Clinical Policy Title:	sunitinib
Policy Number:	RxA.486
Drug(s) Applied:	Sutent®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

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 of age;
4. Disease progression on, contraindication or intolerance to imatinib (Gleevec®) as a single agent therapy;
5. Request meets one of the following (a, b or c):*
   a. Dose does not exceed 50 mg/day - 4 weeks on/2 weeks off;
   b. If co-administered with a CYP3A4 inducer - e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital, St. John's Wort): Dose does not exceed 87.5 mg/day - 4 weeks on/2 weeks off;
   c. 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: 12 months
Medicaid: 6 months

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

1. Diagnosis of advanced renal cell carcinoma (RCC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years of age;
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, b or c):*
   a. Dose does not exceed 50 mg/day - 4 weeks on/2 weeks off;
   b. If co-administered with a CYP3A4 inducer - e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital, St. John's Wort):): Dose does not exceed 87.5 mg/day - 4 weeks on/2 weeks off;
   c. 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: 12 months
Medicaid: 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 of age;
4. Disease is unresectable or metastatic;
5. Prescribed as a single agent;
6. Request meets one of the following (a, b or c):*
   a. Dose does not exceed 37.5 mg/day
   b. If co-administered with a CYP3A4 inducer - e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifapentine, phenobarbital, St. John's Wort): Dose does not exceed 62.5 mg/day;
   c. 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: 12 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. Single-agent therapy for the treatment of recurrent conventional or chondroid 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 (2) 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 (2) 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 of age;
4. 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: 12 months
Medicaid: 6 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. 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).
   *Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration
Commercial: 12 months
Medicaid: 6 months

References

1. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/sarcoma_blocks.pdf. Accessed April 28, 2023.
2. National Comprehensive Cancer Network. Kidney Cancer Version 4.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed April 28, 2023.
3. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 2.2022. Available at https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed April 28, 2023.
4. National Comprehensive Cancer Network. Myeloid/lymphoid Neoplasma with Eosinophilia and Tyrosine Kinase Fusion Genes Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed April 28, 2023.
5. National Comprehensive Cancer Network. Thymomas and Thymic carcinomas Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed April 28, 2023.
6. National Comprehensive Cancer Network. Thyroid carcinoma Version 1.2023. Available at https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed April 28, 2023.

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.	08/2020	12/07/2020

5. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 6. References were updated.		
Policy was reviewed: 1. Continued Therapy Criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance…”. 2. References were reviewed and updated.	9/4/2021	12/7/2021
Policy was reviewed: 1. Initial Approval Criteria I.A.5, I.B.5, I.C.6, I.D.4 and Continued Therapy Approval II.B.4: Updated to include Prescribed regimen must be FDA-approved or recommended by NCCN. 2. Initial Approval Criteria I.C.5:Updated to add prescribed as a single agent. 3. References were reviewed and updated.	04/06/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated contraindication/adverse event criteria from Disease progression on or intolerance to imatinib (Gleevec®) *Prior authorization may be required for imatinib to Disease progression on, contraindication or intolerance to imatinib (Gleevec®) as a single agent therapy. 2. Initial Approval Criteria, I.A, I.B, I.C and I.D: Updated approval duration criteria from 6 months to 12 months for Commercial. 3. Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of renal cell carcinoma (RCC) to Diagnosis of advanced renal cell carcinoma (RCC). 4. Continued Therapy Approval Criteria, II.A.3: Updated to remove prior adjuvant therapy criteria "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)." 5. References were reviewed and updated.	04/28/2023	07/13/2023

Policy was reviewed.	10/19/2023	10/19/2023