**Generic Name:** Sunitinib

**Applicable Drugs:** Sutent®

**Preferred:** Sunitinib malate (generic)

**Non-preferred:** Sutent® (brand)

**Date of Origin:** 2/1/2013

**Date Last Reviewed / Revised:** 10/24/2023

## PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of one of the following conditions A through E AND must meet ALL criteria listed under applicable diagnosis:

A. Chordoma

i. Documentation of recurrent disease.

B. Gastrointestinal stromal tumor (GIST)

i. Documentation of unresectable, recurrent, or metastatic disease.

ii. Documentation of treatment resistance or intolerance to imatinib.

C. Meningioma

i. Documentation of recurrent disease.

D. Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement with ONE (i or ii) of the following:

i. Documentation of chronic phase disease.

ii. Documentation of blast phase myeloid, mixed lineage, or lymphoid disease in combination with induction chemotherapy followed by allogeneic hematopoietic cell transplant (if eligible).

E. Neuroendocrine and Adrenal Tumors and either i or ii:

i. Well-differentiated grade 1/2 or 3 pancreatic neuroendocrine tumors (pNET): documentation of recurrent locoregional advanced disease, and/or distant metastatic disease.

ii. Pheochromocytoma/paraganglioma: documentation of locally unresectable disease and/or distant metastatic disease.

F. Renal cell carcinoma (RCC) meeting the following criteria under respective histology type:

i. Clear cell disease 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 disease: treatment of recurrent or metastatic disease.

G. Soft tissue sarcoma of one of the following subtypes (alveolar soft part sarcoma, angiosarcoma, or solitary fibrous tumor):

i. Documentation of advanced or metastatic disease.

H. Thymic carcinoma

i. Documentation of treatment failure, contraindication, or intolerance to first-line combination chemotherapy regimen (e.g., carboplatin/paclitaxel).

I. Thyroid carcinoma subtypes (i, ii, iii, or iv) AND meet ALL the following criteria below each subtype:

i. Follicular carcinoma

1. Documentation of locally recurrent, advanced, and/or metastatic disease.

2. Documentation of contraindication or failure of radioactive iodine therapy.

ii. Hürthle cell carcinoma

1. Documentation of locally recurrent, advanced, and/or metastatic disease.

2. Documentation of contraindication or failure of radioactive iodine therapy.

iii. Medullary carcinoma

1. Documentation of recurrent or persistent disease or distant metastases.

2. Documentation of contraindication or failure of preferred systemic therapy (e.g., vandetanib, cabozantinib, selpercatinib (RET mutation-positive, pralsetinib (RET mutation-positive).

iv. Papillary carcinoma

1. Documentation of locally recurrent, advanced, and/or metastatic disease.

2. Documentation of contraindication or failure of radioactive iodine therapy.

II. Age ≥ 18 years old.

III. Prescriber is an oncologist or a hematologist.

IV. Medication is prescribed in accordance with FDA labeling or current clinical practice guidelines.

V. Approval of the non-preferred brand product requires a documented failure or contraindication to a preferred generic product.

## EXCLUSION CRITERIA

- N/A

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Up to a 30-day supply (see Table 1 and Table 2 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: Updated progress notes showing current medical necessity criteria are met and the medication is effective with acceptable toxicity.

## 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.

**Table 2. Sutent dosage for off-label indications[10-18]**

| Off-label Indication | Dosage |
|---|---|
| Pheochromocytoma/ paraganglioma[a] | 50 mg once daily x 4 weeks of each 6-week cycle or 37.5 mg once daily |
| Chordoma[a] | 37.5 mg once daily |
| Meningioma[a] | 50 mg once daily x 4 weeks of each 6-week cycle |
| Myeloid/lymphoid neoplasms with eosinophilia[a] | 50 mg once daily |
| Soft tissue sarcoma[a] | 37.5 mg once daily |
| Thymic carcinoma[a] | 50 mg once daily x 4 weeks of each 6-week cycle |
| Thyroid carcinoma[a] | 37.5 mg once daily |

[a]NCCN guideline recommended.

## REFERENCES

1. Sutent. Prescribing information. Pfizer, Inc.; 2021. Accessed October 24, 2023. https://labeling.pfizer.com/ShowLabeling.aspx?format=PDF&id=607
2. NCCN Clinical Practice Guidelines in Oncology for gastrointestinal stromal tumors (GISTs). V1.2023. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf
3. NCCN Clinical Practice Guidelines in Oncology for kidney cancer. V1.2024. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf
4. NCCN Clinical Practice Guidelines in Oncology for bone cancer. V1.2024. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf
5. NCCN Clinical Practice Guidelines in Oncology for central nervous system cancers. V1.2023. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf
6. NCCN Clinical Practice Guidelines in Oncology for myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes. V2.2023. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf
7. NCCN Clinical Practice Guidelines in Oncology for soft tissue sarcoma. V2.2023. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
8. NCCN Clinical Practice Guidelines in Oncology for thymomas and thymic carcinomas. V4.2023. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf

9. NCCN Clinical Practice Guidelines in Oncology for thyroid carcinoma. V3.2022. Accessed October 24, 2023. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf
10. Granberg D, Juhlin CC, Falhammar H. Metastatic pheochromocytomas and abdominal paragangliomas. *J Clin Endocrinol Metab*. 2021;106(5):e1937-e1952. doi:10.1210/clinem/dgaa982
11. Alan O, Akin Telli T, Ercelep O, et al. Chordoma: a case series and review of the literature. *J Med Case Rep*. 2018;12(1):239. doi:10.1186/s13256-018-1784-y
12. Kaley TJ, Wen P, Schiff D, et al. Phase II trial of sunitinib for recurrent and progressive atypical and anaplastic meningioma. *Neuro Oncol.* 2015;17(1):116-21. doi: 10.1093/neuonc/nou148
13. Walz C, Erben P, Ritter M, et al. Response of ETV6-FLT3-positive myeloid/lymphoid neoplasm with eosinophilia to inhibitors of FMS-like tyrosine kinase 3. Blood. 2011;118(8):2239-42. doi: 10.1182/blood-2011-03-343426
14. Yoo C, Kim JE, Yoon SK, et al. Angiosarcoma of the retroperitoneum: report on a patient treated with sunitinib. *Sarcoma.* 2009; 2009:360875. doi: 10.1155/2009/360875
15. Stacchiotti S, Negri T, Libertini M, et al. Sunitinib malate in solitary fibrous tumor (SFT). *Ann Oncol.* 2012;23(12):3171-3179. doi: 10.1093/annonc/mds143
16. Stacchiotti S, Negri T, Zaffaroni N, et al. Sunitinib in advanced alveolar soft part sarcoma: evidence of a direct antitumor effect. *Ann Oncol.* 2011;22(7):1682-1690. doi: 10.1093/annonc/mdq644
17. Thomas A, Rajan A, Berman A, et al. Sunitinib in patients with chemotherapy-refractory thymoma and thymic carcinoma: an open-label phase 2 trial. *Lancet Oncol.* 2015;16(2):177-86. doi: 10.1016/S1470-2045(14)71181-7
18. Carr LL, Mankoff DA, Goulart BH, et al. Phase II study of daily sunitinib in FDG-PET-positive, iodine-refractory differentiated thyroid cancer and metastatic medullary carcinoma of the thyroid with functional imaging correlation. *Clin Cancer Res*. 2010;16(21):5260-5268. doi:10.1158/1078-0432.CCR-10-0994