



Prior Authorization Approval Criteria
Department of Pharmacy Services

Generic Name: sunitinib

Brand Name: Sutent

Medication Class: antineoplastic agent

FDA Approved Uses: -Treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to Gleevec (imatinib).
-Treatment of metastatic renal cell carcinoma (MRCC)

Available Dosage Forms: 12.5mg, 25mg and 50 mg capsules

Usual Dose: 50mg orally once daily for 4 weeks followed by 2 weeks off.
(Dose increase or decrease of 12.5mg is recommended based on individual tolerability or intolerability)

Duration of Therapy: Until disease progression.

Approximate cost (based on AWP 2006): \$76,469.00

Criteria for Use: *(bullet points below are all inclusive unless otherwise noted)*

- Prescribed by an oncologist or hematologist.
 - Baseline left ventricular ejection fraction (LVEF) evaluation is conducted and LVEF >40%
 - Clinically documented renal cell carcinoma.
- Or
- Clinically documented gastrointestinal stromal tumor (GIST) with disease progression and/or intolerance while on Gleevac

Criteria for Continuation of Therapy:

- Disease stable without tumor progression
- LVEF > 50% and < 20% change from baseline
- Absence of symptomatic CHF

Cautions:

- Risk of left ventricular dysfunction.
 - If LVEF < 50% a dose reduction of 12.5mg may be necessary
 - If LVEF < 40% discontinue therapy and restart at a lower dose if LVEF increases to > 40%
- Hypertension
 - If patient has or develops hypertension they should be treated as needed with antihypertensive therapy
 - In severe hypertension, temporary suspension of Sutent is recommended.
 - Patients may normalize during the 2 week off phase. This should be taken into



consideration for patient who had to start antihypertensive therapy or had dose increases of their antihypertensive medications.

Monitoring:

- LVEF
- CBC's with platelet count and serum chemistries including phosphate should be performed at the beginning of each treatment cycle.
- Blood pressure

Contraindications:

- Patients with a hypersensitivity to sunitinib malate or any other component of Sutent.
- Cardiac events within the prior 12 months, such as MI (including severe/unstable angina), coronary peripheral artery bypass graft, symptomatic congestive heart failure, cerebrovascular accident or transient ischemic attack, or pulmonary embolism.
- LVEF < 40% without clinical symptoms of CHF

Not Approved if:

- Patient does not meet the above stated criteria
- Patient has any contraindications to the use of Sutent.

Special Considerations:

-Sutent does not cure either cancer. But it did show to slow the growth of the tumor.
-Probably will only be on for 4-12 months, since survival rate is not high.
-Decreases in LVEF to below the lower limit of normal have been observed. It is unknown whether patients with concomitant cardiac conditions are at higher risk for developing drug related left ventricular dysfunction; these patients should be carefully monitored for clinical signs and symptoms of CHF while receiving Sutent. Baseline evaluation of ejection fraction should be considered. In the presence of clinical manifestations of CHF, discontinuation is recommended.

P&T Approval: _____ Date: _____