Clinical Pharmacy Program Guidelines for Sutent

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<tr>
<th>Program</th>
<th>Prior Authorization</th>
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<tr>
<td>Medication</td>
<td>Sutent® (sunitinib malate)</td>
</tr>
<tr>
<td>Issue Date</td>
<td>9/2013</td>
</tr>
<tr>
<td>Pharmacy and Therapeutics Approval Date</td>
<td>7/2017</td>
</tr>
<tr>
<td>Effective Date</td>
<td>9/2017</td>
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1. **Background:**

Sutent® (sunitinib malate) is a tyrosine kinase inhibitor indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to Gleevec® (imatinib mesylate); treatment of advanced renal cell carcinoma (RCC); and treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.¹ The National Cancer Comprehensive Network (NCCN) recommends use of Sutent for medullary, follicular, Hürthle cell, or papillary thyroid carcinoma; chordoma; meningiomas; and thymic carcinoma.² NCCN also approves the use of Sutent for other soft tissue sarcomas: alveolar soft part sarcoma (ASPS), angiosarcoma, and solitary fibrous tumor/hemangiopericytoma.

2. **Coverage Criteria:**

A. **Gastrointestinal Stromal Tumor (GIST)**

1. **Initial Authorization**

   a. Sutent will be approved based on both of the following criteria:

   (1) Diagnosis of gastrointestinal stromal tumor (GIST)

   -AND-

   (2) History of failure, contraindication, or intolerance to Gleevec (imatanib)

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

2. **Reauthorization**

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

   (1) Patient does not show evidence of progressive disease while on Sutent therapy
Authorization will be issued for 12 months.

B. Renal Cell Carcinoma (RCC)

1. Initial Authorization
   a. Sutent will be approved based on both of the following criteria:
      (1) Diagnosis of renal cell carcinoma (RCC)
      -AND-
      (2) One of the following:
         (a) Disease has 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. Sutent will be approved based on the following criterion:
      (1) Patient does not show evidence of progressive disease while on Sutent therapy

      Authorization will be issued for 12 months.

C. Islet Cell Tumors / Progressive Pancreatic Neuroendocrine Tumors (pNET)

1. Initial Authorization
   a. Sutent will be approved based on the following criterion:
      (1) Diagnosis of islet cell tumor / progressive pancreatic neuroendocrine tumors (pNET)

      Authorization will be issued for 12 months.

2. Reauthorization
a. **Sutent** will be approved based on the following criterion:

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

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

D. **Soft Tissue Sarcoma (off-label)**

1. **Initial Authorization**

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

      (1) Diagnosis of **one** of the following:

      (a) Alveolar soft part sarcoma (ASPS)
      (b) Angiosarcoma
      (c) Solitary fibrous tumor / hemangiopericytoma

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

2. **Reauthorization**

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

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

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

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

1. **Initial Authorization**

   a. **Sutent** 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
ii. 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 thyroid carcinoma

-AND-

(b) **One** of the following

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

-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. **Sutent** will be approved based on the following criterion:

   (1) Patient does not show evidence of progressive disease while on Sutent therapy
Authorization will be issued for 12 months.

F. **Chordoma (off-label)**

1. **Initial Therapy**
   
a. Sutent will be approved based on the following criterion:

   (1) Diagnosis of recurrent chordoma

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

2. **Reauthorization**
   
a. Sutent will be approved based on the following criterion:

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

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

G. **Central Nervous System Cancer (off-label)**

1. **Initial Therapy**
   
a. Sutent will be approved based on all of the following criteria:

   (1) Diagnosis of surgically inaccessible meningiomas

   -AND-

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

   (a) Disease is recurrent

   (b) Disease is progressive

   -AND-

   (3) Further radiation is not possible

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

2. **Reauthorization**
a. **Sutent** will be approved based on the following criterion:

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

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

H. **Thymic Carcinoma (off-label)**

1. **Initial Therapy**

   a. **Sutent** will be approved based on both of the following criteria:

   (1) Diagnosis of thymic carcinoma

   -AND-

   (2) Used as second-line following a failure, contraindication, or intolerance to a first-line chemotherapy regimen (e.g., carboplatin/paclitaxel)

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

2. **Reauthorization**

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

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

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

3. **References:**


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<thead>
<tr>
<th>Program</th>
<th>Prior Authorization/Notification - Sutent® (sunitinib malate)</th>
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<tbody>
<tr>
<td>9/2013</td>
<td>New guideline.</td>
</tr>
<tr>
<td>11/2014</td>
<td>Annual Review</td>
</tr>
<tr>
<td>12/2015</td>
<td>• Guideline updated to clarify the diagnosis requirement for advanced renal cell cancer (RCC) and will now ask that patient</td>
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either has relapse following surgical excision or stage IV disease with medically or surgically unresectable tumor.

- Revised criteria mirror diagnosis criteria for other agents approved for RCC [eg, Nexavar (sorafenib)]

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<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>7/2016</td>
<td>Updated policy template. Updated clinical criteria to align with Employer and Individual.</td>
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<tr>
<td>7/2017</td>
<td>Updated background and criteria removing off-label criteria for lung neuroendocrine tumors as no longer recommended by NCCN. Updated reference.</td>
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