RXADVANCE
2 Park Central Drive
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Clinical Policy Title:	sunitinib
Policy Number:	RxA.486
Drug(s) Applied:	Sutent®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Sunitinib (Sutent®) is a kinase inhibitor.
It 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Sunitinib (Sutent®)	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

Dosage Forms

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

Clinical Policy

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

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/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, rifapentine, 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
Commercial: 6 months
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/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, rifapentine, 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
Commercial: 6 months
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/day (or 62.5 mg/day if co-administered with a CYP3A4 inducer - e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, 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
Commercial: 6 months
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. Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes (FLT3).
   c. Soft tissue sarcoma: angiosarcoma, solitary fibrous tumor/hemangiopericytoma, alveolar soft part sarcoma;
   d. Thymic carcinoma (second-line therapy as a single agent);
   e. Differentiated thyroid carcinoma (i.e., papillary carcinoma, follicular carcinoma, medullary 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®.*
   f. 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
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.;
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, rifapentine, phenobarbital, St. John's Wort);
   b. New dose for pNET does not exceed 37.5 mg/day (or 62.5mg per day if coadministered with a CYP3A4 inducer - e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, 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
Commercial: 12 months

Medicaid: 6 months

III Appendices

APPENDIX A: Abbreviation/Acronym Key

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

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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 once daily	24 mg/day
Nexavar®(sorafenib)	Differentiated thyroid carcinoma 400 mg PO BID	800 mg/day
Caprelsa®(vandetanib)	Medullary thyroid carcinoma 300 mg PO once daily	300 mg/day
Cometriq® (cabozantinib)	Medullary thyroid carcinoma 140 mg PO once daily	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

- Boxed warning(s):
  - Hepatotoxicity

APPENDIX D: General Information

- None

References

1. Sutent® Prescribing Information. New York, NY: Pfizer Inc.; August 2020. Available at: http://labeling.pfizer.com/ShowLabeling.aspx?id=607. Accessed August 15, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at http://www.nccn.org/professionlas/drug_compendium. Accessed August 15, 2020.
3. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma_blocks.pdf. Accessed August 15, 2020.

4. National Comprehensive Cancer Network. Kidney Cancer Version 1.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August 15, 2020.
5. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed August 15, 2020.
6. National Comprehensive Cancer Network. Myeloid/lymphoid Neoplasma with Eosinophilia and Tyrosine Kinase Fusion Genes Version 3.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed October 6, 2020.
7. National Comprehensive Cancer Network. Thymomas and Thymic carcinomas Version 1.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed October 6, 2020.
8. National Comprehensive Cancer Network. Thyroid carcinoma Version 2.2020. Available at https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed October 6, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Initial Approval Criteria updated: New indications (Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (FLT3), Alveolar Soft Part Sarcoma, Medullary Carcinoma) were added to section D as per NCCN Guidelines (off-label). 4. Commercial approval duration was updated for initial and Continued approval criteria. 5. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 6. APPENDIX B: Therapeutic Alternatives was rephrased to “Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements”. 7. Appendix D was added. 8. References were updated.	08/2020	12/07/2020