PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/17/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

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**, 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 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):[2-11]
- **Bone Cancer**: NCCN guidelines (version 2.2024 – March 12, 2024) recommend sunitinib as a systemic therapy agent for recurrent chordoma (category 2A).[3]
- **Central Nervous System Cancers**: NCCN guidelines (version 1.2024 – May 31, 2024) recommend sunitinib for meningioma for surgically inaccessible recurrent or progressive disease when radiation is not possible (category 2B).[4]

- **Gastrointestinal Stromal Tumor (GIST)**: NCCN guidelines (version 1.2024 – March 8, 2024) 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 1.2025 – July 1, 2024) 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 (all category 2A).[6]
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes**: NCCN guidelines (version 2.2024 – June 19, 2024) recommend sunitinib for myeloid/lymphoid neoplasms with *FLT3* rearrangements (category 2A).[7]
- **Neuroendocrine and Adrenal Tumors**: NCCN guidelines (version 1.2024 – June 20, 2024) 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 sunitinib for treatment (pancreas only) of 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 1.2024 – April 26, 2024) recommend sunitinib as a 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 1.2024 – November 21, 2023) recommend single agent sunitinib as "Preferred" second-line systemic therapy for thymic carcinoma (category 2A).[10]
- **Thyroid Carcinoma**: NCCN guidelines (version 3.2024 – June 18, 2024) 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 also 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 disease 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 BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (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 BOTH of 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 BOTH of 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 BOTH of 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 BOTH of 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 ALL of 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 BOTH of 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 BOTH of 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.

9. **Thymic Carcinoma.** Approve for 1 year if the patient meets BOTH of 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 ALL of 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 BOTH of 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) including the following; criteria will be updated as new published data are available:**

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 July 14, 2024. Search term: sunitinib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2024 – March 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
4. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (version 1.2024 – May 31, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
6. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – July 1, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2024 – June 19, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
8. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2024 – June 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
9. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2024 – April 26, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
10. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 1.2024 – November 21, 2023). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 3.2024 – June 18, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed July 16, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
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 carcinoma (formerly Hürthle cell carcinoma)" based on guideline changes.	06/28/2023
Annual Revision	No criteria changes.	07/17/2024

"Cigna Companies" refers to operating subsidiaries of The Cigna Group. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of The Cigna Group. © 2024 The Cigna Group.