Clinical Policy: Sunitinib (Sutent)

Reference Number: CP.PHAR.73
Effective Date: 09.11
Last Review Date: 02.18
Line of Business: Medicaid

Revision Log

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

Description

Sunitinib (Sutent®) is a kinase inhibitor.

FDA Approved Indication(s)

Sutent is indicated:

- For the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate
- For the treatment of advanced renal cell carcinoma (RCC)
- For the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy
- For the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

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

I. Initial Approval Criteria

A. Gastrointestinal Stromal Tumor (must meet all)**:**

1. Diagnosis of GIST;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease progression on or intolerance to imatinib mesylate;
5. Dose does not exceed 50 mg/day - 4 weeks on/2 weeks off (or 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 RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Sutent is requested for (a or b):

a. Adjuvant therapy post-nephrectomy;
b. Treatment of relapsed or stage IV RCC;

5. Dose does not exceed 50 mg/day - 4 weeks on/2 weeks off (or 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 pNET;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is unresectable or metastatic;
5. Dose does not exceed 37.5 mg/day (or 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. NCCN Compendium Indications (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a, b, c, or d):
   a. Chordoma;
   b. Soft tissue sarcoma: angiosarcoma, solitary fibrous tumor/hemangiopericytoma;
   c. Thymic carcinoma (second-line therapy as a single agent);
   d. Thyroid carcinoma: papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, medullary carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Documentation supports failure of or presence of clinically significant adverse effects or contraindication to at least two FDA approved medications for the relevant diagnosis (provided that such agent is commercially available):
   a. Thyroid carcinoma (i or ii):
      i. Papillary, follicular, or Hurthle cell carcinoma: lenvatinib or sorafenib;
      ii. Medullary carcinoma: vandetanib or cabozantinib;
4. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to the CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Sutent for one of the covered indications and has received this medication for at least 30 days;
2. Member is responding positively to therapy;

3. If receiving adjuvant therapy for RCC, member has not yet received nine 6-week cycles of therapy (one 6-week cycle consists of 4 weeks on/2 weeks off);
4. If request is for a dose increase, request meets one of the following (a, b, or c)**:**
   a. New dose for GIST or RCC does not exceed 50 mg/day 4 weeks on/2 weeks off (or 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. New dose for pNET does not exceed 37.5 mg/day (or 62.5mg per day if co-administered with a CYP3A4 inducer - e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort);
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 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 the CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
GIST: gastrointestinal stromal tumor
pNET: pancreatic neuroendocrine tumor
RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
imatinib mesylate (Gleevec®)	GIST 400 mg/day up to 400 mg BID	800 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: General Information

- Use of Sutent in chordoma, soft tissue sarcoma (angiosarcoma, and solitary fibrous tumor/hemangiopericytoma), thymic carcinoma, and refractory thyroid carcinoma

(papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma, and medullary carcinoma) are category 2A recommendations per NCCN compendium.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
GIST	50 mg/day PO - 4 weeks/2 weeks off OR 87.5 mg/day PO - 4 weeks on/2 weeks off if co-administered with a CYP3A4 inducer.	87.5 mg/day
RCC	50 mg/day PO - 4 weeks/2 weeks off OR 87.5 mg/day PO - 4 weeks on/2 weeks off if co-administered with a CYP3A4 inducer. *(Limited to nine 6-week cycles in the adjuvant setting.)*	87.5 mg/day
pNET	37.5 mg/day PO OR 62.5 mg/day PO if coadministered with a CYP3A4 inducer.	62.5 mg/day

VI. Product Availability

Capsules: 12.5 mg, 25 mg, 37.5 mg, 50 mg

VII. References

1. Sutent Prescribing Information. New York, NY: Pfizer Inc.; November 2017. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=607. Accessed December 7, 2017.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionlas/drug_compendium. Accessed December 07, 2017.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2017. Available at www.nccn.org. Accessed July 5, 2017.
4. National Comprehensive Cancer Network. Kidney Cancer Version 2.2018. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed December 07, 2017.
5. National Comprehensive Cancer Network. Neuroendocrine Tumors (Version 3.2017). Available at www.nccn.org. Accessed July 5, 2017.
6. Haas NB, Manola J, Uzzo RG, et al. Adjuvant sunitinib or sorafenib for high-risk, non-metastatic renal-cell carcinoma (ECOG-ACRIN E2805): a double-blind, placebo-controlled, randomized, phase 3 trial. Lancet 2016;387(10032):2008-2016.
7. Ravaud A, Motzer RJ, Pandha HS, et al. Adjuvant sunitinib in high-risk renal-cell carcinoma after nephrectomy. N Engl J Med 2016;375:2246-2254.

Reviews, Revisions, and Approvals	Date	P&T 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.	08.15	08.15

Reviews, Revisions, and Approvals	Date	P&T Approval Date
• 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.		
• 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
• 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
• Criteria added for new FDA indication: adjuvant RCC post-nephrectomy. • Policy converted to new template. • Added age restriction and prescriber specialty requirement to all indications. • Revised off-label indications: removed neuroendocrine tumors for lung (category III) and thymomas (NCCN guidelines specific thymic carcinoma only), added trial of FDA-approved drugs for thyroid carcinoma. • Appendices and references updated.	01.02.17	02.18

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.

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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.

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