UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Sutent

Program	Prior Authorization
Medication	Sutent® (sunitinib malate)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	3/2020
Effective Date	5/2020

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 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.[1] The National Cancer Comprehensive Network (NCCN) recommends use of Sutent for medullary, follicular, Hürthle cell, or papillary thyroid carcinoma; chordoma; meningiomas; and thymic carcinoma.[2] NCCN also approves the use of Sutent for other soft tissue sarcomas: alveolar soft part sarcoma (ASPS), angiosarcoma, and solitary fibrous tumor/hemangiopericytoma.

2. Coverage Criteria:

A. Gastrointestinal Stromal Tumor (GIST)

1. Initial Authorization

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

(1) Diagnosis of gastrointestinal stromal tumor (GIST)

-AND-

(2) History of failure, contraindication, or intolerance to Gleevec (imatanib)

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.

B. Renal Cell Carcinoma (RCC)

1. Initial Authorization

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

(1) Diagnosis of renal cell carcinoma (RCC)

-AND-

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

(a) Disease has relapsed

-OR-

(b) Diagnosis of Stage IV disease

-OR-

(c) **Both** 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.

C. Islet Cell Tumors / Progressive Pancreatic Neuroendocrine Tumors (pNET)

1. Initial Authorization

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

(1) Diagnosis of islet cell tumor / progressive pancreatic neuroendocrine tumors (pNET)

-AND-

(2) Disease is **one** of the following:

(a) Unresectable, locally advanced
(b) Metastatic

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. 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.

E. 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. Hürthle cell carcinoma
iii. Papillary carcinoma

-AND-

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

i. Unresectable locoregional 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) History of failure, contraindication, or intolerance to **one** of the following:

i. Caprelsa (vandetanib)
ii. 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.

F. 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.

G. 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.

H. Thymic Carcinoma

1. Initial Therapy

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

(1) Diagnosis of thymic carcinoma

-AND-

(2) Used as second-line following a failure, contraindication, or intolerance to a first-line chemotherapy regimen (e.g., carboplatin/paclitaxel)

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. NCCN Recommended Regimens

1. **Initial Authorization**

   a. **Sutent** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

   Authorization will be issued for 12 months.

2. **Reauthorization**

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

      (1) Documentation of positive clinical response to Sutent therapy

   Authorization will be issued for 12 months.

3. References:

1. Sutent [package insert]. New York, NY: Pfizer Labs; May 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed January 30, 2020.

Program	Prior Authorization/Notification - Sutent® (sunitinib malate)
Change Control	
9/2013	New guideline.
11/2014	Annual Review
12/2015	▪ Guideline updated to clarify the diagnosis requirement for advanced renal cell cancer (RCC) and will now ask that patient either has relapse following surgical excision or stage IV disease with medically or surgically unresectable tumor. • Revised criteria mirror diagnosis criteria for other agents approved for RCC [eg, Nexavar (sorafenib)]
7/2016	Updated policy template. Updated clinical criteria to align with Employer and Individual.
7/2017	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. Added NCCN recommended review criteria. Updated references.

3/2019	Minor changes to wording and formatting. Updated references.
3/2020	Annual review. Updated references.