Clinical Policy: Pazopanib (Votrient)
Reference Number: ERX.SPMN.58
Effective Date: 03/14
Last Review Date: 09/16

See Important Reminder at the end of this policy for important regulatory and legal information.

Policy/Criteria
It is the policy of health plans affiliated with Envolve Pharmacy Solutions® that pazopanib (Votrient®) is medically necessary for members meeting the following criteria:

I. Initial Approval Criteria
   A. Renal Cell Carcinoma and Soft Tissue Sarcoma (must meet all):
      1. Age ≥ 18 years;
      2. Documented diagnosis of one of the following (a or b):
         a. Advanced* renal cell carcinoma;
         b. Advanced* soft tissue sarcoma and both of the following:
            i. Has received prior chemotherapy;
            ii. Does not have adipocytic/lipogenic soft tissue sarcoma or gastrointestinal stromal tumor;
      3. Request is for ≤ 800 mg of Votrient daily as monotherapy.

   *Advanced: progressive, recurrent, unresectable, or metastatic

   Approval duration: 3 months

   B. Other diagnoses/indications: Refer to ERX.SPMN.16 - Global Biopharm Policy.

II. Continued Approval
   A. Renal Cell Carcinoma and Soft Tissue Sarcoma (must meet all):
      1. Currently receiving medication via health plan benefit or member has previously met all initial approval criteria;
      2. No evidence of disease progression.

   B. Other diagnoses/indications (must meet 1 or 2):
      1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
      2. Refer to ERX.SPMN.16 - Global Biopharm Policy.

Background
Renal Cell Carcinoma
Renal cell carcinoma (RCC), particularly clear cell, comprises the majority of renal tumors, includes several hereditary subtypes, and is adversely associated with smoking and obesity. Diagnosis and staging (stages I through IV) is informed by medical history, laboratory studies, and imaging. Treatment options include surgery, ablation (e.g., cryo- or
radiofrequency ablation), cytokine therapy (e.g., interferon, interleukin-2), targeted therapy (e.g., tyrosine kinase inhibitors, antiVEGF antibodies), and chemotherapy (e.g., gemcitabine, doxorubicin).\(^1\) As a multi-tyrosine kinase inhibitor, Votrient is FDA approved for treatment of patients with advanced RCC and is recognized as first-line treatment of patients with relapsed or stage IV surgically unresectable RCC, including after cytokine or tyrosine kinase failure.\(^1,2\)

**Soft Tissue Sarcoma**

Sarcomas make up a group of rare solid tumors that are divided into soft tissue sarcomas (STS) and sarcomas of bone.\(^3\) All sarcomas are derived from mesenchymal cell origin.\(^3\) The most common types of STS in adults include undifferentiated pleomorphic sarcoma, gastrointestinal stromal tumors, liposarcoma, leiomyosarcoma, synovial sarcoma, and malignant peripheral nerve sheath tumors.\(^3\) Diagnosis and staging (stages I through IV) are informed by clinical history, pathology, imaging, and molecular genetic testing.\(^3\) Treatment options include surgery, radiation therapy, chemotherapy (e.g., single agents, such as dacarbazine, or anthracycline-based combination regimens), and targeted therapy (e.g., Votrient, Gleevec, Sutent).\(^3\) Votrient is FDA approved for the treatment of patients with advanced STS who have received prior chemotherapy.\(^2,3\) Both chemotherapy and targeted therapies are treatments of choice in advanced, unresectable, or metastatic disease.\(^2,3\)

**Appendices**

**Appendix A: Abbreviation Key**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
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<tbody>
<tr>
<td>RCC</td>
<td>renal cell carcinoma</td>
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<td>STS</td>
<td>soft tissue sarcoma</td>
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**Reviews, Revisions, and Approvals**

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<tr>
<th>Description</th>
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<tr>
<td>Policy created.</td>
<td>02/14</td>
<td>03/14</td>
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<tr>
<td>Added clinical trial data on efficacy to background. Added dosing &amp; dose modification information. Added monotherapy &amp; special population sections. Added information about approval of off-label use and figure 2. -Appendices: Removed appendix on malignant adipocyte soft tissue sarcoma subtypes. Added Appendix B: Conditions that preclude initiation of Votrient. Revised Appendix C (discontinuation of therapy due to developing safety concerns). Added Appendix E (drug interactions) and Appendix F/G (off-label uses). -Votrient algorithm: Added “Currently receiving other chemotherapy?”. Combined total bilirubin criteria for initiation and continuation into Appendix B and C. Added baseline LFT requirement for initiation.</td>
<td>02/15</td>
<td>03/15</td>
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<td>Policy converted to new template.</td>
<td>08/16</td>
<td>09/16</td>
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<td>-Criteria: added age restriction; added explanatory detail per NCCN guidelines around the term 'advanced' in the context of RCC and STS; added max dose and monotherapy criteria; changed initial approval</td>
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Reviews, Revisions, and Approvals

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<td>period to 3 months; removed baseline LFT question and all safety criteria. Directed all off-label use requests to global biopharm policy. Appendices: removed all except for abbreviation key.</td>
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References


Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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