



PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/23/2025

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 WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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:** Guidelines (version 2.2025 – February 28, 2025) recommend sunitinib as a systemic therapy agent for recurrent chordoma (category 2A).³
- **Central Nervous System Cancers:** Guidelines (version 1.2025 – June 3, 2025) recommend sunitinib for meningioma for surgically inaccessible recurrent or progressive disease when radiation is not possible (category 2B).⁴
- **Gastrointestinal Stromal Tumor (GIST):** Guidelines (version 1.2025 – April 17, 2025) recommend sunitinib as preferred second-line therapy for unresectable, progressive, or metastatic disease (category 1).⁵ The first-line therapy is imatinib. Sunitinib is recommended as neoadjuvant therapy and for unresectable, progressive, or metastatic 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:** Guidelines (version 3.2025 – January 9, 2025) 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:** Guidelines (version 2.2024 – June 19, 2024) recommend sunitinib for myeloid/lymphoid neoplasms with *FLT3* rearrangements (category 2A).⁷
- **Neuroendocrine and Adrenal Tumors:** Guidelines (version 2.2025 – May 28, 2025) 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:** Guidelines (version 1.2025 – May 2, 2025) 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, extraskeletal myxoid chondrosarcoma, and for solitary fibrous tumor (both category 2A).⁹
- **Thymomas and Thymic Carcinomas:** Guidelines (version 2.2025 – May 19, 2025) recommend single agent sunitinib as “Preferred” second-line systemic therapy for thymic carcinoma (category 2A).¹⁰
- **Thyroid Carcinoma:** Guidelines (version 1.2025 – March 27, 2025) 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). The guidelines note that a majority of oncocytic carcinoma are non-iodine-avid, so

“radioactive-iodine refractory” may not be applicable to oncocytic carcinoma. 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 \geq 18 years of age; AND
 - B) Patient meets ONE of the following (i or ii):
 - i. Patient has tried imatinib; 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 \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 BOTH of the following (A and B):
- A) Patient is \geq 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 \geq 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 \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 ALL of 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 BOTH of 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 BOTH of the following (A and B):
- A) Patient is \geq 18 years of age; AND
 - B) Patient has ONE of the following diagnosis (i, ii, iii, or iv):
 - i.** Alveolar soft part sarcoma; OR
 - ii.** Angiosarcoma; OR
 - iii.** Solitary fibrous tumor; OR
 - iv.** Extraskelatal myxoid chondrosarcoma.

- 9. Thymic Carcinoma.** Approve for 1 year if the patient meets BOTH of the following (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 BOTH of the following (A and B):

Note: Examples of differentiated thyroid carcinoma include papillary, follicular, and oncocytic carcinoma (formerly Hürthle cell carcinoma).

A) Patient is \geq 18 years of age; AND

B) Patient meets ONE of the following (i or ii);

i. Patient meets BOTH of the following (a and b):

a) Patient has papillary or follicular thyroid carcinoma; AND

b) The disease is refractory to radioactive iodine therapy; OR

ii. Patient has oncocytic (formerly Hürthle cell) carcinoma.

11. Thyroid Carcinoma, Medullary. Approve for 1 year if the patient meets BOTH of 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 COVERED

- **Sutent® (sunitinib malate capsules - Pfizer; generic)**

is(are) considered not medically necessary 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. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025. Search term: sunitinib.
3. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – February 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
4. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (version 1.2025 – June 3, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
5. The NCCN Gastrointestinal Stromal Tumor (GIST) Clinical Practice Guidelines in Oncology (version 1.2025 – April 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
6. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – January 9, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
7. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2025 – April 4, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
8. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 2.2025 – May 28, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
9. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.

10. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (version 12.2025 – May 19, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.
11. The NCCN Thyroid Carcinoma Clinical Practice Guidelines in Oncology (version 1.2025 – March 27, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 21, 2025.

History

Type of Revision	Summary of Changes	Review Date
Annual Revision	<p>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.</p> <p>Thyroid Carcinoma, Differentiated: For examples of thyroid carcinoma, changed Hürthle cell carcinoma name to “oncocytic carcinoma (formerly Hürthle cell carcinoma)” based on guideline changes.</p>	06/28/2023
Annual Revision	No criteria changes.	07/17/2024
Annual Revision	<p>Gastrointestinal Stromal Tumor: Deleted Ayvakit as therapy option from criteria.</p> <p>Soft Tissue Sarcoma: Added Extraskeletal myxoid chondrosarcoma as one of the diagnosis for approval.</p> <p>Thyroid Carcinoma, Differentiated: Moved Note listing the different types of differentiate thyroid carcinoma to be under the indication. Separated criteria such that radioactive iodine-refractory disease is applicable to only follicular or papillary carcinoma and not for oncocytic carcinoma.</p>	07/23/2025

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