sunitinib (Sutent®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO154

Description

Sunitinib (Sutent) is an orally administered tyrosine kinase inhibitor targeting multiple receptors.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
sunitinib malate (generic Sutent)	12.5 mg capsule	Gastrointestinal stromal tumor Renal cell carcinoma, adjuvant following nephrectomy	28 capsules/42 days for all indications except neuroendocrine pancreatic tumor
	25 mg capsule		
	37.5 mg capsule	Renal cell carcinoma, advanced Neuroendocrine pancreatic tumor	28 capsules/28 days for pancreatic neuroendocrine tumor
	50 mg capsule		
sunitinib (Sutent)	12.5 mg capsule	Gastrointestinal stromal tumor Renal cell carcinoma, adjuvant following nephrectomy	28 capsules/42 days for all indications except neuroendocrine pancreatic tumor
	25 mg capsule		
	37.5 mg capsule	Renal cell carcinoma, advanced Neuroendocrine pancreatic tumor	28 capsules/28 days for pancreatic neuroendocrine tumor
	50 mg capsule		

Initial Evaluation

I. **Sunitinib (Sutent)** may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Medication is prescribed by, or in consultation with, an oncologist; **AND**
   C. Sunitinib (Sutent) will be used as monotherapy; **AND**
   D. The request is for generic sunitinib malate; **OR**
      1. The request is for brand Sutent and treatment with generic sunitinib malate is contraindicated or not tolerated; **AND**
   E. A diagnosis of one of the following:
      1. **Gastrointestinal stromal tumor (GIST)**; **AND**

i. Treatment with generic imatinib or brand imatinib (Gleevec) has been ineffective, contraindicated, or not tolerated; **OR**

2. **Pancreatic neuroendocrine tumor (pNET)**; **AND**
   i. The member has unresectable, locally advanced (stage III), or metastatic (stage IV) disease; **OR**
3. **Renal cell carcinoma (RCC); AND**
   i. Disease is advanced (stage III) or metastatic (stage IV)

II. Sunitinib (Sutent) is considered not medically necessary when criteria above are not met and/or when used for:
   A. Adjuvant treatment for renal cell carcinoma

III. Sunitinib (Sutent) is considered investigational when used for all other conditions, including but not limited to:
   A. Angiosarcoma
   B. Breast cancer
   C. Colorectal cancer
   D. Central nervous system cancers
   E. Neuroendocrine tumors other than those of pancreatic origin
   F. Gastric cancer
   G. Lung cancer
   H. Soft tissue sarcoma
   I. Thyroid carcinoma
   J. Osteosarcoma
   K. Cholangiocarcinoma
   L. Adenoid cystic carcinoma

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
III. The request is for generic sunitinib malate; **OR**
   A. The request is for brand Sutent and treatment with generic sunitinib malate is contraindicated or not tolerated; **AND**

IV. Sunitinib (Sutent) will be used as monotherapy; **AND**
V. Disease response to treatment defined by stabilization of disease or decrease in tumor size or tumor spread

