UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1101-14
Program	Prior Authorization/Notification
Medication	Sutent® (sunitinib malate)
P&T Approval Date	8/2008, 6/2009, 6/2010, 9/2010, 12/2010, 9/2011, 8/2012, 7/2013, 8/2014, 8/2015, 6/2016, 7/2016, 7/2017, 3/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Sutent® (sunitinib malate) is a tyrosine kinase inhibitor indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to Gleevec® (imatinib mesylate); treatment of advanced renal cell carcinoma (RCC); adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy; and treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

The National Cancer Comprehensive Network (NCCN) recommends use of Sutent for medullary, follicular, oncocytic, or papillary thyroid carcinoma; chordoma; meningiomas; thymic carcinoma; and treatment of myeloid/lymphoid neoplasms with eosinophilia and FMS-like tyrosine kinase 3 (FLT3) rearrangement. NCCN also approves the use of Sutent for other soft tissue sarcomas: alveolar soft part sarcoma (ASPS), angiosarcoma, and solitary fibrous tumor/hemangiopericytoma.

Coverage Information:

Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Sutent** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Gastrointestinal Stromal Tumor (GIST)</u>

1. **<u>Initial Authorization</u>**

   a. **Sutent** will be approved based on **<u>both</u>** of the following criteria:

      (1) Diagnosis of gastrointestinal stromal tumor (GIST)

-AND-

(2) **<u>One</u>** of the following:

(a) History of disease progression on, contraindication, or intolerance to Gleevec (imatinib), Stivarga (regorafenib), or standard dose Qinlock (ripretinib)

-OR-

(b) SDH-deficient GIST

Authorization will be issued for 12 months.

2. **<u>Reauthorization</u>**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

C. <u>Renal Cell Carcinoma (RCC)</u>

1. **<u>Initial Authorization</u>**

a. **Sutent** will be approved based on **<u>both</u>** of the following criteria:

(1) Diagnosis of renal cell carcinoma (RCC)

-AND-

(2) **<u>One</u>** of the following:

(a) Disease has relapsed

-OR-

(b) Disease is advanced

-OR-

(c) **<u>Both</u>** of the following:

i. Used in adjuvant setting
ii. Patient has a high risk of recurrence following nephrectomy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

D. Neuroendocrine and Adrenal Tumors

1. **Initial Authorization**

a. **Sutent** will be approved based on the following criterion:

(1) Diagnosis of progressive pancreatic neuroendocrine tumors (pNET)

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

E. Soft Tissue Sarcoma

1. **Initial Authorization**

a. **Sutent** will be approved based on the following criterion:

(1) Diagnosis of **one** of the following:

(a) Alveolar soft part sarcoma (ASPS)
(b) Angiosarcoma
(c) Solitary fibrous tumor / hemangiopericytoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

F. Thyroid Carcinoma

1. **Initial Authorization**

a. **Sutent** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of **one** of the following:

i. Follicular carcinoma
ii. Oncocytic carcinoma
iii. Papillary carcinoma

-AND-

(b) **One** of the following:

i. Unresectable locoreginal recurrent disease
ii. Persistent disease
ii. Metastatic disease

-AND-

(c) **One** of the following:

i. Patient has symptomatic disease
ii. Patient has progressive disease

-AND-

(d) Disease is refractory to radioactive iodine treatment

-OR-

(2) **All** of the following:

(a) Diagnosis of medullary thyroid carcinoma

-AND-

(b) **One** of the following

i. Patient has progressive disease
ii. Patient has symptomatic metastatic disease

-AND-

(c) **One** of the following:

i. Clinical trials or preferred systemic therapy options are not available or appropriate
ii. There is progression on preferred systemic therapy options [e.g. Caprelsa (vandetanib), Cometriq (cabozantinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

G. Chordoma

1. **Initial Therapy**

a. **Sutent** will be approved based on the following criterion:

(1) Diagnosis of recurrent chordoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

H. Central Nervous System Cancer

1. **Initial Therapy**

a. **Sutent** will be approved based on **all** of the following criteria:

(1) Diagnosis of surgically inaccessible meningiomas

-AND-

(2) **One** of the following:

(a) Disease is recurrent
(b) Disease is progressive

-AND-

(3) Further radiation is not possible

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

I. Thymic Carcinoma

1. **Initial Therapy**

a. **Sutent** will be approved based on the following criteria:

(1) Diagnosis of thymic carcinoma

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

J. Myeloid/Lymphoid Neoplasms

1. **Initial Authorization**

a. **Sutent** will be approved based on **both** of the following criteria:

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

-AND-

(2) Patient has a FMS-like tyrosine kinase 3 (FLT3) rearrangement in chronic or blast phase

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Sutent** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Sutent therapy

Authorization will be issued for 12 months.

K. <u>NCCN Recommended Regimens</u>

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Sutent [package insert]. New York, NY: Pfizer Labs; August 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed February 5, 2024.

Program	Prior Authorization/Notification - Sutent® (sunitinib malate)
Change Control	
8/2014	Annual review with updated criteria for thyroid carcinoma. Expanded disease description for RCC. Updated Background and References.
9/2014	Administrative change - Tried/Failed exemption for State of New Jersey removed.
8/2015	Annual review. Updated thyroid cancer and lung neuroendocrine tumor criteria. Added new criteria for meningiomas and thymic carcinoma. Updated background and references.
6/2016	Annual review. Updated thyroid cancer criteria to include persistent disease. Updated background and references.
7/2016	Updated thyroid and thymic cancer criteria.
7/2017	Annual review. Updated background and criteria removing off label criteria for lung neuroendocrine tumors as no longer recommended by NCCN. Updated reference.
3/2018	Updated background and criteria to include new labeled indication of adjuvant therapy for high risk RCC following nephrectomy. Updated references.
3/2019	Annual review with no changes to coverage criteria. Updated

	references.
3/2020	Annual review. Added general NCCN recommendations for use criteria. Updated reference.
3/2021	Annual review. Added NCCN recommendation for Myeloid/Lymphoid Neoplasms to background and updated treatment criteria. References updated.
3/2022	Annual review. Updated renal cell and neuroendocrine carcinoma criteria per NCCN guidelines. Updated references.
3/2023	Annual review. Updated Myeloid/Lymphoid and Thymic cancer criteria per NCCN guidelines. Updated reference. Added state mandate footnote.
3/2024	Annual review. Updated GIST, neuroendocrine/adrenal tumors, and thyroid carcinoma per NCCN recommendations.