found on the last page.

**OVERVIEW**
Approximately 90% of renal tumors are renal cell carcinoma (RCC), and approximately 80% of these are clear cell tumors. Surgical resection, with either radical nephrectomy or nephron-sparing surgery, is an effective treatment option for clinically localized RCC. After surgical excision, 20 to 30% of patients with localized tumors experience relapse. For clear cell tumors, tyrosine kinase inhibitors (TKIs) and anti-vascular endothelial growth factor antibodies are recommended as first- and second-line therapies in patients who have relapsed. Votrient (pazopanib) is an oral TKI that is recommended as a first-line treatment option in patients with relapsed or medically unresectable predominantly clear cell stage IV renal carcinoma.

Soft tissue sarcomas (STS), one of two broad categories of sarcomas, are solid tumors of the fat, muscle, nerve and nerve sheath, blood vessels, and other connective tissues. Collectively, sarcomas account for approximately one and fifteen percent of all adult and pediatric malignancies. Surgical resection is the standard primary treatment for most STS. Radiation therapy and/or chemotherapy may be used prior to surgery to reduce large high-grade tumors and, in some cases, postoperative radiation therapy should be considered. Chemotherapy is used to treat advanced or metastatic STS. Votrient (pazopanib) is an option for palliative therapy for patients with progressive, unresectable, or metastatic non-lipogenic STS.

**FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS**
Votrient (pazopanib) is indicated for the treatment of patients with advanced RCC. In addition, Votrient (pazopanib) 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 has not been demonstrated.

**COVERAGE GUIDELINES**
The plan may authorize coverage of Votrient (pazopanib) for Members when all of the following criteria are met:

**For Advanced Renal Cell Carcinoma**
1. Documented diagnosis of advanced renal cell carcinoma
   AND
2. The prescribing physician is an oncologist

**For Advanced Soft Tissue Sarcoma**
1. Documented diagnosis of advanced soft tissue sarcoma
   AND
2. The prescribing physician is an oncologist AND
3. The Member has received prior chemotherapy, including anthracycline treatment, or was unsuited for such therapy

**Off-label Use Coverage for Other Cancer Diagnoses**
Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the "Sullivan Law": (M.G.L. c.175, s.47K).

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such 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.

**Note:** The plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, the plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

**"Standard Reference Compendia"**
1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

**"Peer Reviewed Medical Literature"**
- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

When the plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:
1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question.
   a) whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question (e.g., in some clinical studies it may be
unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover); b) that nonrandomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and, c) that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

LIMITATIONS
1. The plan will not authorize the use of Votrient (pazopanib) for conditions other than those listed above without appropriate documentation.
2. The efficacy of Votrient (pazopanib) for the treatment of patients with adipocytic soft tissue sarcoma or gastrointestinal stromal tumors has not been demonstrated.
3. The following quantity limitations apply for Votrient (pazopanib) tablets:
   • Votrient (pazopanib) 200mg: 120 tablets per 30 days

CODES
None

REFERENCES

APPROVAL HISTORY
March 9, 2010: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
• January 11, 2011: Administrative Update: Effective 4/1/2011, Off-label Use Coverage for Other Cancer Diagnoses language updated. The plan requires prescribers to submit clinical documentation supporting the drug’s effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s)
• March 8, 2011: Removal of the limitation; Votrient (pazopanib) 400mg - 60 tablets per 30 days
• February 14, 2012: No changes
• June 12, 2012: Added pharmacy coverage guidelines and limitation for advanced soft tissue sarcoma
• May 14, 2013: No changes
• April 8, 2014: No changes
• April 14, 2015: No changes
• January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct
• April 12, 2016: No changes
**BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member’s health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence. For Tufts Health Plan Medicare Preferred, refer to Tufts Health Plan Medicare Preferred prior authorization criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.