

Complete Patient and Physician information (PLEASE PRINT)

STEP
1

Member Name:	Physician Name:
Address:	Address:
Member ID:	Phone #:
Member DOB:	Fax #:
	Tax ID or NPI #:

If Applicable: Pharmacy Name: _____
 Pharmacy Phone: _____

Complete the Clinical Assessment:

Please attach all relevant medical records and test results.

STEP
2

Diagnosis	<input type="checkbox"/> Advanced Renal Cell Carcinoma <input type="checkbox"/> Gastrointestinal Stromal Tumor (GIST) after disease progression or intolerance to imatinib therapy. <input type="checkbox"/> Pancreatic neuroendocrine tumor that is unresectable locally advanced or metastatic	<input type="checkbox"/> Other (please state): _____ _____ _____ _____
Physician Specialty	<input type="checkbox"/> Oncology	<input type="checkbox"/> Other (please state): _____
Clinical Consideration	For GIST patients ONLY: <input type="checkbox"/> Intolerance to imatinib (Gleevec) therapy <input type="checkbox"/> Disease progression on imatinib (Gleevec) therapy	
Supporting Documentation	Diagnosis: ICD-9/10 Code #/ Description / J Code (required):	
	Please attach a copy of the prescription or provide ALL of the information below: Sutent [®] (sunitinib)	
	Strength _____ Sig _____ Qty _____ Refills _____	
<p>We will not process incomplete forms. If we do not receive the completed form & all relevant medical records & test results within 10 calendar days of this request, it will be denied.</p>		

STEP
3

I certify that the above is correct and accurate to the best of my knowledge and that the form is complete. (please sign and date)

 Prescriber Signature

 Date

STEP
4

**Fax completed form to the Rocky Mountain Health Plans Pharmacy Help Desk:
 970-248-5034**

Name of Person filling out form: _____

Pharmacy Technician initials _____ Date Initiated _____

Confidentiality Notice:

This facsimile transmission (and/or documents accompanying it) may contain confidential information. This information is intended only for the use of the individual(s) named above. If you have received this transmission in error, or cannot identify the recipient for distribution purposes, please notify us immediately at 970-244-7760. Plans underwritten by Rocky Mountain HMO or Rocky Mountain HealthCare Options. 01/10/12

RMHP Formulary Coverage Policy

THIS INFORMATION IS NOT ALL-INCLUSIVE AND IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY

Sutent (sunitinib)

CLASSIFICATION

- Antineoplastic, tyrosine kinase inhibitor

DESCRIPTION

- Sunitinib malate is a multi-targeting receptor tyrosine kinase inhibitor, decreasing tumor cell proliferation and angiogenesis. Sunitinib targets several receptor tyrosine kinases (RTK). Inhibition of these RTK prevents tumor growth, pathologic angiogenesis, and metastatic progression of cancer
- Sunitinib malate is indicated for the treatment of gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate. Sunitinib improved time-to-tumor progression and improved time of progression-free survival
- Sunitinib is indicated for the treatment of advanced renal cell carcinoma (RCC). The approval for RCC is based on partial response rates and duration of responses. Improved survival or disease-related symptoms have not been demonstrated in randomized trials
- Sunitinib malate is indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease. Sunitinib significantly improved progression-free survival, overall survival, and objective response rate compared to placebo in a randomized, double-blind, multinational study (n=171) in patients with well-differentiated pancreatic neuroendocrine tumors that were advanced, metastatic, or both.
- A phase I dose-escalation study demonstrated sunitinib ability to induce tumor shrinkage and tumor necrosis in patients with advanced solid malignancies

FORMULARY COVERAGE

Prior authorization: Required

Good Health Formulary: Tier 3

Commercial Formulary: Tier 3

Medicare Part D coverage: Tier 5

COVERAGE CRITERIA

Sutent® (sunitinib) meets the definition of **medical necessity** for the following:

- Gastrointestinal stromal tumor, after disease progression on or intolerance to imatinib (*documentation required*).
- Advanced Renal Cell Carcinoma
- Progressive, well-differentiated pancreatic neuroendocrine tumors that are unresectable locally advanced or metastatic.

