Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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 and Adrenal Tumors (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 limited or progressive Gastrointestinal Stromal Tumor (GIST) disease, following progression on or intolerance to imatinib;

OR
- B. Individual is using for primary GIST treatment when life-threatening side effects occur on imatinib mesylate **AND** any of the following types of GIST disease: localized, resectable disease with high risk of morbidity, unresectable disease, recurrent disease or metastatic disease (NCCN 2A);

OR
- C. Individual is using for post-operative treatment of GIST after life-threatening side effects on imatinib therapy;

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

AND

1. Completed resection of primary GIST(NCCN 2A); **OR**
2. Has persistent gross residual disease (NCCN 2A);

OR

D. Individual is using in combination with everolimus for GIST progression after monotherapy with imatinib, sunitinib, and regorafenib (NCCN 2A);

OR

E. Individual is using for Angiosarcoma as monotherapy (NCCN 2A);

OR

F. Individual is using for Solitary Fibrous Tumor as monotherapy (NCCN 2A);

OR

VIII. Individual has a diagnosis of papillary, follicular, or Hürthle 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, vandetanib, or cabozantinib are not available or appropriate **OR** if there is progression on vandetanib or cabozantinib (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).

Note: Sutent (sunitinib) has a black box warning for hepatotoxicity. Hepatotoxicity may be severe, with deaths reported, and has been observed in clinical trials and post-marketing experience.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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. Accessed: June 23, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 10, 2020.
    a. Thyroid Carcinoma. V1.2020. Revised November 27, 2019.
    b. Soft Tissue Sarcoma. V2.2020. Revised May 28, 2020.
    c. Neuroendocrine and Adrenal Tumors. V1.2020. Revised July 10, 2020.
    d. Kidney Cancer. V2.2020. Revised August 5, 2019.
    e. Bone Cancer. V1.2020. Revised August 12, 2019.

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.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.