Specialty Guideline Management

Votrient (pazopanib)

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
- Votrient is indicated for the treatment of advanced renal cell carcinoma (RCC)
- Votrient is indicated for the treatment of advanced soft tissue sarcoma (STS) in patients who have received prior chemotherapy

Compendial Uses
- Relapsed or surgically unresectable RCC
- Uterine sarcoma
- Soft tissue sarcoma of one of the following subtypes:
  - Gastrointestinal stromal tumors (GIST)
  - Angiosarcoma
  - Pleomorphic rhabdomyosarcoma
  - Retroperitoneal/intra-abdominal sarcoma
  - Extremity/superficial trunk sarcoma
- Papillary, Hürthle cell, or follicular thyroid carcinoma:
  - Unresectable recurrent or persistent locoregional disease
  - Distant metastatic disease
- Medullary thyroid carcinoma:
  - Progressive disease
  - Symptomatic distant metastatic disease
- Metastatic dermatofibrosarcoma protuberans (DFSP)

All other indications are considered experimental/investigational and are not covered benefits.

B. INITIAL CRITERIA FOR APPROVAL

1. Renal Cell Carcinoma
   Authorization of 12 months may be granted to members prescribed Votrient as a single agent for the treatment of relapsed or medically unresectable renal cell carcinoma.

2. Soft Tissue Sarcoma (STS)
   Authorization of 12 months may be granted to members prescribed Votrient for the treatment of soft tissue sarcoma that is not an adipocytic sarcoma and the member meets ONE of the following criteria:
   a. The STS subtype is gastrointestinal stromal tumor (GIST) and the disease has progressed on treatment with imatinib, sunitinib, or regorafenib.
   b. The STS subtype is pleomorphic rhabdomyosarcoma and Votrient will be used as a single agent.
   c. The STS subtype is angiosarcoma and Votrient will be used as a single agent.
   d. The STS subtype is retroperitoneal/intra-abdominal sarcoma and Votrient will be used as a single agent for progressive, unresectable, or metastatic disease.
   e. The STS subtype is extremity/superficial trunk sarcoma and Votrient will be used as a single agent for progressive, unresectable, or metastatic disease.

3. Uterine Sarcoma
   Authorization of 12 months may be granted to members prescribed Votrient as a single agent for the treatment of uterine sarcoma who meet ANY of the following criteria:
a. The disease is stage II, III, or IV  
b. The disease is stage I and the disease is medically inoperable

4. Thyroid Carcinoma

4.1. Papillary, Hurthle cell, or Follicular Thyroid Carcinoma
Authorization of 12 months may be granted to members prescribed Votrient for the treatment of papillary, Hurthle cell, or follicular thyroid carcinoma when the member meets ALL of the following criteria:
   a. The disease is unresectable or metastatic  
   b. The disease is progressive or symptomatic  
   c. The disease is radio-iodine refractory  
   d. Nexavar is not an appropriate option for the member

4.2. Medullary Thyroid Carcinoma
Authorization of 12 months may be granted to members prescribed Votrient for the treatment of medullary thyroid carcinoma when the member meets ALL of the following criteria:
   a. The member has progressive disease or symptomatic distant metastatic disease  
   b. The disease has progressed on vandetanib or cabozantinib OR vandetanib or cabozantinib are not appropriate options for the member.

5. Dermatofibrosarcoma Protuberans (DFSP)
Authorization of 12 months may be granted to members prescribed Votrient as a single agent for the treatment of metastatic DFSP.

C. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

D. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.
1. Dosing Limits
   The following dosing limit applies:
   • All indications: 800 mg/day

REFERENCES