MEDICATION POLICY

Generic Name: Sunitinib

Therapeutic Class or Brand Name: Sutent®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 1/2/18

GPI Code: 2153307030

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through D:
   A. Gastrointestinal stromal tumor (GIST) for patients who have had disease progression on or are intolerant to Gleevec®.
   B. Advanced renal cell carcinoma (RCC).
   C. High risk of recurrent RCC following nephrectomy.
   D. Pancreatic Neuroendocrine Tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

II. Minimum age requirement: 18 years old.

III. Prescriber is an oncologist.

Exclusion Criteria:

- N/A

Other Criteria:

- Dosing for GIST and RCC: 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off.
- Dosing for pNET: 37.5 mg orally once daily, with or without food, continuously without a scheduled off-treatment period.
- Dose Modifications: Dose interruptions and/or dose adjustments of 12.5 mg recommended based on individual safety and tolerability.
- Use of Sutent® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions for higher doses [doses of up to 87.5 mg per day (GIST and RCC) or 62.5 mg per day (pNET) may be authorized

when Sutent® must be administered concomitantly with medications that decrease Sutent® plasma concentrations (see Appendix).

Quantity/Days Supply Restrictions:

- Authorized in quantities of up to 50 mg per day (see under Other Criteria for possible exceptions for higher doses).
- The quantity is limited to a maximum of a 30 day supply per fill.

Approval Length:

- **Authorization:**
  - High risk of recurrent RCC following nephrectomy: 54 weeks (nine 6-week cycles).
  - All other diagnoses: 1 year.
- **Re-Authorization:**
  - High risk of recurrent RCC following nephrectomy: N/A
  - All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and improvement or maintenance on medication.

Appendix:

Examples of Strong CYP3A4 Inducers (May Decrease Sutent® Plasma Concentrations)	
carbamazepine	phenytoin
dexamethasone	rifabutin
St. John's Wort*	rifampin
phenobarbital	rifapentine
*St. John's Wort may decrease Sutent® plasma concentrations unpredictably and should be avoided.	

References:

1. https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Sutent.pdf.
2. http://blue.regence.com/trgmedpol/drugs/dru128.pdf.
3. Medi-Span.
4. http://labeling.pfizer.com/ShowLabeling.aspx?id=607.

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<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td>1/2/2018</td><td>1. Added “I. C. High risk of recurrent RCC following nephrectomy” under Prior Authorization Criteria.
2. Changed “1 year” to “High risk of recurrent RCC following nephrectomy: 54 weeks (nine 6-week cycles); All other diagnoses: 1 year” following Authorization under Approval Length.
3. Changed “An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and improvement or maintenance on medication” to “High risk of recurrent RCC following nephrectomy: N/A; All other diagnoses: An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and improvement or maintenance on medication” following Re-Authorization under Approval Length.</td></tr>
<tr><td>10/8/2016</td><td>1. Policy reviewed: no changes made.</td></tr>
<tr><td>5/14/2015</td><td>1. Added “Use of Sutent® with strong CYP3A4 inhibitors or inducers should be avoided. Exceptions for higher doses [doses of up to 87.5 mg per day (GIST and RCC) or 62.5 mg per day (pNET) may be authorized when Sutent® must be administered concomitantly with medications that decrease Sutent® plasma concentrations (see Appendix)” under Other Criteria.
2. Changed “Authorized in quantities of up to 50 mg per day (doses of up to 87.5 mg per day may be authorized when Sutent® is administered concomitantly with medications that decrease Sutent® plasma concentrations (see Appendix)” to “Authorized in quantities of up to 50 mg per day (see under Other Criteria for possible exceptions for higher doses)” under Quantity/Days Supply Restrictions.
3. Changed “An updated letter or progress notes showing improvement or maintenance on medication” to “An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and improvement or maintenance on medication” for Re-Authorization under Approval Length.
4. Changed table under Appendix from:
<table>
<tr><td colspan="2">Sutent® Drug Interactions</td></tr>
<tr><td colspan="2">Medications that may DECREASE Sutent® plasma concentrations (CYP 3A4 Inducers)*</td></tr>
<tr><td>carbamazepine</td><td>phenytoin</td></tr>
<tr><td>dexamethasone</td><td>rifabutin</td></tr>
<tr><td>hypericum perforatum (St. John’s Wort)</td><td>rifampin</td></tr>
<tr><td>phenobarbital</td><td>rifapentine</td></tr>
<tr><td colspan="2">Medications that may INCREASE Sutent® plasma concentrations (CYP 3A4 inhibitors)*</td></tr>
<tr><td>aprepitant</td><td>itraconazole</td></tr>
<tr><td>clarithromycin</td><td>ketoconazole</td></tr>
<tr><td>erythromycin</td><td>voriconazole</td></tr>
<tr><td>atazanavir</td><td>indinavir</td></tr>
<tr><td>nefazodone</td><td>nelfinavir</td></tr>
<tr><td>ritonavir</td><td>saquinavir</td></tr>
<tr><td>telithromycin</td><td></td></tr>
</table>
*This is not an exhaustive list. Please consult a pharmacist or appropriate references if unsure.
to:
<table>
<tr><td colspan="2">Examples of Strong CYP3A4 Inducers (May Decrease Sutent® Plasma Concentrations)</td></tr>
<tr><td>carbamazepine</td><td>phenytoin</td></tr>
<tr><td>dexamethasone</td><td>rifabutin</td></tr>
<tr><td>St. John’s Wort*</td><td>rifampin</td></tr>
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<tr><td colspan="2">*St. John’s Wort may decrease Sutent® plasma concentrations unpredictably and should be avoided.</td></tr>
</table>
5. Updated “http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Sutent.pdf” to “https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Sutent.pdf” under References.</td></tr>
</table>

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Historical Tracking Of Changes Made To Policy	
1/16/2014	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Added** "Prescriber is an oncologist" **requirement to Prior Authorization Criteria**. 4. **Added** "The quantity is limited to a maximum of a 30 day supply per fill" **under Quantity/Days Supply Restrictions**. 5. **Updated references** to include Medi-Span.