Clinical Policy: Sunitinib (Sutent)

Reference Number: PA.CP.PHAR.73
Effective Date: 01/18
Last Review Date: 04/19 Revision Log

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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Pennsylvania Health and Wellness ® 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. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease progression on or intolerance to imatinib mesylate;
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: 6 months

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

1. Diagnosis of renal cell carcinoma (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. 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: 6 months

C. Pancreatic Neuroendocrine Tumor (must meet all)**:**
1. Diagnosis of pancreatic neuroendocrine tumor (pNET);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 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: 6 months

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 cacinoma (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®, Nexavar®);
      **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® and Cometriq®);
      **Prior authorization may be required for Caprelsa and Cometriq.*
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 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: 6 months

E. Other diagnoses/indications

1. Refer to PA.CP.PMN.53.

II. Continued Approval

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

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
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: 6 months

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. 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	800 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	400 mg PO BID	
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® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

IV. 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

V. Product Availability

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

VI. 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. Accessed February 8, 2019.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2019. Available at 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. Accessed February 8, 2019.
5. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 4.2018. Available at www.nccn.org. Accessed February 8, 2019.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: no significant changes; added HIM and Commercial lines of business; references reviewed and updated.	02.13.18	04.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	04/2019	