

**Clinical Policy: Sunitinib (Sutent)**

Reference Number: CP.PHAR.73

Effective Date: 09.01.11

Last Review Date: 05.19

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

**Description**

Sunitinib (Sutent<sup>®</sup>) 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  18 years;
4. Disease progression on or intolerance to imatinib (Gleevec<sup>®</sup>);  
*\*Prior authorization may be required for imatinib.*
5. Request meets one of the following (a or b):
  - a. 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);
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:****Medicaid/HIM** - 6 months**Commercial** - Length of Benefit

**B. Renal Cell Carcinoma (must meet all):**

1. Diagnosis of RCC;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Sutent is requested for (a or b):
  - a. Adjuvant therapy post-nephrectomy;
  - b. Treatment of relapsed or stage IV RCC;
5. Request meets one of the following (a or b):
  - a. 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).
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid/HIM** - 6 months

**Commercial** - Length of Benefit

**C. Pancreatic Neuroendocrine Tumor (must meet all):**

1. Diagnosis of pNET;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Disease is unresectable or metastatic;
5. Request meets one of the following (a or b):
  - a. 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).
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid/HIM** - 6 months

**Commercial** - Length of Benefit

**D. NCCN Compendium Indications (off-label) (must meet all):**

1. Diagnosis of one of the following (a, b, c, d, or e):
  - a. Chordoma;
  - b. Soft tissue sarcoma: angiosarcoma, solitary fibrous tumor/hemangiopericytoma;
  - c. Thymic carcinoma (second-line therapy as a single agent);
  - d. Differentiated thyroid carcinoma (i.e., papillary carcinoma, follicular carcinoma, Hurthle cell carcinoma) and 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) (e.g., Lenvima<sup>®</sup>, Nexavar<sup>®</sup>);

*\*Prior authorization may be required for Lenvima and Nexavar.*

- e. Medullary thyroid carcinoma and 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) (e.g., Caprelsa<sup>®</sup> and Cometriq<sup>®</sup>);  
*\*Prior authorization may be required for Caprelsa and Cometriq.*
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration:**

**Medicaid/HIM** - 6 months

**Commercial** - Length of Benefit

**E. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**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 a covered indication 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:**

**Medicaid/HIM** - 6 months

**Commercial** - Length of Benefit

**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 off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

**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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid 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
Lenvima (lenvatinib)	Differentiated thyroid carcinoma 24 mg PO QD	24 mg/day
Nexavar (sorafenib)	Differentiated thyroid carcinoma 400 mg PO BID	800 mg/day
Caprelsa (vandetanib)	Medullary thyroid carcinoma 300 mg PO QD	300 mg/day
Cometriq (cabozantinib)	Medullary thyroid carcinoma 140 mg PO QD	140 mg/day

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

**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

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): None reported
- Boxed warning(s): Hepatotoxicity

**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.; December 2018. Available at: <http://labeling.pfizer.com/ShowLabeling.aspx?id=607>. Accessed February 8, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at [http://www.nccn.org/professionlas/drug\\_compendium](http://www.nccn.org/professionlas/drug_compendium). Accessed February 8, 2019.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2019. Available at [www.nccn.org](http://www.nccn.org). Accessed February 8, 2019.
4. National Comprehensive Cancer Network. Kidney Cancer Version 3.2019. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/kidney.pdf](https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf). Accessed February 8, 2019.
5. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 4.2018. Available at [www.nccn.org](http://www.nccn.org). Accessed February 8, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
Under pNET, “unresectable locally advanced” is edited to “unresectable” for clarity.	07.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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.		
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
2Q 2018 annual review: no significant changes; added HIM and Commercial lines of business; references reviewed and updated.	02.13.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.19.19	05.19

**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.

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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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