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 (label, NCCN 2A); **AND**
VI. Individual has unresectable, locally advanced, or metastatic disease;

OR
VII. Individual has a diagnosis of Pheochromocytoma/Paraganglioma; **AND**
VIII. Individual is using for treatment of secreting tumors as a single agent for locally unresectable disease or distant metastases;

OR
IX. Individual has a diagnosis of Soft Tissue Sarcoma; **AND**
   A. Individual is using for the treatment of gross residual disease, tumor rupture, 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 gross residual disease, tumor rupture, 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 GIST (NCCN 2A);

OR

E. Individual is using as monotherapy for Angiosarcoma, Solitary Fibrous Tumor, extraskeletal myxoid chondrosarcoma, or Alveolar Soft Part Sarcoma (NCCN 2A);

OR

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

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

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

OR

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

XIV. 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

XV. Individual has a diagnosis of Thymomas and Thymic Carcinoma; **AND**

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

OR

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

OR

XVIII. 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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. 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.

5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 5, 2024.
    a. Thymomas and Thymic Carcinomas. V1.2024. Revised November 21, 2023.
    b. Neuroendocrine and Adrenal Tumors. V1.2024. Revised June 20, 2024.
    c. Bone Cancer. V2.2024. Revised March 12, 2024.
    d. Central Nervous System Cancers. V1.2024. Revised May 31, 2024.
    e. Thyroid Carcinoma. V3.2024. Revised June 18, 2024.
    f. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V2.2024. Revised June 19, 2024.
    g. Kidney Cancer. V1.2025. Revised July 1, 2024.
    h. Soft Tissue Sarcoma. V1.2024. Revised April 26, 2024.
    i. Gastrointestinal Stromal Tumors (GISTs). V1.2024 Revised March 8, 2024.

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.