Clinical Pharmacy Program Guidelines for Votrient

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<th>Program</th>
<th>Prior Authorization</th>
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<tr>
<td>Medication</td>
<td>Votrient™ (pazopanib)</td>
</tr>
<tr>
<td>Issue Date</td>
<td>9/2014</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics</td>
<td>7/2017</td>
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<tr>
<td>Approval Date</td>
<td>9/2017</td>
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1. **Background:**

Votrient™ (pazopanib) is a multi-tyrosine kinase inhibitor indicated for the treatment of advanced renal cell carcinoma and advanced soft tissue sarcoma in patients who have received prior chemotherapy. The efficacy of Votrient for the treatment of patients with adipocytic soft tissue sarcoma or gastrointestinal stromal tumors has not been demonstrated.¹ Additionally, the National Cancer Comprehensive Network (NCCN) recommends use of Votrient in treatment of medullary, follicular, Hürthle cell and papillary thyroid carcinomas; ovarian cancer; dermatofibrosarcoma protuberans; and uterine sarcoma.²

2. **Coverage Criteria:**

A. **Renal Cell Carcinoma (RCC)**

   1. **Initial Authorization**

      a. **Votrient** will be approved based on **both** of the following criterion:

         (1) Diagnosis of renal cell carcinoma (RCC)

         -AND-

         (2) **One** of the following:

         a) Disease is relapsed

         -OR-

         b) **Both** of the following:

         i. Medically or surgically unresectable tumor
         ii. Diagnosis of Stage IV disease
Authorization will be issued for 12 months.

2. Reauthorization

a. Votrient will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

B. Soft Tissue Sarcoma (STS)

1. Initial Authorization

a. Votrient will be approved based on one of the following criteria:

(1) Diagnosis of one of the following:

(a) Angiosarcoma
(b) Pleomorphic rhabdomyosarcoma
(c) Retroperitoneal/Intra-abdominal of nonliposarcomal origin with disease that is unresectable or progressive
(d) Soft Tissue Sarcoma of the Extremity/Superficial Trunk or Head/Neck, of nonliposarcomal origin, with disease that is synchronous stage IV or recurrent and has disseminated metastases

-OR-

(2) Both of the following:

(a) Diagnosis of progressive gastrointestinal stromal tumors (GIST)

-AND-

(b) History of failure, contraindication, or intolerance to one of the following:

i. Gleevec (imatinib)
ii. Sutent (sunitinib)
iii. Stivarga (regorafenib)

Authorization will be issued for 12 months.
2. **Reauthorization**
   
a. **Votrient** will be approved based on the following criterion:

   (1) Patient does not show evidence of progressive disease while on Votrient therapy

   **Authorization will be issued for 12 months.**

C. **Thyroid Carcinoma (off-label)**

1. **Initial Authorization**
   
a. **Votrient** will be approved based on one of the following criteria:

   (1) **All** of the following:

   (a) Diagnosis of one of the following:

      i. Follicular carcinoma
      ii. Hürthle cell carcinoma
      iii. Papillary carcinoma

   -AND-

   (b) **One** of the following:

      i. Unresectable recurrent disease
      ii. Persistent locoregional disease
      iii. Metastatic disease

   -AND-

   (c) **One** of the following:

      i. Patient has symptomatic disease
      ii. Patient has progressive disease

   -AND-

   (d) Disease is refractory to radioactive iodine treatment

   -OR-
(2) **All** of the following:

(a) Diagnosis of medullary carcinoma

-AND-

(b) **One** of the following:

   i. Disease is progressive
   ii. Disease is symptomatic with distant metastases

-AND-

(c) History of failure, contraindication, or intolerance to **one** of the following:

   i. Caprelsa (vandetanib)
   ii. Cometriq (cabozantinib)

**Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. **Votrient** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Votrient therapy

**Authorization will be issued for 12 months.**

D. **Uterine Sarcoma (off-label)**

1. **Initial Authorization**

   a. **Votrient** will be approved based on the following criterion:

      (1) Diagnosis of uterine sarcoma

**Authorization will be issued for 12 months.**

2. **Reauthorization**

   a. **Votrient** will be approved based on the following criterion:
(1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

E. Dermatofibrosarcoma Protuberans (DFSP) (off-label)

1. Initial Authorization
   a. Votrient will be approved based on the following criterion:
      (1) Diagnosis of metastatic dermatofibrosarcoma protuberans (DFSP)

Authorization will be issued for 12 months.

2. Reauthorization
   a. Votrient will be approved based on the following criterion:
      (1) Patient does not show evidence of progressive disease while on Votrient therapy

Authorization will be issued for 12 months.

F. Ovarian Cancer (off-label)

1. Initial Authorization
   a. Votrient will be approved based on all of the following criteria:
      (1) Diagnosis of one of the following:
          (a) Epithelial Ovarian Cancer
          (b) Fallopian Tube Cancer
          (c) Primary Peritoneal Cancer

-AND-

(2) Disease is stage II-IV

-AND-

(3) Patient is in complete remission following primary treatment

Authorization will be issued for 12 months.
2. **Reauthorization**

   a. **Votrient** will be approved based on the following criterion:

   (1) Patient does not show evidence of progressive disease while on Votrient therapy

   **Authorization will be issued for 12 months.**

3. **References:**


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<thead>
<tr>
<th>Program</th>
<th>Prior Authorization – Votrient (pazopanib)</th>
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<tbody>
<tr>
<td></td>
<td><strong>Change Control</strong></td>
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<tr>
<td>Date</td>
<td>Change</td>
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<tr>
<td>9/2014</td>
<td>New guideline</td>
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<tr>
<td>7/2016</td>
<td>Updated clinical criteria to align with Employer and Individual notification policy and updated policy to new template</td>
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<tr>
<td>7/2017</td>
<td>Annual review with no changes to coverage criteria. Updated references.</td>
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