PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/28/2023

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sunitinib, a kinase inhibitor, is indicated in adults for the following uses:[1]
- **Gastrointestinal stromal tumor (GIST)**, after disease progression on or intolerance to imatinib mesylate tablets.
- **Pancreatic neuroendocrine tumors**, which 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

Sunitinib is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):[2]
- **Bone Cancer**: NCCN guidelines (version 3.2023 – April 4, 2023) recommend sunitinib as a systemic therapy agent for recurrent chordoma (category 2A).[3]
- **Central Nervous System Cancers**: NCCN guidelines (version 1.2023 – March 24, 2023) recommend sunitinib for meningioma for surgically inaccessible recurrent or progressive disease when radiation is not possible (category 2B).[4]

- **Gastrointestinal Stromal Tumor**: NCCN guidelines (version 1.2023 – March 13, 2023) recommend sunitinib as preferred second-line therapy for unresectable, progressive, or metastatic disease (category 1).[5] The first line therapies include imatinib or Ayvakit™ (avapritinib tablets; for GIST with *PDGFRA* exon 18 mutation that are insensitive to imatinib, including the *PDGFRA* D842V mutation).[5] The guidelines also state in a footnote that for unresectable disease, sunitinib, Stivarga® (regorafenib tablets) and Votrient® (pazopanib tablets) are special considerations for succinate dehydrogenase (SDH)-deficient GIST (category 2A). Sunitinib is also recommended in combination with everolimus as "useful in certain circumstances" for unresectable, recurrent/progressive, or metastatic disease after progression on approved therapies (category 2A).
- **Kidney Cancer**: NCCN guidelines (version 4.2023 – January 18, 2023) recommend single-agent sunitinib as adjuvant treatment following nephrectomy for stage 3 disease with clear cell histology (category 3).[6] NCCN guidelines also recommend single-agent sunitinib 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).[6]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: NCCN guidelines (version 1.2023 – May 19, 2023) recommend sunitinib for myeloid/lymphoid neoplasms with *FLT3* rearrangements (category 2A).[7]
- **Neuroendocrine and Adrenal Tumors**: NCCN guidelines (version 2.2022 – December 21, 2022) recommend sunitinib 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).[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 (category 2A). Sunitinib is also recommended as a single agent for locally unresectable or distant metastatic pheochromocytoma and paraganglioma.[8]
- **Soft Tissue Sarcoma**: NCCN guidelines (version 2.2023 – April 25, 2023) recommend sunitinib as single-agent therapy as "useful in certain circumstances" for angiosarcoma (category 2A).[9] The guidelines also recommend sunitinib as a preferred single-agent therapy for alveolar soft part sarcoma and for solitary fibrous tumor (both category 2A).[9]
- **Thymomas and Thymic Carcinomas**: NCCN guidelines (version 1.2023 – December 15, 2022) recommend single agent sunitinib as second-line systemic therapy for thymic carcinoma (category 2A).[10]
- **Thyroid Carcinoma**: NCCN guidelines (version 2.2023 – May 18, 2023) recommend sunitinib 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, oncocytic (formerly Hürthle cell carcinoma), and papillary cancer subtypes (all category 2A). Sunitinib 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).[11]

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

Sutent® (sunitinib malate capsules (Pfizer; generic)
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Gastrointestinal Stromal Tumor.** Approve for 1 year if the patient meets the following (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 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 (A and B):
   - **A)** Patient is ≥ 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 (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or advanced disease.

Other Uses with Supportive Evidence

4. **Bone Cancer.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent chordoma.

5. **Meningioma.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 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 ≥ 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 ≥ 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 ≥ 18 years of age; AND
   B) Patient has one of the following diagnoses (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 (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.

10. **Thyroid Carcinoma, Differentiated.** Approve for 1 year 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 oncocytic carcinoma (formerly Hürthle cell 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 ≥ 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 COVERED

Sutent® (sunitinib malate capsules (Pfizer; generic) is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Sutent® capsules [prescribing information]. New York, NY: Pfizer; August 2021.
2. The NCCN Drugs and Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 16, 2023. Search term: sunitinib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 3.2023 – April 4, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
4. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (version 1.2023 – March 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2023 – March 13, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
6. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – January 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2023 – May 19, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
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9. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 2.2023 – April 25, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
10. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 1.2023 – December 15, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 2.2023 – May 18, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 19, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Gastrointestinal Stromal Tumor:** An option for a patient who has succinate dehydrogenase (SDH)-deficient gastrointestinal stromal tumor was added to the criteria. **Myeloid/Lymphoid Neoplasms:** The wording "with eosinophilia" was removed from the condition of approval and added as a criteria requirement. **Pheochromocytoma/Paraganglioma:** This condition of approval was added with criteria as per NCCN guideline recommendations.	06/29/2022
Update	**1/17/2023:** Sutent is available as a generic, changed filename from Sutent Prior Authorization Policy to Sunitinib Prior Authorization Policy.	--
Annual Revision	**Renal Cell Cancer:** Deleted criteria for approval of sunitinib as adjuvant therapy after nephrectomy since it is a low level of evidence (category 3) for NCCN recommendation. **Thyroid Carcinoma, Differentiated:** For examples of thyroid carcinoma, changed Hürthle cell carcinoma name to "oncocytic	06/28/2023

	carcinoma (formerly Hürthle cell carcinoma)" based on guideline changes.	