Clinical Policy: Sunitinib (Sutent)

Reference Number: ERX.SPA.77
Effective Date: 03.01.14
Last Review Date: 05.20
Line of Business: Commercial, 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 (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 (Gleevec®);
   **Prior authorization may be required for imatinib*
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 50 mg per day - 4 weeks on/2 weeks off (or 87.5 mg per 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*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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. Request meets one of the following (a or b):*
   a. Dose does not exceed 50 mg per day - 4 weeks on/2 weeks off (or 87.5 mg per 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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. Request meets one of the following (a or b):*
   a. Dose does not exceed 37.5 mg per day (or 62.5 mg per 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 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 carcinomas (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*).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

E. Other diagnoses/indications
1. Refer to ERX.PA.01 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 a health plan affiliated with Envolve Pharmacy Solutions, 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. GIST or RCC: New dose does not exceed 50 mg per day - 4 weeks on/2 weeks off (or 87.5 mg per 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: New dose does not exceed 37.5 mg per day (or 62.5 mg per day if co-administered with a CYP3A4 inducer [e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentin, phenobarbital, St. John's Wort]);
   c. Any indication: New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 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 – ERX.PA.01 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 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): hepatotoxicity

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.; May 2019. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=607. Accessed February 15, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionlas/drug_compendium. Accessed February 15, 2020.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 6.2019. Available at www.nccn.org. Accessed February 15, 2020.
4. National Comprehensive Cancer Network. Kidney Cancer Version 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed February 15, 2020.
5. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 4.2018. Available at www.nccn.org. Accessed February 15, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy converted to new template. Removed all safety criteria. Added dosing criteria per PI. Modified approval duration to 3 months for initial and 6 months for re-auth. Added NCCN compendial uses that are approvable via global biopharm policy. RCC: clarified “advanced disease” as “relapsed or stage IV”. pNET: removed requirement for disease to be progressive.	08.16	09.16
Policy converted to new template. Age added. Under pNET, “unresectable locally advanced” is edited to “unresectable” for clarity. Under dosing, additional CYP inducer examples are added.	07.17	08.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Off-label coverage not addressed in the FDA labeled criteria sets is deleted – requests are directed to the off-label policy. References updated.		
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. Added NCCN off-label indications. Appendices and references updated. Approval durations modified to length of benefit.	01.02.17	02.18
2Q 2018 annual review: no significant changes; references reviewed.	02.13.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.19.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.15.20	05.20

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.