

## Sutent® (sunitinib) (Oral)

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### I. Length of Authorization

Coverage is provided for six months and may be renewed, for adjuvant RCC may be renewed up to 9 cycles of therapy.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Sutent 50 mg: 1 capsule per day
- Sutent 37.5 mg: 1 capsule per day
- Sutent 25 mg: 1 capsule per day
- Sutent 12.5 mg: 1 capsule per day

#### B. Max Units (per dose and over time) [Medical Benefit]:

- Adjuvant RCC
  - 50 mg daily for up to 9 cycles
- All other indications
  - 50 mg daily

### III. Initial Approval Criteria

Coverage if provided in the following conditions:

- Patient Age is 18 years and older; **AND**

#### Renal Cell Carcinoma (RCC) †

- Must be used as a single agent; **AND**
  - Patient's disease must be advanced ‡; **OR**
  - Used as adjuvant treatment for high-risk of recurrence, in patient's with clear cell histology, following nephrectomy‡; **OR**
  - Used for relapse or surgically unresectable stage IV disease ‡; **AND**
    - Used as first-line or subsequent therapy for predominant clear cell histology; **OR**

- Used as systemic therapy for non-clear cell histology.

### **Gastrointestinal stromal tumors (GIST) †**

- Used as primary treatment in patients with life-threatening side effects to imatinib; **AND**
  - Any of the following: localized/resectable disease with high risk of morbidity, unresectable disease, recurrent disease or metastatic disease; **OR**
- Used as post-operative treatment in patients who have life-threatening side effects to imatinib; **AND**
  - Following complete resection of primary GIST; **OR**
  - With persistent gross residual disease; **OR**
- Used for disease progression, on or intolerance to, imatinib †; **OR**
- Used in combination with everolimus for progression after monotherapy with imatinib, sunitinib or regorafenib

### **Pancreatic neuroendocrine tumors (pNET) †**

- Patient has unresectable locally advanced or metastatic disease; **AND**
- Must be used as a single agent; **AND**
- Patient has progressive disease, significant tumor burden, or is symptomatic

### **Soft Tissue Sarcoma – Angiosarcoma ‡**

- Must be used as a single agent

### **Soft Tissue Sarcoma – Solitary Fibrous Tumor/Hemangiopericytoma ‡**

- Must be used as a single agent

### **Thymomas and Thymic carcinomas ‡**

- Must be used as a single agent for second-line therapy

### **Thyroid carcinoma ‡**

- Patient has either: Follicular, Hurthle Cell, or Papillary Carcinoma; **AND**
  - Patient has unresectable, recurrent, persistent, or metastatic disease; **AND**
  - Other therapies and/or clinical trials are not available or appropriate ; **AND**
  - Patient has progressive and/or symptomatic disease that is iodine-refractory; **OR**
- Patient has medullary thyroid carcinoma; **AND**
  - Patient has recurrent, progressive or symptomatic metastatic disease; **AND**
    - Clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
    - Patient has progressed on vandetanib or cabozantinib

### **Chordoma ‡**

- Patient's disease must be recurrent; **AND**

- Must be used as a single agent

†FDA approved indication(s); ‡Compendia approved indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include hepatotoxicity, cardiotoxicity (heart failure, cardiomyopathy, myocardial ischemia/infarction, QT prolongation, Torsades de Pointes), hypertension, tumor lysis syndrome (TLS), thrombotic microangiopathy (TMA), dermatologic toxicity (erythema multiforme (MF), Stevens-Johnsons syndrome (SJS), toxic epidermal necrolysis (TEN)), hypoglycemia, osteonecrosis of the jaw, impaired wound healing, etc.

#### Renal Cell Carcinoma (RCC)

- May be renewed up to 9 cycles of therapy

#### V. Dosage/Administration

Indication	Dose
Advanced RCC, GIST	50mg once daily for 4 weeks of a 6 week cycle
Adjuvant RCC	50mg once daily for 4 weeks of a 6 week cycle, for nine 6-week cycles
Pancreatic neuroendocrine tumors	37.5mg daily continuous dosing
Soft Tissue Sarcoma (all)	37.5mg daily continuous dosing
Thyroid Carcinoma	50mg once daily for 4 weeks of a 6 week cycle

#### VI. Billing Code/Availability Information

HCPCS code:

- J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399 - Unclassified drugs or biologicals (Hospital Outpatient Use ONLY)

NDC:

- Sutent 12.5 mg capsule – 00069-0550-xx
- Sutent 25 mg capsule – 00069-0770-xx
- Sutent 37.5 mg capsule – 00069-0830-xx
- Sutent 50 mg capsule – 00069-0980-xx

## VII. References

1. Sutent® [package insert]. New York, NY; Pfizer; November 2017; Accessed June 2018.
2. Niccoli P, Raoul J, Bang Y, et al, “Updated Safety and Efficacy Results of the Phase III Trial of Sunitinib (SU) Versus Placebo (PBO) for Treatment of Pancreatic Neuroendocrine Tumors (NET),” J Clin Oncol, 2010, 28(15s):4000 [abstract 4000 from 2010 ASCO Annual Meeting].
3. Kulke MH, Lenz HJ, Meropol NJ, et al, “Activity of Sunitinib in Patients with Advanced Neuroendocrine Tumors,” J Clin Oncol, 2010, 26(20):3403-10. [PubMed 18612155]
4. Cohen EE, Needles BM, Cullen KJ, et al, “Phase 2 Study of Sunitinib in Refractory Thyroid Cancer,” J Clin Oncol, 2008, 26(Supp):6025 [abstract 6025 from 2008 ASCO Annual Meeting].
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) sunitinib. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2018.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C25.4	Malignant neoplasm of endocrine pancreas
C37	Malignant neoplasm of thymus
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified

### SUTENT® (sunitinib) Prior Auth Criteria

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ICD-10	ICD-10 Description
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C49.A0	Gastrointestinal stromal tumor unspecified site
C49.A1	Gastrointestinal stromal tumor of esophagus
C49.A2	Gastrointestinal stromal tumor of stomach
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C49.A9	Gastrointestinal stromal tumor of other sites
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C73	Malignant neoplasm of thyroid gland
C7B.00	Secondary carcinoid tumors, unspecified site
C7B.01	Secondary carcinoid tumors of distant lymph nodes
C7B.02	Secondary carcinoid tumors of liver
C7B.03	Secondary carcinoid tumors of bone
C7B.04	Secondary carcinoid tumors of peritoneum
C7B.8	Other secondary neuroendocrine tumors
D15.0	Benign neoplasm of thymus
E16.1	Other hypoglycemia
E16.3	Increased secretion of glucagon
E16.8	Other specified disorders of pancreatic internal secretion
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.528	Personal history of other malignant neoplasm of kidney
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.858	Personal history of malignant neoplasm of other endocrine glands

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

### Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC