BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.095

Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	July 28, 2017
Subject:	Sutent	**Page:**	1 of 6

Last Review Date: December 12, 2025

Sutent

Description

Sutent (sunitinib)

Background
Sutent (sunitinib malate) is a small molecule inhibitor of multiple membrane-bound and intracellular kinases involved in normal cellular functions and in pathologic processes such as oncogenesis, tumor angiogenesis, and maintenance of the tumor microenvironment (1).

Regulatory Status
FDA-approved indications: Sutent is a kinase inhibitor indicated for the treatment of adult patients with: (1)

1. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
2. Advanced renal cell carcinoma (RCC)
3. Adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy
4. Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease

Off-Label Uses: (2-5)

1. Recurrent chordoma
2. Relapsed or unresectable renal cell carcinoma
3. Neuroendocrine tumors
    a. Unresectable
    b. Metastatic disease
4. Soft tissue sarcoma

   a. Angiosarcoma
   b. Solitary fibrous tumor
   c. Hemangiopericytoma
   d. Alveolar Soft Part Sarcoma (ASPS)
5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
   a. Unresectable recurrent or persistent
   b. Distant metastatic disease
6. Medullary thyroid carcinoma
   a. Progressive disease
   b. Symptomatic distant metastatic disease
7. Thymic carcinoma

Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests (ALT, AST, and bilirubin) should be monitored at baseline, during each cycle, and as clinically indicated. Sutent should be interrupted or discontinued based on the grade of hepatotoxicity (1).

The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Related policies
Afinitor, Avastin, Ayvakit, Cabometyx, Caprelsa, Cometriq, Inlyta, Lenvima, Nexavar, Opdivo, Qinlock, Stivarga, Tarceva, Votrient, Xalkori

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sutent may be considered **medically necessary** if the conditions indicated below are met.

Sutent may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Gastrointestinal stromal tumor (GIST)
    a. After disease progression on imatinib mesylate (Gleevec) OR intolerant to imatinib mesylate (Gleevec)

2. Renal cell carcinoma (RCC) with **ONE** of the following:
    a. Relapsed or unresectable
    b. Adjuvant treatment for patients with high risk of recurrent RCC following nephrectomy

3. Neuroendocrine tumors
    a. Unresectable or metastatic disease

4. Soft tissue sarcoma with **ONE** of the following subtypes:
    a. Angiosarcoma
    b. Solitary fibrous tumor
    c. Hemangiopericytoma
    d. Alveolar Soft Part Sarcoma (ASPS)

5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
    a. Unresectable or metastatic disease

6. Medullary thyroid carcinoma
    a. Progressive or symptomatic distant metastatic disease

7. Thymic carcinoma

8. Recurrent chordoma

AND ALL of the following for **ALL** indications:

1. Prescriber agrees to monitor ALT, AST, and bilirubin tests before initiation of therapy, every cycle, and as clinically indicated
2. **Brand Sutent only:** Inadequate treatment response, intolerance, or contraindication to generic Sutent: sunitinib

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Gastrointestinal stromal tumor (GIST)
2. Renal cell carcinoma (RCC)
3. Neuroendocrine tumors
4. Soft tissue sarcoma with **ONE** of the following subtypes:
   a. Angiosarcoma
   b. Solitary fibrous tumor
   c. Hemangiopericytoma
   d. Alveolar Soft Part Sarcoma (ASPS)
5. Papillary, Hurthle Cell, or Follicular thyroid carcinoma
6. Medullary thyroid carcinoma
7. Thymic carcinoma
8. Chordoma

AND ALL of the following for **ALL** indications:

a. **NO** severe hepatic impairment (Child-Pugh Class C)
b. **NO** disease progression or unacceptable toxicity
c. **Brand Sutent only:** Inadequate treatment response, intolerance, or contraindication to generic Sutent: sunitinib

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
12.5 mg	84 capsules per 84 days **OR**
25 mg	84 capsules per 84 days **OR**
37.5 mg	84 capsules per 84 days **OR**
50 mg	84 capsules per 84 days

Maximum daily limit: 87.5 mg

*** Only 2 strengths are allowed in combination to accommodate non-commercially available products**

******Utilizing the highest strengths available to achieve the dosage is recommended to minimize dosing errors and improve compliance

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sutent (sunitinib) is a kinase inhibitor, designed to block enzymes that promote cancer growth. Sutent has been approved to treat gastrointestinal stromal tumors (GIST), renal cell carcinoma (RCC) and neuroendocrine tumors. Sutent is also used off-label for the treatment of soft tissue sarcoma, thyroid carcinoma, thymic carcinoma and recurrent chordoma. Sutent carries a boxed warning for severe and sometimes fatal hepatotoxicity. Liver function tests should be obtained before initiation of Sutent, and it should be monitored during each cycle and as clinically indicated. The safety and effectiveness of Sutent have not been established in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Sutent while maintaining optimal therapeutic outcomes.

References

1. Sutent [package insert]. New York, NY; Pfizer Inc.; August 2021.
2. NCCN Drugs & Biologics Compendium® Sunitinib 2025. National Comprehensive Cancer Network, Inc. Accessed on November 11, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and Adrenal Tumors (Version 3.2025). National Comprehensive Cancer Network, Inc. October 2025. Accessed on November 11, 2025.
4. NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 1.2025). National Comprehensive Cancer Network, Inc. May 2025. Accessed on November 11, 2025.
5. NCCN Clinical Practice Guidelines in Oncology® Thymomas and Thymic carcinomas (Version 1.2026). National Comprehensive Cancer Network, Inc. October 2025. Accessed on November 11, 2025.

Policy History

Date	Action
July 2017	New addition to PA
September 2017	Annual review Addition of quantity limits
December 2017	Addition of recurrent RCC following nephrectomy alveolar soft part sarcoma (ASPS) and recurrent chordoma
March 2018	Annual review
June 2019	Annual review and reference update
June 2020	Annual review and reference update
September 2020	Annual review and reference update
June 2021	Annual review and reference update
August 2021	Revised initiation requirement per new PI: Prescriber agrees to monitor LFTs every cycle and as clinically indicated
December 2021	Annual review and reference update
September 2022	Annual review and reference update
March 2023	Annual review and reference update
April 2023	Added Medex requirement for brand Sutent per FEP
June 2023	Annual review and reference update
March 2024	Annual review and reference update
March 2025	Annual review and reference update
December 2025	Annual review and reference update. Removed MedEx requirement and switched to t/f

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.