Sutent® (sunitinib)
(Oral)

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I. Length of Authorization [1]

Coverage is provided for 6 months and may be renewed (unless otherwise specified).

- Adjuvant RCC may be renewed for up to nine 6-week cycles of therapy.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- 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) [HCPCS Unit]:

- RCC, GIST, Thyroid Carcinoma, and Thymic Carcinoma: 50 mg daily x 28 days of every 42 day cycle
- Myeloid/Lymphoid Neoplasms with Eosinophilia: 50 mg daily
- Pancreatic Neuroendocrine Tumors, Pheochromocytoma/ Paraganglioma, Soft Tissue Sarcoma, and Bone Cancer – Chordoma: 37.5 mg daily

III. Initial Approval Criteria [1]

Coverage if provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1]

- Patient will avoid concomitant therapy with all of the following, or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented:

- Coadministration with strong CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Coadministration with strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, nefazodone, etc.); **AND**

Renal Cell Carcinoma (RCC) † [1,5]

- Used as a single agent; **AND**
  - Patient has advanced disease †; **OR**
  - Used as adjuvant treatment for high-risk of recurrence, in patients with clear cell histology, following nephrectomy †; **OR**
  - Patient has relapsed or stage IV disease ‡; **AND**
    - Used as first-line or subsequent therapy for clear cell histology; **OR**
    - Used as systemic therapy for non-clear cell histology

Gastrointestinal Stromal Tumors (GIST) † ‡ [1,5,17]

- Used as a single agent; **AND**
  - Used for disease progression on, or intolerance to, imatinib †; **OR**
  - Patient has unresectable, succinate dehydrogenase (SDH)-deficient disease; **OR**
  - Used as reintroduction therapy for palliation of symptoms in patients who previously tolerated sunitinib with an effective response; **OR**
- Used in combination with everolimus; **AND**
  - Patient has unresectable, recurrent/progressive, or metastatic disease; **AND**
  - Disease has progressed on prior treatment with approved therapies including each of the following: imatinib, sunitinib OR dasatinib, regorafenib, AND ripretinib

Pancreatic Neuroendocrine Tumors (pNET) † ‡ [1,5]

- Used as a single agent for well-differentiated disease; **AND**
- Patient has unresectable locally advanced, metastatic, or recurrent disease; **AND**
- Patient has progressive disease, significant tumor burden, or is symptomatic

Pheochromocytoma/Paraganglioma ‡ [5,23]

- Used as a single agent as primary treatment for secreting tumors; **AND**
- Patient has locally unresectable or metastatic disease

Soft Tissue Sarcoma ‡ [5,6]

- Used as a single agent; **AND**
- Patient has one of the following subtypes of disease:
  - Alveolar Soft Part Sarcoma (ASPS)
  - Angiosarcoma

- Solitary Fibrous Tumor

Thymic Carcinomas ‡ [5,12,15]

- Used as a single agent; **AND**
  - Patient is unable to tolerate first-line combination regimens; **AND**
    - Used as postoperative treatment after R1 (microscopic residual tumor) or R2 (macroscopic residual tumor) resection; **OR**
    - Used as first-line therapy for unresectable, locally advanced, or metastatic disease; **OR**
  - Used as second-line therapy; **AND**
    - Patient has unresectable or metastatic disease

Thyroid Carcinoma ‡ [5]

- Patient has Follicular, Hürthle Cell, or Papillary carcinoma; **AND**
  - Patient has unresectable recurrent, persistent, or metastatic disease; **AND**
  - Treatment with clinical trials or other systemic therapies are not available or appropriate; **AND**
  - Patient has progressive and/or symptomatic disease that is not susceptible to radioactive iodine (RAI) therapy; **OR**
- Patient has Medullary carcinoma; **AND**
  - Patient has recurrent or persistent metastatic disease; **AND**
  - Disease is symptomatic or progressive; **AND**
    - Treatment with clinical trials, vandetanib, or cabozantinib are not available or appropriate; **OR**
    - Patient has progressed on vandetanib or cabozantinib