Sutent® (sunitinib) is considered **experimental** for the following:

- Any condition or diagnosis not FDA approved or Compendia supported
- Metastatic breast cancer, in patients previously treated with an anthracycline and a taxane
- Non-small cell lung cancer that is advanced or metastatic, in previously-treated patients

Required Provider Specialty:

- Approval is limited to Oncology

DOSAGE/ADMINISTRATION:

Adult Dosing (safety and efficacy in pediatric patients has not been established):

- Gastrointestinal stromal tumor (after disease progression on or intolerance to imatinib): 50 mg ORALLY once daily for 4 weeks on followed by 2 weeks off; may repeat cycle every 6 weeks
- Advanced renal cell carcinoma: 50 mg ORALLY once daily for 4 weeks on followed by 2 weeks off; may repeat cycle every 6 weeks
- Pancreatic neuroendocrine tumor (unresectable, locally advanced, or metastatic): 37.5mg ORALLY once daily to be given continuously without a scheduled off-treatment period.

Dosing adjustments:

- Dose interruptions and/or adjustments in 12.5mg increments or decrements are recommended based on individual safety and tolerability.
- Hepatic impairment:
 - Mild to moderate (Child-Pugh Class A or B): dose adjustment not necessary
 - Severe (Child-Pugh Class C): has not been studied
 - Interrupt therapy for grade 3 or 4 drug-related hepatic adverse events; discontinue if no resolution
- Use with strong CYP3A4 inhibitors (e.g. ketoconazole): reduce the dose of sunitinib to a minimum of 37.5 mg orally daily for gastrointestinal stromal tumor or advanced renal cell carcinoma or to a minimum of 25 mg orally daily for pancreatic neuroendocrine tumors.
- Use with strong CYP3A4 inducers (e.g. rifampin): increase the dose of sunitinib to a maximum of 87.5 mg orally daily for gastrointestinal stromal tumor or advanced renal cell carcinoma or to 62.5 mg orally daily for pancreatic neuroendocrine tumors. Concomitant use with St. John's Wort is not recommended.
- Ejection fraction of less than 50% and greater than 20% below baseline but no clinical evidence of congestive heart failure: reduce the dose or interrupt treatment
- Discontinue if severe hypertension develops, may restart once hypertension is controlled
- Interrupt sunitinib therapy for major surgical procedures for precautionary reasons.

PRECAUTIONS:

- **BLACK BOX WARNING:** Hepatotoxicity that is severe and potentially fatal
- Concurrent use with antiarrhythmic medications increase risk for ventricular arrhythmias, including Torsades de Pointes.
- Bradycardia; increased risks for ventricular arrhythmias, including torsades de pointes
- Preexisting cardiac disease increases risks for ventricular arrhythmias, including torsades de pointes
- Cardiovascular events have been reported (e.g. heart failure, myocardial disorders, and cardiomyopathy), some fatal
- Concomitant use with antiarrhythmics or strong CYP3A4 inhibitors; use with caution
- Concomitant use with St. John's Wort should be avoided
- Congestive heart failure may occur; discontinue if symptoms of CHF develop
- Electrolyte disturbances increase risks for ventricular arrhythmias, including torsades de pointes
- Gastrointestinal complications, serious (including fatal cases), have occurred rarely

- Hemorrhagic events, serious (some fatal cases), including gastrointestinal, respiratory, tumor, urinary tract, pulmonary, and brain hemorrhages, have occurred
- Severe hypertension has occurred; temporary suspension of sunitinib treatment may be necessary
- QT interval prolongation, history; increased risks for ventricular arrhythmias, including torsades de pointes
- Thyroid dysfunction, including hypothyroidism and hyperthyroidism, has been reported; monitoring is recommended
- Adrenal insufficiency, following stress (e.g. surgery, trauma, or severe infection) may occur; monitoring recommended
- Left ventricular ejection fraction (LVEF) greater than 20% but less than 50% below baseline, without clinical evidence of congestive heart failure has occurred; dose interruption or discontinuation recommended
- Pregnancy; avoid during treatment (Pregnancy category D for all trimesters)
- Major surgeries may impair wound healing; temporary drug interruption recommended

Billing/Coding information

- n/a

COST

- AWP (April 2010): Sutent 50mg tablets (28): \$9,151.80
- AWP (January 2012):
 - Sutent 12.5mg tablets (28): \$2,831.64
 - Sutent 25mg tablets (28): \$5,663.28
 - Sutent 50mg tablets (28): \$10,625.44

COMMITTEE APPROVAL:

- March 2006

GUIDELINE UPDATE INFORMATION:

April 2010	Policy created
January 2012	Policy updated; new FDA indication added

REFERENCES:

- DRUGDEX®, accessed 04/02/2010, 01/05/12
- Product Information: SUTENT® oral capsules, sunitinib malate oral capsules. Pfizer Labs, New York, NY, 2009.