

<b>Clinical Policy Title:</b>	sunitinib
<b>Policy Number:</b>	RxA.486
<b>Drug(s) Applied:</b>	Sutent®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	08/28/2024
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Gastrointestinal Stromal Tumor (must meet all):

1. Diagnosis of gastrointestinal stromal tumor;
2. Disease progression on, contraindication or intolerance to imatinib (Gleevec®) as a single agent therapy.

#### Approval duration

**All Lines of Business (except Medicare):** 6 months

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

1. Diagnosis of advanced renal cell carcinoma (RCC);
2. Sutent® is requested for (a or b):
  - a. Adjuvant therapy post-nephrectomy;
  - b. Treatment of relapsed or stage IV RCC.

#### Approval duration

**All Lines of Business (except Medicare):** 6 months

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

1. Diagnosis of pancreatic neuroendocrine tumor;
2. Disease is unresectable or metastatic;
3. Prescribed as a single agent.

#### Approval duration

**All Lines of Business (except Medicare):** 6 months

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

1. Diagnosis of one of the following (a, b, c, d, e, or f):
  - 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®);

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

\*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®.

**Approval duration**

**All Lines of Business (except Medicare):** 6 months

**II. Continued Therapy Approval**

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

- 1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

**Approval duration**

**All Lines of Business (except Medicare):** 12 months

**References**

1. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2024. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/sarcoma\\_blocks.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sarcoma_blocks.pdf). Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Kidney Cancer Version 1.2025. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/kidney.pdf](https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf). Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Neuroendocrine Tumors Version 2.2024. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/neuroendocrine.pdf](https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf). Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Myeloid/lymphoid Neoplasma with Eosinophilia and Tyrosine Kinase Fusion Genes Version 2.2024. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/mlne.pdf](https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf). Accessed August 28, 2024.
5. National Comprehensive Cancer Network. Thymomas and Thymic carcinomas Version 1.2024. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/thymic.pdf](https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf). Accessed August 28, 2024.
6. National Comprehensive Cancer Network. Thyroid carcinoma Version 1.2024. Available at [https://www.nccn.org/professionals/physician\\_gls/pdf/thyroid.pdf](https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf). Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> <li>1. Policy title table was updated.</li> <li>2. Line of Business Policy Applies to was update to all lines of business.</li> <li>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).</li> <li>4. Commercial approval duration was updated for initial and Continued approval criteria.</li> <li>5. Continued therapy criteria II.A.1 was rephrased to “Currently receiving</li> </ol>	08/2020	12/07/2020

<p>medication that has been authorized by RxAdvance...".</p> <p>6. References were updated.</p>		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>References were reviewed and updated.</li> </ol>	9/4/2021	12/7/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>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.</li> <li>Initial Approval Criteria I.C.5: Updated to add prescribed as a single agent.</li> <li>References were reviewed and updated.</li> </ol>	04/06/2022	07/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>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.</li> <li>Initial Approval Criteria, I.A, I.B, I.C and I.D: Updated approval duration criteria from 6 months to 12 months for Commercial.</li> <li>Initial Approval Criteria, I.B.1: Updated diagnostic criteria from Diagnosis of renal cell carcinoma (RCC) to Diagnosis of advanced renal cell carcinoma (RCC).</li> <li>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)."</li> <li>References were reviewed and updated.</li> </ol>	04/28/2023	07/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>Removed age restrictions.</li> </ol>	8/28/2024	9/13/2024

<ol style="list-style-type: none"><li>2. Removed prescriber restrictions.</li><li>3. Removed dose restrictions.</li><li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li><li>5. Removed reauthorization requirement for positive response to therapy.</li><li>6. Updated approval duration verbiage.</li><li>7. References were reviewed and updated.</li></ol>		
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