Bone Cancer – Chordoma ‡ [5,13,14]

- Used as a single agent; **AND**
- Patient has recurrent disease with conventional or chondroid histology

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes ‡ [5,16]

- Patient has eosinophilia and FLT3 rearrangement; **AND**
  - Patient has chronic or blast phase myeloid or lymphoid neoplasms; **AND**
    - Used as a single agent; **OR**
  - Patient has blast phase lymphoid, myeloid, or mixed lineage neoplasms; **AND**
    - Used in combination with ALL- or AML-type induction chemotherapy followed by allogeneic HCT (if eligible)

† FDA approved indication(s); ‡ Compendia approved indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: hepatotoxicity, cardiovascular events (e.g., heart failure, cardiomyopathy, myocardial ischemia/infarction, etc.), QT prolongation and Torsades de Pointes, hypertension, hemorrhagic events and viscus perforation, tumor lysis syndrome (TLS), thrombotic microangiopathy (TMA), proteinuria and nephrotic syndrome, dermatologic toxicity [erythema multiforme (EM), Stevens-Johnsons syndrome (SJS), toxic epidermal necrolysis (TEN)], reversible posterior leukoencephalopathy syndrome (RPLS), thyroid dysfunction, hypoglycemia, osteonecrosis of the jaw, impaired wound healing, etc.; **AND**

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes [2]

- Disease response as evidenced by at least one of the following:
  - Decrease in spleen size or improvements in other myelofibrosis symptoms (such as fatigue, bone pain, frequent infections, fever, night sweats, easy bruising/bleeding, etc.)
  - Stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenic analysis, QPCR, or FISH

Adjuvant Renal Cell Carcinoma (RCC) [1]

- May be renewed for up to nine 6-week cycles of therapy

All Other Indications

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

V. Dosage/Administration [1,14,15,19-23]

Indication	Dose
Advanced RCC & GIST	50mg once daily for 4 weeks of a 6 week cycle, until disease progression or unacceptable toxicity.
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, until disease progression or unacceptable toxicity.
Pheochromocytoma/ Paraganglioma	37.5mg daily continuous dosing, until disease progression or unacceptable toxicity.

Soft Tissue Sarcoma	37.5mg daily continuous dosing, until disease progression or unacceptable toxicity.
Thyroid Carcinoma	50mg once daily for 4 weeks of a 6 week cycle, until disease progression or unacceptable toxicity.
Thymic Carcinomas	50mg once daily for 4 weeks of a 6 week cycle, until disease progression or unacceptable toxicity.
Bone Cancer - Chordoma	37.5mg daily continuous dosing, until disease progression or unacceptable toxicity.
Myeloid/Lymphoid Neoplasms with Eosinophilia	37.5mg – 50mg daily continuous dosing, until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 - Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

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; August 2021; Accessed June 2022.
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6. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Soft Tissue Sarcoma Version 2.2022. National Comprehensive Cancer Network, 2022. 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 Guidelines, go online to NCCN.org. Accessed June 2022.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C22.3	Angiosarcoma of liver
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
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum

ICD-10	ICD-10 Description
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
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
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland
C74.11	Malignant neoplasm of medulla of right adrenal gland
C74.12	Malignant neoplasm of medulla of left adrenal gland
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland

ICD-10	ICD-10 Description
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
C7A.8	Other malignant neuroendocrine tumors
C7A.098	Malignant carcinoid tumors of other sites
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.09	Secondary carcinoid tumors of other sites
C7B.8	Other secondary neuroendocrine tumors
C94.8	Other specified leukemias
C94.80	Other specified leukemias not having achieved remission
C94.81	Other specified leukemias, in remission
C94.82	Other specified leukemias, in relapse
C95.1	Chronic leukemia of unspecified cell type
C95.10	Chronic leukemia of unspecified cell type not having achieved remission
C95.11	Chronic leukemia of unspecified cell type, in remission
C95.12	Chronic leukemia of unspecified cell type, in relapse
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
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
Z85.831	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), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at:

https://www.cms.gov/medicare-coverage-database/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/LCA): 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