

sunitinib malate (SUTENT)

Diagnoses Considered for Coverage:

- Advanced renal cell carcinoma (RCC)- treatment or adjuvant use (prevention of recurrence) following surgery
- Advanced thyroid gland carcinoma
- Chordoma
- Gastrointestinal stromal tumor (GIST)
- Myeloid, lymphoid, or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement
- Pheochromocytoma/Paraganglioma
- Progressive pancreatic neuroendocrine tumor (PNET)
- Soft Tissue Sarcoma
 - Angiosarcoma
 - Solitary fibrous tumor
 - Aveolar soft part sarcoma
- Thymic carcinoma

Coverage Criteria:

1. For covered diagnoses, approve if:

- Meets clinical requirements below:

Diagnosis	Coverage criteria
Renal cell carcinoma (RCC)	<ul style="list-style-type: none"> • Dose does not exceed 50 mg per day for four weeks per 6-week cycle, and • Being used as a single agent, and • One of the following: <ul style="list-style-type: none"> • Patient has relapsed or metastatic disease (stage IV), or • Being used as adjuvant therapy (prevention of recurrence) for patients at high risk of recurrence after kidney surgery
GI stromal tumor (GIST)	<p>For single agent use:</p> <ul style="list-style-type: none"> • Disease progression with imatinib (Gleevec), or • Patient is succinate dehydrogenase (SDH)-deficient <p>For use in combination with everolimus:</p>

		<ul style="list-style-type: none"> • Dose does not exceed 50 mg per day for four weeks per 6-week cycle, and • Being used as subsequent therapy after disease progression with all the following: <ul style="list-style-type: none"> ○ imatinib (Gleevec) ○ Sutent (sunitinib) ○ Stivarga (regorafenib) • Qinlock (ripretinib)
	Progressive pancreatic neuroendocrine tumor (PNET)	<ul style="list-style-type: none"> • Disease is non-resectable, is partially resectable or is not a candidate for surgery OR Disease progression to other areas of body (metastatic), and • Being used as a single agent, and • Dose does not exceed 50 mg per day.
	Medullary thyroid gland carcinoma	<ul style="list-style-type: none"> • Being used as a single agent, and • Dose does not exceed 50 mg per day, and • Meets one of the following (a or b): <ul style="list-style-type: none"> a. Inadequate response, intolerable side effect, or contraindication to Caprelsa (vandetanib) or Cometriq (cabozantinib), or b. For RET mutation positive disease inadequate response, intolerable side effect or contraindication to Retevmo (selpercatinib) or Gavreto (pralsetinib).
	Advanced differentiated (follicular, Hurthle cell, and papillary) thyroid cancer	<ul style="list-style-type: none"> • Being used as a single agent, and • Inadequate response, intolerable side effect, or contraindication to Lenvima (lenvatinib) or Nexavar (sorafenib), and • Dose does not exceed 50 mg per day.
	Chordoma	<ul style="list-style-type: none"> • Being used for recurrent disease, and • Being used as a single agent, and • Dose does not exceed 37.5 mg per day.
	Solitary fibrous tumor	<ul style="list-style-type: none"> • Being used as a single agent, and • Dose does not exceed 37.5 mg per day.
	Angiosarcoma	
	Aveolar soft part sarcoma	
	Thymic carcinoma	<ul style="list-style-type: none"> • Being used as second-line therapy, and

		<ul style="list-style-type: none"> Dose does not exceed 50 mg per day for four weeks per 6-week cycle.
	Pheochromocytoma/ Paraganglioma	<ul style="list-style-type: none"> Disease is locally advanced, unresectable, or metastatic, and Being used as a single agent, and Dose does not exceed 37.5 mg per day.
	Myeloid, lymphoid, or mixed lineage neoplasms	<ul style="list-style-type: none"> Patient has eosinophilia, and Patient has FMS-like tyrosine kinase 3 (FLT3) rearrangement, and Dose does not exceed 50 mg per day.

Coverage Duration: one year

References:

1. Prescribing Information. Sutent. Pfizer US Pharmaceuticals Corporation. 2020
2. National Comprehensive Cancer Network. Bone Cancer (Version: 1.2024). http://www.nccn.org/professionals/physician_gls/pdf/bone.pdf.
3. National Comprehensive Cancer Network. Gastrointestinal Stromal Tumors (GIST) (Version: 1.2023 March 13, 2023). https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf.
4. National Comprehensive Cancer Network. Kidney Cancer (Version: 1.2024 June 21, 2023). https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
5. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes (Version: 1.2024 December 21, 2023). https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf.
6. National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors (Version: 1.2023 August 2, 2023). https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf.
7. National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version: 3.2023 December 12, 2023). https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.
8. National Comprehensive Cancer Network. Thymomas and Thymic Carcinomas (Version: 1.2024 November 21, 2023). https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf. Accessed March 10, 2022.
9. National Comprehensive Cancer Network. Thyroid Carcinoma (Version: 4.2023). https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf. Accessed August 16, 2023.

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