Supporting Evidence

I. Sunitinib (Sutent) was evaluated for gastrointestinal stromal tumor (GIST) in a randomized, double-blind, placebo-controlled trial in adults that had previously progressed on imatinib (Gleevec) or were intolerant to therapy. Outcomes included time-to-tumor progression (TTP), progression-free survival (PFS), and objective response rate (ORR) and were statistically significant in favor of sunitinib (Sutent). At the time of disease progression, treatment was unblinded and those originally on placebo were allowed to crossover to open-label sunitinib (Sutent). At the final analysis overall survival (OS) was not statistically different between the treatment arms.
II. A second study of sunitinib (Sutent) for GIST was conducted as an open-label, single-arm trial in adults that had previously progressed on, or had intolerance to, imatinib (Gleevec). Five of the 55 subjects included had a partial response to therapy (9.1%, CI 3-20%).
III. For renal cell carcinoma (RCC), sunitinib (Sutent) was evaluated in a randomized trial versus IFN-a in treatment-naïve RCC. The outcomes evaluated were PFS and ORR, both of which were statistically significant in favor of sunitinib (Sutent).
IV. In the adjuvant treatment setting for RCC, sunitinib (Sutent) was evaluated in a randomized, double-blind, placebo-controlled trial adults with high risk of recurrence following nephrectomy. Subjects were required to have clear cell histology. Subjects were treated for nine cycles maximum. The primary outcome was disease-free survival (DFS) which was statistically significant in favor of sunitinib (Sutent). Overall survival was a secondary endpoint; however, data was not mature at time of analysis and the medication is associated with a significant safety profile.
V. For pancreatic neuroendocrine tumors (pNET), sunitinib (Sutent) was evaluated in a randomized, double-blind, placebo-controlled trial in adults with unresectable disease. The Independent Data Monitoring Committee was terminated early which may have led to an overestimate of the PFS. The outcomes of PFS and ORR were statistically significant in favor of sunitinib (Sutent); however, OS data was not mature at time of analysis. In a follow up analysis at five years a statistical significant different in OS was not demonstrated; however, this may have been confounded by crossover.
VI. Sunitinib has not been evaluated for safety and/or efficacy in pediatric patients. The dosing for sunitinib (Sutent) outside of pancreatic neuroendocrine tumors, is four weeks on two weeks off. A maximum of nine 6-week cycles of therapy for adjuvant RCC has been evaluated and FDA-approved for adjuvant RCC. This is approximately 13 months of therapy total.

Investigational or Not Medically Necessary Uses

I. Adjuvant treatment for renal cell carcinoma
   A. Following one year of treatment with sunitinib (Sutent), patients experienced a 1-year improvement in disease free survival compared to placebo; however, there was no improvement in overall survival. Sunitinib (Sutent) is associated with significant toxicity and patients experienced a decline in quality of life while on treatment compared to placebo. NCCN has listed adjuvant sunitinib (Sutent) as a Category 3 recommendation, as there is still no clear role for adjuvant systemic therapy in this setting. Observation or clinical trials are still considered the standard of care given the lack of clinically meaningful supportive data for systemic therapy in the adjuvant setting.

II. Sunitinib (Sutent) has not been sufficiently studied for safety or efficacy and/or is currently being evaluated in clinical trials for the following indications:
   A. Angiosarcoma
   B. Breast cancer
   C. Colorectal cancer
   D. Central nervous system cancers
   E. Neuroendocrine tumors other than those of pancreatic origin
   F. Gastric cancer
   G. Lung cancer
   H. Soft tissue sarcoma
   I. Thyroid carcinoma
   J. Osteosarcoma
   K. Cholangiocarcinoma
   L. Adenoid cystic carcinoma

References

1. Sutent [Prescribing Information]. New York, NY. Pfizer Labs. May 2019.
2. Demetri GD, Van oosterom AT, Garrett CR, et al. Efficacy and safety of sunitinib in patients with advanced gastrointestinal stromal tumour after failure of imatinib: a randomised controlled trial. Lancet. 2006;368(9544):1329-38.
3. Motzer RJ, Hutson TE, Tomczak P, et al. Sunitinib versus interferon alfa in metastatic renal-cell carcinoma. N Engl J Med. 2007;356(2):115-24.
4. Ravaud A, Motzer RJ, Pandha HS, et al. Adjuvant Sunitinib in High-Risk Renal-Cell Carcinoma after Nephrectomy. N Engl J Med. 2016;375(23):2246-2254.
5. Raymond E, Dahan L, Raoul JL, et al. Sunitinib malate for the treatment of pancreatic neuroendocrine tumors. N Engl J Med. 2011;364(6):501-13.
6. Faivre S, Niccoli P, Castellano D, et al. Sunitinib in pancreatic neuroendocrine tumors: updated progression-free survival and final overall survival from a phase III randomized study. Ann Oncol. 2017;28(2):339-343.

Policy Implementation/Update:

Action and Summary of Changes	Date
Addition of trial and failure of generic sunitinib prior to use of branded Sutent. Addition of monotherapy requirements evaluated upon renewal. Updated initial approval duration from three months to six months.	09/2021
Prior authorization criteria transitioned to policy format. Addition of age edit, monotherapy requirements, and clarification of renal cell carcinoma uses.	11/2019
Review of adjuvant RCC setting	01/2018
Policy created	03/2012