VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Sutent Prior Authorization Policy
- Sutent® (sunitinib malate capsules – Pfizer)

REVIEW DATE: 06/23/2021

OVERVIEW

Sutent, a multi-kinase inhibitor, is indicated in adults for the following uses:[1]

- **Gastrointestinal stromal tumor**, 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):[2]

- **Bone Cancer**: NCCN guidelines (version 1.2021 – November 20, 2020) recommend Sutent as a systemic therapy agent for recurrent chordoma (category 2A).[3]
- **Central Nervous System Cancers**: NCCN guidelines (version 5.2020 – April 15, 2021) recommend Sutent (category 2B) for meningioma for surgically inaccessible recurrent or progressive disease when radiation is not possible.[4]
- **Gastrointestinal Stromal Tumor**:[5] NCCN guidelines (version 1.2021 – October 30, 2020) recommend Sutent (category 2A) as preferred second-line therapy for unresectable, recurrent, or metastatic disease. The first line therapies include imatinib or Ayvakit (avapritinib tablets; for GIST with *PDGFRA* exon 18 mutation, including the *PDGFRA* D842V mutation). Third-line therapy is Stivarga (regorafenib) and fourth-line therapy is Qinlock (ripretinib). Sutent + Afinitor (everolimus) is an additional option after failure on approved therapies.
- **Kidney Cancer**: NCCN guidelines (version 4.2021 – April 19, 2021) recommend single-agent Sutent (category 3) as adjuvant treatment following nephrectomy for stage 3 disease with clear cell histology.[6] NCCN guidelines also recommend single-agent Sutent (category 2A) 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.[6]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: NCCN guidelines (version 3.2021 – August 21, 2020) recommend Sutent (category 2A) for myeloid/lymphoid neoplasms with FLT3 rearrangements.[7]
- **Neuroendocrine and Adrenal Tumors**: NCCN guidelines (version 1.2021 – April 14, 2021) recommend Sutent as a preferred single agent for the management of symptomatic, clinically significant tumor burden and/or progressive locoregional advanced disease and/or distant metastatic disease.[8] 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.[8]
- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2021 – April 28, 2021) recommend Sutent as single agent therapy as other recommended regimen option for angiosarcoma (category 2A).[9] The guidelines also recommend Sutent as a preferred single agent regimen for alveolar soft part sarcoma (category 2A) and for solitary fibrous tumor (category 2A).[9]

- **Thymomas and Thymic Carcinomas**: The NCCN guidelines (version 1.2021 – December 4, 2020) recommend single agent Sutent (category 2A) as second-line systemic therapy for thymic carcinoma.[10]
- **Thyroid Carcinoma**: NCCN guidelines (version 1.2021 – April 9, 2021) 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.[11] 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.[11]

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.** Approve for 3 years 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 for 3 years 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 for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 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 3 years 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 for 3 years 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 for 3 years 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 for 3 years 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 for 3 years 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 for 3 years 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 for 3 years 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).

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® capsules [prescribing information]. New York, NY: Pfizer; August 2020.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 20, 2021. Search term: sunitinib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 1.2021– November 20, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
4. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (version 5.2020– April 15, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2021– October 30, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
6. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2021– April 19, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 3.2021– August 21, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
8. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2021– April 14, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
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10. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 1.2021– December 4, 2020). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 18, 2021.
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