# PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Sutent® (sunitinib malate capsules – Pfizer)

**DATE REVIEWED:** 05/27/2020

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**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]

## Guidelines
Sutent features prominently in the National Comprehensive Cancer Network (NCCN) compendium for all of the indications listed in the FDA-approved and Other Uses with Supportive Evidence.[2]

**POLICY STATEMENT**
Prior authorization is recommended for prescription benefit coverage of Sutent. All approvals are provided for 3 years in duration.

**Automation:** None.

**RECOMMENDED AUTHORIZATION CRITERIA**
Coverage of Sutent is recommended in those who meet the following criteria:

**FDA-Approved Indications**

1. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient has tried imatinib (Gleevec tablets, generics).

2. **Renal Cell Carcinoma (RCC) –Clear Cell or Non-Clear Cell Histology.** Approve for 3 years if the patient meets ONE of the following criteria (A or B):
   **A)** The patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy; OR
   **B)** The patient has relapsed or Stage IV disease.

3. **Neuroendocrine Tumors of the Pancreas.** Approve for 3 years for advanced or metastatic disease.

**Other Uses with Supportive Evidence**

4. **Alveolar Soft Part Sarcoma (ASPS).** Approve for 3 years.

5. **Angiosarcoma.** Approve for 3 years.

6. **Chordoma.** Approve for 3 years in patients with recurrent disease.

7. **Differentiated (i.e., papillary, follicular, and Hürthle cell) Thyroid Carcinoma.** Approve for 3 years if refractory to radioactive iodine therapy.

8. **Medullary Thyroid Carcinoma.** Approve for 3 years if the patient has tried Caprelsa® (vandetanib tablets) or Cometriq® (cabozantinib capsules).

9. **Meningioma.** Approve for 3 years if the patient has recurrent or progressive disease.

10. **Solitary Fibrous Tumor/Hemangiopericytoma.** Approve for 3 years.

11. **Thymic Carcinoma.** Approve for 3 years if the patient has tried chemotherapy (e.g., carboplatin/paclitaxel) or radiation therapy.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sutent has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Sutent® capsules [prescribing information]. New York, NY: Pfizer; May 2019.
2. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 25, 2020. Search term: sunitinib.