MEDICAL MUTUAL®

Drug Policy

Policy:	Sutent (sunitinib capsules)	Annual Review Date: 09/16/2021 Last Revised Date: 09/16/2021

OVERVIEW

Sutent, a multi-kinase inhibitor, is indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate (Gleevec® tablets, generics); for the treatment of advanced renal cell carcinoma (RCC); for the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy; and for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (PNET) in patients with unresectable locally advanced or metastatic disease.[1] Sutent inhibits multiple receptor tyrosine kinases, some of which are implicated in tumor growth, pathologic angiogenesis, and metastatic progression of cancer.

POLICY STATEMENT

This policy involves the use of Sutent. Prior authorization is recommended for pharmacy benefit coverage of Sutent. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Sutent as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Sutent be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, this drug must be prescribed by or in consultation with a hematologist, dermatologist, or oncologist. A trial of generic sunitinib is required before approval of brand Sutent for all new starts [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or other information. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sutent is recommended in those who meet the following criteria:

For all indications: If brand Sutent is prescribed, the patient must have tried generic suntinib capsules AND the brand product is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand product and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction; AND

1. **Gastrointestinal Stromal Tumor.** Approve if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried imatinib or Ayvakit (avapritinib tablets).

2. **Neuroendocrine Tumors of the Pancreas.** Approve if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has advanced or metastatic disease.

3. **Renal Cell Cancer.** Approve if the patient meets the following criteria (A and B):
   1. Patient is ≥ 18 years of age; AND
   2. Patient meets ONE of the following criteria (i or ii):
      1. Patient has clear cell histology and meets the following criteria (a and b):
         a) Patient has high risk of recurrence following nephrectomy; AND
         b) Sutent is being used as adjuvant therapy; OR
      ii. Patient has relapsed or advanced disease.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

Other Uses with Supportive Evidence

4. **Bone Cancer.** Approve if the patient meets the following criteria (A and B);
   A) Patient is ≥ 18 years of age; AND
   B) Patient has recurrent chordoma.

5. **Meningioma.** Approve if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has recurrent or progressive disease.

6. **Myeloid/Lymphoid Neoplasms with Eosinophilia.** Approve if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) The tumor has an *FLT3* rearrangement.

7. **Soft Tissue Sarcoma.** Approve if the patient meets the following (A and B):
   a. Patient is ≥ 18 years of age; AND
   b. Patient has ONE of the following diagnosis (i, ii, or iii):
      i. Alveolar Soft Part Sarcoma; OR
      ii. Angiosarcoma; OR
      iii. Solitary Fibrous Tumor/Hemangiopericytoma.

8. **Thymic Carcinoma.** Approve if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one systemic chemotherapy regimen.
   Note: Examples of a systemic chemotherapy regimen include one or more of the following products: carboplatin, paclitaxel, cisplatin, doxorubicin, cyclophosphamide, or etoposide.

9. **Thyroid Carcinoma, Differentiated.** Approve if the patient meets the following (A, B and C):
   a. Patient is ≥ 18 years of age; AND
   b. Patient has differentiated thyroid carcinoma; AND
   Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and Hürthle cell thyroid carcinoma.
   c. Patient is refractory to radioactive iodine therapy.

10. **Thyroid Carcinoma, Medullary.** Approve if the patient meets the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has tried at least one systemic therapy.
   Note: Examples of systemic therapy include: Caprelsa (vandetanib tablets), Cometriq (carbozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

11. **Another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation.**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve*

12. **Patient has been started on Sutent (continuation of therapy)**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days (1 year)
B) *Extended Approval:* 365 days (1 year)

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Sutent® capsules [prescribing information]. New York, NY: Pfizer; November 2017.

2. The NCCN Drugs and Biologics Compendium. © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 11, 2019. Search term: sunitinib.