Sutent (sunitinib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Sutent (sunitinib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Sutent (sunitinib) may be approved if the following criteria are met:

I. Individual has a diagnosis of Advanced Renal cell carcinoma (RCC) or kidney cancer;
OR
II. Individual is using as adjuvant treatment in adults at high risk of recurrent RCC following nephrectomy;

OR
III. Individual has a diagnosis of Bone cancer, recurrent Chordoma (NCCN 2A);

OR
IV. Individual has a diagnosis of Neuroendocrine Tumors of the Pancreas (Label, NCCN 2A); **AND**
V. Individual is using for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors; **AND**
VI. Individual has unresectable, locally advanced, or metastatic disease;

OR
VII. Individual has a diagnosis of Soft Tissue Sarcoma;
AND
A. Individual is using for the treatment of unresectable, recurrent, or metastatic Gastrointestinal Stromal Tumor (GIST); **AND**
B. Individual has had progression on imatinib or experienced intolerance to imatinib;

OR
C. Individual is using in combination with everolimus for unresectable, recurrent, or metastatic GIST after failure on approved therapies (such as imatinib, sunitinib, regorafenib, and ripretinib) (NCCN 2A);
OR
D. Individual is using as monotherapy for succinate-dehydrogenase (SDH)- deficient unresectable GIST (NCCN 2A);
OR
E. Individual is using as monotherapy for Angiosarcoma, Solitary Fibrous Tumor, or Alveolar Soft Part Sarcoma (NCCN 2A);

OR

VIII. Individual has a diagnosis of papillary, follicular, or Oncocytic Cell Thyroid Carcinoma (NCCN 2A); **AND**

IX. Individual has progressive and/or symptomatic disease that is iodine-refractory (NCCN 2A); **AND**

X. Clinical trials or other systemic therapies are not available or appropriate (NCCN 2A);

OR

XI. Individual has a diagnosis of Medullary Thyroid Carcinoma; **AND**

XII. Individual is using in the treatment of progressive or symptomatic distant metastases if clinical trials or systemic therapy options are not available or appropriate **OR** if there is progression on systemic therapy options (NCCN 2A);

OR

XIII. Individual has a diagnosis of Thymomas and Thymic Carcinoma (NCCN 2A); **AND**

XIV. Individual is using as a single agent for second-line therapy (NCCN 2A);
OR

XV. Individual cannot tolerate first-line combination regiments and is using as a single agent;

OR

XVI. Individual has a diagnosis of myeloid or lymphoid neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase.

Note:
Sutent (sunitinib) has a black box warning for hepatotoxicity. Hepatotoxicity may be severe, and in some cases fatal. Monitor hepatic function and interrupt, dose reduce, or discontinue as recommended.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. Walz C, Erben P, Ritter M, et al. Response of ETV6-FLT3-positive myeloid/lymphoid neoplasm with eosinophilia to inhibitors of FMS-like tyrosine kinase 3. Blood. 2011;118(8):2239-2242. doi:10.1182/blood-2011-03-343426. Available at: https://ashpublications.org/blood/article/118/8/2239/29444/Response-of-ETV6-FLT3-positive-myeloid-lymphoid. Accessed July 10, 2023.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 21, 2023.
    a. Thymomas and Thymic Carcinomas. V1.2023. Revised December 15, 2022.
    b. Neuroendocrine and Adrenal Tumors. V2.2022. Revised December 21, 2022.

c. Bone Cancer. V3.2023. Revised April 4, 2023.
d. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
e. Thyroid Carcinoma. V2.2023. Revised May 18, 2023.
f. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V1.2023. Revised May 19, 2023.
g. Kidney Cancer. V4.2023. Revised January 18, 2023.
h. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
i. Gastrointestinal Stromal Tumors (GISTs). V1.2023. Revised March 13,2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.