Reference number(s)
2022-A

Specialty Guideline Management sunitinib-Sutent

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sutent	sunitinib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1,2]

Gastrointestinal Stromal Tumor (GIST)

Sutent is indicated for the treatment of adult patients with GIST after disease progression on or intolerance to imatinib mesylate.

Advanced Renal Cell Carcinoma (RCC)

Sutent is indicated for the treatment of adult patients with advanced RCC.

Adjuvant Treatment of Renal Cell Carcinoma (RCC)

Sutent is indicated for the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.

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Advanced Pancreatic Neuroendocrine Tumors (pNET)

Sutent is indicated for the treatment of progressive, well-differentiated pNET in adult patients with unresectable locally advanced or metastatic disease.

Compendial Uses[3-4]

- Relapsed or stage IV RCC
- Gastrointestinal stromal tumors
- Pancreatic neuroendocrine tumors (pNET)
- Soft tissue sarcoma
- Pheochromocytoma/Paraganglioma
- Thymic carcinomas
- Medullary, papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma
- Recurrent chordoma
- Dedifferentiated chondrosarcoma
- Myeloid/lymphoid or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming KIT and PDGFRA mutation, where applicable.
- Documentation of laboratory report confirming FLT3 rearrangement, where applicable.

Coverage Criteria

Renal Cell Carcinoma (RCC)[1-3]

- Authorization of 12 months may be granted for treatment of relapsed, advanced, or stage IV RCC as a single agent.
- Authorization of up to 54 weeks total may be granted for adjuvant treatment of members who are at high risk of recurrent renal cell carcinoma following nephrectomy.

Gastrointestinal Stromal Tumor (GIST)[1-3]

Authorization of 12 months may be granted for treatment of GIST when any of the following criteria are met:

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- The requested medication will be used as a single agent for treatment of residual, unresectable, tumor rupture, or recurrent/metastatic imatinib-sensitive KIT and PDGFRA mutant-postitve (except PDGFRA exon 18 mutation positive) disease after failure of imatinib due to disease progression or intolerable adverse effects.
- The requested medication will be used in combination with everolimus for treatment of residual, unresectable, tumor rupture, or recurrent/metastatic imatinib-sensitive KIT and PDGFRA mutant-postitve (except PDGFRA exon 18 mutation positive) disease after progression and when the member has failed at least four FDA-approved therapies (e.g., imatinib, avapritinib, regorafenib, ripretinib).
- The requested medication will be used as a single agent for treatment of residual, unresectable, tumor rupture, or recurrent/metastatic succinate dehydrogenase (SDH)-deficient GIST.
- The requested medication will be used as a single agent for neoadjuvant therapy to decrease surgical morbidity of SDH-deficient GIST.

Pancreatic Neuroendocrine Tumor[1-3]

Authorization of 12 months may be granted for treatment of pancreatic neuroendocrine tumors.

Soft Tissue Sarcoma[3]

Authorization of 12 months may be granted for treatment of the following subtypes of soft tissue sarcoma as a single agent: alveolar soft part sarcoma (ASPS), angiosarcoma, solitary fibrous tumor, or extraskeletal myxoid chondrosarcoma.

Pheochromocytoma/Paraganglioma[3]

Authorization of 12 months may be granted for treatment of locally unresectable or metastatic pheochromocytoma or paraganglioma as a single agent.

Thymic Carcinoma[3]

Authorization of 12 months may be granted for treatment of thymic carcinoma as a single agent when the member has failed or cannot tolerate first-line combination or subsequent chemotherapy regimen.

Papillary, Oncocytic/Hürthle Cell, or Follicular Thyroid Carcinoma[3]

Authorization of 12 months may be granted for treatment of papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma as a single agent when both of the following criteria are met:

- The disease is locoregional, unresectable, progressive and/or symptomatic, or metastatic.
- Radioactive iodine (RAI) therapy is not indicated, is contraindicated, or has been unsuccessful.

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Medullary Thyroid Carcinoma[3,4]

Authorization of 12 months may be granted for treatment of recurrent or metastatic medullary thyroid carcinoma as a single agent when either of the following criteria are met:

- Member has disease progression while on FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]).
- Member has a contraindication or intolerance to FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]).

Chordoma[3]

Authorization of 12 months may be granted for treatment of recurrent conventional chordoma, including chondroid, as a single-agent.

Chondrosarcoma[3]

Authorization of 12 months may be granted for treatment of dedifferentiated chondrosarcoma as a single agent or in combination with nivolumab.

Myeloid/Lymphoid Neoplasms with Eosinophilia[3]

Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and FLT3 rearrangement in the chronic phase or blast phase.

Continuation of Therapy

GIST[1-3]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of GIST when there is no evidence of unacceptable toxicity while on the current regimen.

RCC[1-3]

Authorization of 12 months may be granted for treatment of relapsed, advanced, or stage IV RCC when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Authorization of up to 54 weeks (up to nine 6-week cycles) total may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of RCC when both of the following criteria are met:

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- Disease is not recurrent.
- Member has not exceeded a maximum of nine 6-week cycles.

All Other Indications

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for all other indications in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Sutent [package insert]. New York, NY: Pfizer Labs; October 2025.
2. Sunitinib malate [package insert]. Parsippany, NJ: Teva Pharmaceuticals; January 2025.
3. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 21, 2026.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 1.2026. Available at: https://www.nccn.org. Accessed May 8, 2026.

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