

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Sunitinib Prior Authorization Policy

- Sutent<sup>®</sup> (sunitinib malate capsules – Pfizer)

**REVIEW DATE:** 06/29/2022

---

### OVERVIEW

Sutent, a kinase inhibitor, is indicated in adults for the following uses:<sup>1</sup>

- **Gastrointestinal stromal tumor (GIST)**, after disease progression on or intolerance to imatinib mesylate tablets.
- **Pancreatic neuroendocrine tumors**, that is progressive and well-differentiated in patients with unresectable locally advanced or metastatic disease.
- **Renal cell carcinoma**, advanced, and for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

### Guidelines

Sutent is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):<sup>2</sup>

- **Bone Cancer:** NCCN guidelines (version 2.2022 – October 8, 2021) recommend Sutent as a systemic therapy agent for recurrent chordoma (category 2A).<sup>3</sup>
- **Central Nervous System Cancers:** NCCN guidelines (version 1.2022 – June 2, 2022) recommend Sutent for meningioma for surgically inaccessible recurrent or progressive disease when radiation is not possible (category 2B).<sup>4</sup>
- **Gastrointestinal Stromal Tumor:** NCCN guidelines (version 1.2022 – January 21, 2022) recommend Sutent as preferred second-line therapy for unresectable, progressive, or metastatic disease (category 1).<sup>5</sup> The first line therapies include imatinib or Ayvakit<sup>™</sup> (avapritinib tablets; for GIST with *PDGFRA* exon 18 mutation that are insensitive to imatinib, including the *PDGFRA* D842V mutation).<sup>5</sup> The guidelines also state in a footnote that for unresectable disease, Sutent, Stivarga<sup>®</sup> (regorafenib tablets) and Votrient<sup>®</sup> (pazopanib tablets) are special considerations for succinate dehydrogenase (SDH)-deficient GIST (category 2A). Sutent is also recommended in combination with everolimus (useful in certain circumstances) for unresectable, recurrent/progressive, or metastatic disease after progression on approved therapies (category 2A).
- **Kidney Cancer:** NCCN guidelines (version 1.2023 – June 17, 2022) recommend single-agent Sutent as adjuvant treatment following nephrectomy for stage 3 disease with clear cell histology (category 3).<sup>6</sup> NCCN guidelines also recommend single-agent Sutent for relapse or stage IV disease as a first-line and subsequent therapy option for clear cell histology and as a preferred systemic therapy option for non-clear cell histology (category 2A).<sup>6</sup>
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes:** NCCN guidelines (version 1.2022 – April 14, 2022) recommend Sutent for myeloid/lymphoid neoplasms with *FLT3* rearrangements (category 2A).<sup>7</sup>
- **Neuroendocrine and Adrenal Tumors:** NCCN guidelines (version 1.2022 – May 23, 2022) recommend Sutent as a preferred single-agent for the management of recurrent, locoregional advanced disease and/or distant metastatic disease (category 1 for progressive disease; category 2A for all others).<sup>8</sup> NCCN guidelines also recommend for treatment (pancreas only) for unresectable locally advanced/metastatic disease with favorable biology (e.g. relatively low Ki-67 [ $<55\%$ ], positive SSR-based PET imaging) that has clinically significant tumor burden or evidence of progression (category 2A). Sutent is also recommended as a single-agent for locally unresectable or distant metastatic pheochromocytoma and paraganglioma.<sup>8</sup>

06/29/2022

© 2022. All Rights Reserved.

This document is confidential and proprietary. Unauthorized use and distribution are prohibited.

- **Soft Tissue Sarcoma:** NCCN guidelines (version 2.2022 – May 17, 2022) recommend Sutent as single-agent therapy as useful in certain circumstances for angiosarcoma (category 2A).<sup>9</sup> The guidelines also recommend Sutent as a preferred single-agent therapy for alveolar soft part sarcoma and for solitary fibrous tumor (both category 2A).<sup>9</sup>
- **Thymomas and Thymic Carcinomas:** NCCN guidelines (version 2.2022 – May 3, 2022) recommend single agent Sutent as second-line systemic therapy for thymic carcinoma (category 2A).<sup>10</sup>
- **Thyroid Carcinoma:** NCCN guidelines (version 2.2022 – May 5, 2022) recommend Sutent as one of the kinase inhibitors to be considered if clinical trials or other systemic therapies are not available or appropriate for the treatment of progressive and/or symptomatic iodine refractory thyroid cancer.<sup>11</sup> This recommendation is for follicular, Hürthle cell, and papillary cancer subtypes (all category 2A). Sutent can be considered for treatment of progressive or symptomatic medullary thyroid disease if clinical trials or preferred systemic therapy options are not available or appropriate, or if there is progression on preferred systemic therapy options (category 2A).<sup>11</sup>

### **POLICY STATEMENT**

Prior Authorization is recommended for prescription benefit coverage of Sutent. All approvals are provided for the duration noted below.

**Automation:** None.

### **RECOMMENDED AUTHORIZATION CRITERIA**

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

#### **FDA-Approved Indications**

1. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient meets one of the following criteria (i or ii):
    - i. Patient has tried imatinib or Ayvakit (avapritinib tablets); OR
    - ii. Patient has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor.
2. **Neuroendocrine Tumors of the Pancreas.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient has advanced or metastatic disease.
3. **Renal Cell Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq 18$  years of age; AND
  - B) Patient meets one of the following criteria (i or ii):
    - i. 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.

#### **Other Uses with Supportive Evidence**

4. **Bone Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has recurrent chordoma.
5. **Meningioma.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has recurrent or progressive disease.
6. **Myeloid/Lymphoid Neoplasms.** Approve for 1 year if the patient meets the following (A, B, and C):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has eosinophilia; AND
  - C) The tumor has an *FLT3* rearrangement.
7. **Pheochromocytoma/Paraganglioma.** Approve for 1 year if the patient meets the following (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has unresectable or metastatic disease.
8. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets the following (A and B):
  - A) Patient is  $\geq$  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.
9. **Thymic Carcinoma.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient is  $\geq$  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.
10. **Thyroid Carcinoma, Differentiated.** Approve for 1 year if the patient meets the following (A, B, and C):
  - A) Patient is  $\geq$  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.
11. **Thyroid Carcinoma, Medullary.** Approve for 1 year if the patient meets the following (A and B):
  - A) Patient is  $\geq$  18 years of age; AND
  - B) Patient has tried at least one systemic therapy.  
Note: Examples of systemic therapy include: Caprelsa (vandetanib tablets), Cometriq (cabozantinib capsules), Retevmo (selpercatinib capsules), and Gavreto (pralsetinib capsules).

### **CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Sutent is not recommended in the following situations:

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<sup>®</sup> capsules [prescribing information]. New York, NY: Pfizer; August 2021.
2. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022. Search term: sunitinib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
4. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (version 1.2022 – June 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2022 – January 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
6. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – June 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 24, 2022.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2022 – April 14, 2022). © 2022 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
8. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – May 23, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
9. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 17, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
10. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 2.2022 – May 3, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2022 – May 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed June 27, 2022.

