Clinical Policy: Sunitinib (Sutent)

Reference Number: CP.PHAR.73
Effective Date: 09/11
Last Review Date: 08/17 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for sunitinib (Sutent®).

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that Sutent is **medically necessary** when one of the following criteria are met:

I. Initial Approval Criteria

A. Gastrointestinal Stromal Tumor (must meet all)**:**
1. Diagnosis of gastrointestinal stromal tumor (GIST);
2. Disease progression on or intolerance to imatinib mesylate;
3. Prescribed dose does not exceed (a or b):
   a. 50 mg/day - 4 weeks on/2 weeks off;
   b. 87.5 mg/day - 4 weeks on/2 weeks off - if co-administered with a CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort).

Approval duration: 6 months

B. Renal Cell Carcinoma (must meet all)**:**
1. Diagnosis of renal cell carcinoma (RCC);
2. Disease has relapsed or is stage IV;
3. Prescribed dose does not exceed (a or b):
   a. 50 mg/day - 4 weeks on/2 weeks off;
   b. 87.5 mg/day - 4 weeks on/2 weeks off - if co-administered with a CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort).

Approval duration: 6 months

C. Pancreatic Neuroendocrine Tumor (must meet all)**:**
1. Diagnosis of pancreatic neuroendocrine tumor (pNET);
2. Disease is unresectable or metastatic;
3. Prescribed dose does not exceed (a or b):
   a. 37.5 mg/day;
   b. 62.5 mg/day if co-administered with a CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort).

Approval duration: 6 months

D. Other diagnoses/indications: Refer to CP.PHAR.57 - Global Biopharm Policy.
1. Uses outlined in the NCCN compendium meeting NCCN categories 1 or 2a are covered for the following indications:
   a. Bone cancers: chordoma;
   b. Neuroendocrine tumors: lung;
   c. Soft tissue sarcomas:
      i. Angiosarcoma;
      ii. Solitary fibrous tumor/hemangiopericytoma;
   d. Thymomas and thymic carcinomas;
   e. Thyroid carcinomas:
      i. Follicular carcinoma;
      ii. Hurthle cell carcinoma;
      iii. Medullary carcinoma;
      iv. Papillary carcinoma.

II. Continued Approval

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Prescribed dose does not exceed (a or b)**:**
   a. GIST and RCC (i or ii):
      i. 50 mg/day - 4 weeks on/2 weeks off;
      ii. 87.5 mg/day - 4 weeks on/2 weeks off - if co-administered with a CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort);
   b. pNET (i or ii):
      i. 37.5 mg/day;
      ii. 62.5mg per day if co-administered with a CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort);
3. Member is responding positively to therapy (e.g., no disease progression or unacceptable toxicity).

Approval duration: 12 months

B. Other diagnoses/indications (1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to CP.PHAR.57 - Global Biopharm Policy.

Background

Description/Mechanism of Action:

Sunitinib is a small molecule that inhibits multiple receptor tyrosine kinases (RTKs), some of which are implicated in tumor growth, pathologic angiogenesis, and metastatic progression of cancer.

Formulations:
Sutent oral capsules: 12.5 mg, 25 mg, 37.5 mg, 50 mg

FDA Approved Indications:
Sutent is a multi-kinase inhibitor/oral capsule formulation indicated for the treatment of patients with:

- GIST after disease progression on or intolerance to imatinib mesylate.
- Advanced RCC.
- Progressive, well-differentiated pNET in patients with unresectable locally advanced or metastatic disease.

Appendices
Appendix A: Abbreviation Key
GIST: gastrointestinal stromal tumor
KIT: stem cell factor receptor
pNET: pancreatic neuroendocrine tumor
RCC: renal cell carcinoma

Reviews, Revisions, and Approvals	Date	Approval Date
Added background on GIST, RCC, pNET Added safety warning for proteinuria, nephrotic syndrome, and severe dermatologic conditions Added Appendix B to policy and algorithm	07/14	08/14
Added statement limiting to adult use in indication section per PI. Shortened background by adding overviews of each disease state from NCCN guidelines. Added age restriction to Figure 1 Appendix B (reasons to discontinue): Moved CHF into Appendix B and added thrombotic microangiopathy Appendices C and D: Added staging criteria per guidelines for RCC and pNET Deleted all references except for the PI which was updated to 4.2015. Added three sets of NCCN guidelines per the three indications.	08/15	08/15
Policy converted to new template. Removed age requirement since not referenced in FDA indication section. Removed question related to ALT or AST > 2.5x ULN, or if due to liver metastases, ALT or AST > 5.0 x ULN since not listed as a contraindication or reason to discontinue per PI. Added maximum dosage requirement for GIST, RCC, and pNET. Shortened initial approval duration to 3 months. NCCN recommended uses added. Shortened background section.	07/16	08/16

Reviews, Revisions, and Approvals	Date	Approval Date
Under pNET, "unresectable locally advanced" is edited to "unresectable" for clarity. Under dosing, additional CYP inducer examples are added. NCCN coverage is limited to 1 and 2a (2b removed); central nervous system cancers (meningioma) and alveolar soft part sarcoma consequently are removed. NCCN uses falling within FDA labeled indications are not listed separately. Safety information removed.	07/17	08/17

References

1. Sutent Prescribing Information. New York, NY: Pfizer Inc.; April 2015. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=607. Accessed July 10, 2017.
2. Sunitinib malate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at nccn.org. Accessed July 5, 2017.
3. Soft tissue sarcoma (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed July 5, 2017.
4. Kidney cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed July 5, 2017.
5. Neuroendocrine tumors (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at nccn.org. Accessed July 5, 2017.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.