

Applicable Drugs: Sutent (sunitinib)

Preferred: sunitinib malate (generic)

Non-preferred: Sutent (brand)

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 11/17/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented of one of the following diagnoses A through C AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

- A. Gastrointestinal stromal tumor (GIST)
 - i. Documentation of unresectable, recurrent, or metastatic disease.
 - ii. Documentation of treatment resistance or intolerance to imatinib.
- B. Renal cell carcinoma (RCC) and meets one of the following criteria:
 - i. Clear cell histology and either 1 or 2:
 - 1. Adjuvant therapy in Stage III disease post nephrectomy and high risk for relapse.
 - 2. Treatment of recurrent or metastatic disease.
 - ii. Non clear cell histology:
 - 1. Treatment of recurrent or metastatic disease.
- C. Pancreatic neuroendocrine tumor (pNET):
 - i. Documentation of progressive, well-differentiated (grade 1, 2, or 3) disease.
 - ii. Treatment of recurrent or metastatic disease.

Other Uses With Supportive Evidence

- A. Bone cancer
- B. Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement
- C. Neuroendocrine and Adrenal Tumors
 - i. Pheochromocytoma/paraganglioma
- D. Soft tissue sarcoma of one of the following subtypes (alveolar soft part sarcoma, angiosarcoma, extraskeletal myxoid chondrosarcoma, or solitary fibrous tumor).
- E. Thymic carcinoma

F. Thyroid carcinoma subtypes (i, ii, iii, or iv)

- i. Follicular carcinoma
- ii. Oncocytic carcinoma
- iii. Medullary carcinoma
- iv. Papillary carcinoma

II. Age $\geq$ 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Up to a 30-day supply (see Table 1 for dosages by indication).

APPROVAL LENGTH

- **Authorization:**
 - Adjuvant treatment in patients at 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 does not show evidence of progressive disease.

APPENDIX

Table 1. Recommended Sutent dosage by FDA indication and dosage modification for concomitant use with a strong CYP3A4 inhibitor or inducer.¹

Indication	Recommended dosage ^a	Dosage modification for strong CYP3A4 Inhibitors ^b	Dosage modification for strong CYP3A4 Inducers ^c
GIST	50 mg once daily x 4 weeks of each 6-week cycle	37.5 mg once daily x 4 weeks of each 6-week cycle	87.5 mg once daily x 4 weeks of each 6-week cycle
Advanced RCC	50 mg once daily x 4 weeks of each 6-week cycle	37.5 mg once daily x 4 weeks of each 6-week cycle	87.5 mg once daily x 4 weeks of each 6-week cycle
Adjuvant RCC	50 mg once daily x 4 weeks of each 6-week cycle (9 cycle maximum)	37.5 mg once daily x 4 weeks of each 6-week cycle (9 cycle maximum)	87.5 mg once daily x 4 weeks of each 6-week cycle (9 cycle maximum)
pNet	37.5 mg once daily	25 mg once daily	62.5 mg once daily

^a See prescribing information for detailed information about recommendations for dosage modifications to manage adverse reactions.

^b Strong CYP3A4 inhibitors such as ketoconazole.

^c Strong CYP3A4 inducers such as rifampin.

Abbreviations: Gastrointestinal stromal, GIST; Renal cell carcinoma, RCC; pancreatic neuroendocrine tumors, pNET.

REFERENCES

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DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.