Sutent

Description

Sutent (sunitinib)

Background
Sutent (sunitinib malate) is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment (1).

Regulatory Status
FDA-approved indication: Sutent is a kinase inhibitor indicated for the treatment of patients with:
(1)
1. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
2. Advanced renal cell carcinoma (RCC)
3. Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy
4. Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease

Off Label Uses: (2-4)
1. Recurrent chordoma
2. Relapsed or unresectable renal cell carcinoma
3. Neuroendocrine tumors
   a. Unresectable
   b. Metastatic disease
4. Soft tissue sarcoma
a. Angiosarcoma 
b. Solitary fibrous tumor 
c. Hemangiopericytoma 
d. Alveolar Soft Part Sarcoma (ASPS) 
5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma 
   a. Unresectable recurrent or persistent 
   b. Distant metastatic disease 
6. Medullary thyroid carcinoma 
   a. Progressive disease 
   b. Symptomatic distant metastatic disease 
7. Thymic carcinoma

Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests should be obtained before initiation of Sutent, and it should be monitored at least 2 weeks during the first 2 months of treatment. Thereafter, monitor monthly or more frequently as clinically indicated. Temporarily hold and then reduce or permanently discontinue Sutent depending on the severity and persistence of hepatotoxicity as manifested by elevated liver function tests or hepatocellular necrosis. Sutent should be interrupted for grade 3 or 4 drug-related hepatic adverse events and discontinue if there is no resolution (1).

The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Related policies
Afinitor, Avastin, Cabometyx, Caprelsa, Cometriq, Inlyta, Lenvima, Nexavar, Opdivo, Stivarga, Tarceva, Votrient, Xalkori

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sutent may be considered medically necessary in patients that are 18 years of age or older with gastrointestinal stromal tumors (GIST), renal cell carcinoma (RCC), neuroendocrine tumors, soft tissue sarcoma, thyroid carcinoma, thymic carcinoma, or recurrent chordoma; and if the conditions indicated below are met.

Sutent is considered investigational in patients who are less than 18 years of age and for all other indications.
Prior-Approval Requirements

Age  18 years of age and older

Diagnoses

Must have **ONE** of the following:

1. Gastrointestinal stromal tumor (GIST)
   a. After disease progression on imatinib mesylate (Gleevec) OR intolerant to imatinib mesylate (Gleevec)

2. Renal cell carcinoma (RCC) with **ONE** of the following:
   a. Relapsed or unresectable
   b. Adjuvant treatment for patients with high risk of recurrent RCC following nephrectomy

3. Neuroendocrine tumors
   a. Unresectable or metastatic disease

4. Soft tissue sarcoma with **ONE** of the following subtypes:
   a. Angiosarcoma
   b. Solitary fibrous tumor
   c. Hemangiopericytoma
   d. Alveolar Soft Part Sarcoma (ASPS)

5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
   a. Unresectable or metastatic disease

6. Medullary thyroid carcinoma
   a. Progressive or symptomatic distant metastatic disease

7. Thymic carcinoma

8. Recurrent chordoma

**AND ALL** of the following for **ALL** indications:

1. Assessment of ALT, AST, and bilirubin tests before initiation of therapy
a. Agreement to monitor levels every 2 weeks during the first 2 months of treatment, then monitored at least monthly

Prior – Approval Renewal Requirements

Age  18 years of age and older

Diagnoses

Must have ONE of the following:

1. Gastrointestinal stromal tumor (GIST)
2. Renal cell carcinoma (RCC)
3. Neuroendocrine tumors
4. Soft tissue sarcoma with ONE of the following subtypes:
   a. Angiosarcoma
   b. Solitary fibrous tumor
   c. Hemangiopericytoma
   d. Alveolar Soft Part Sarcoma (ASPS)
5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
6. Medullary thyroid carcinoma
7. Thymic carcinoma
8. Chordoma

AND ALL of the following for ALL indications:
   a. NO severe hepatic impairment (Child-Pugh Class C)
   b. NO disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity
**Section:** Prescription Drugs  
**Effective Date:** July 1, 2019  
**Subsection:** Antineoplastic Agents  
**Original Policy Date:** July 28, 2017  
**Subject:** Sutent  
**Page:** 5 of 6

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 84 days</th>
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<tbody>
<tr>
<td>12.5 mg</td>
<td>84 capsules per 84 days OR</td>
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<tr>
<td>25 mg</td>
<td>84 capsules per 84 days OR</td>
</tr>
<tr>
<td>37.5 mg</td>
<td>84 capsules per 84 days OR</td>
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<tr>
<td>50 mg</td>
<td>84 capsules per 84 days</td>
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**Maximum of daily limit: 87.5 mg**  
* Only 2 strengths are allowed in combination to accommodate non-commercially available products  
** Utilizing the highest strengths available to achieve the dosage is recommended to minimize dosing errors and improve compliance

**Duration**  
12 months

**Prior – Approval Renewal Limits**  
Same as above

**Rationale**

**Summary**
Sutent is a kinase inhibitor, designed to block enzymes that promote cancer growth. Sutent has been approved to treat gastrointestinal stromal tumors (GIST), renal cell carcinoma (RCC), neuroendocrine tumors, soft tissue sarcoma, thyroid carcinoma, thymic carcinoma or recurrent chordoma. Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests should be obtained before initiation of Sutent, and it should be monitored at least 2 weeks during the first 2 months of treatment. The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Sutent while maintaining optimal therapeutic outcomes.

**References**


<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>July 2017</td>
<td>New addition to PA</td>
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<tr>
<td>September 2017</td>
<td>Annual review</td>
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<td></td>
<td>Addition of quantity limits</td>
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<tr>
<td>December 2017</td>
<td>Addition of recurrent RCC following nephrectomy alveolar soft part sarcoma (ASPS) and recurrent chordoma</td>
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<tr>
<td>March 2018</td>
<td>Annual review</td>
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<td>June 2019</td>
<td>Annual review and reference update</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.