Cigna National Formulary Coverage Policy

Drug Quantity Management – Per RX
Oncology – Sutent® (sunitinib malate capsules, generic)

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Product Identifier(s)

Effective 1/1/23 to 4/11/23: 110264

Effective 4/12/23: 21055

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage potential dose escalation and provide a sufficient quantity of sunitinib (Sutent, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration.

Drug Quantity Limits

Product	Strength and Form	Maximum Quantity per Rx
Sutent®	12.5 mg capsules	30 capsules
	25 mg capsules	30 capsules
(sunitinib capsules, generic)	37.5 mg capsules	30 capsules
	50 mg capsules	30 capsules

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Sunitinib (Sutent, generic) 12.5 mg capsules

1. If the individual is taking a dose that does not correspond to a commercially-available dosage form (that is, the dose requires multiple same strength tablets be used AND would otherwise require two or more strengths to be used), approve the requested quantity, not to exceed a total of 210 capsules per dispensing.
   Note: This is a quantity sufficient to provide a dose of up to 87.5 mg (12.5 mg x 7 capsules).

Sunitinib (Sutent, generic) 25 mg capsules

1. If the individual is taking a concomitant strong cytochrome P450(CYP) 3A4 inducer AND has end-stage renal disease on hemodialysis, approve up to 210 capsules per dispensing.
   Note: This quantity allows for the highest recommended dose for use with strong CYP3A4 inducer in an individual with renal impairment (175 mg). Examples of strong CYP3A4 inducers are apalutamide, carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, and St. John's wort.

Sunitinib (Sutent, generic) 37.5 mg capsules

No overrides recommended.

Sunitinib (Sutent, generic) 50 mg capsules

1. If the individual has end-stage renal disease on hemodialysis and needs to increase the daily dose to 100 mg daily, approve 60 capsules per dispensing.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Sunitinib (Sutent, generic), a multi-kinase inhibitor, is indicated in adults for the following uses:[1]

- **Gastrointestinal stromal tumor**, after disease progression on or intolerance to imatinib mesylate tablets.
- **Pancreatic neuroendocrine tumors**, that is progressive and well-differentiated in patients with unresectable locally advanced or metastatic disease.
- **Renal cell carcinoma,** advanced, and for the adjuvant treatment of adult patients at high risk of recurrent renal cell carcinoma following nephrectomy.

In addition to the cancers for which sunitinib is approved, it is also discussed in several guidelines from the National Comprehensive Cancer Network (NCCN) [bone cancer, central nervous system cancers, myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes, soft tissue sarcoma, thymomas and thymic carcinomas, and thyroid cancer].[2-11]

Dosing

For the treatment of gastrointestinal stromal tumor and advanced renal cell carcinoma the recommended dose is 50 mg orally once daily (QD) for 4 weeks of treatment, followed by 2 weeks off (4/2 schedule) until unacceptable toxicity or disease progression.[1] The recommended dose for the adjuvant treatment of renal cell carcinoma is 50 mg QD on a schedule of 4 weeks of treatment followed by 2 weeks off (4/2 schedule), for nine 6-week cycles. The recommended dose for treatment of progressive, well-differentiated pancreatic neuroendocrine tumors is 37.5 mg orally QD continuously without a scheduled off-treatment period until unacceptable toxicity or disease progression.

For bone cancer and soft tissue sarcoma, sunitinib has been used at a dose of 37.5 mg QD.[3,14-15] For central nervous system cancers, myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase fusion genes, and thymomas/thymic carcinomas, sunitinib has been used at a dose of 50 mg QD.[4,12,16] In thyroid cancer, sunitinib has been used at a dose of 37.5 mg or 50 mg QD.[17,18]

Dose modifications are recommended to manage adverse events (AEs) as outlined in Table 1.

Table 1. Dose Reduction Recommendations for Sunitinib.[1]

Indication	GIST	RCC		pNET
First dose reduction	37.5 mg QD	37.5 mg QD	37.5 mg QD	25 mg QD
Second dose reduction	25 mg QD	25 mg QD	NA	NA

GIST – Gastrointestinal stromal tumor; RCC – Renal cell carcinoma; pNET – Pancreatic neuroendocrine tumor; QD – Once daily; NA – Not applicable.

Strong cytochrome P450(CYP)3A4 inhibitors may increase sunitinib plasma concentrations.[1] If concomitant use cannot be avoided, a dose reduction for sunitinib to a minimum dose as follows is recommended:

- Gastrointestinal stromal tumor and renal cell carcinoma: 37.5 mg QD on a 4/2 schedule.
- Pancreatic neuroendocrine tumors: 25 mg QD.

Strong CYP3A4 inducers may decrease sunitinib plasma concentrations.[1] If concomitant use cannot be avoided, a dose increase for sunitinib to a maximum dosage as follows is recommended:

- Gastrointestinal stromal tumor and renal cell carcinoma: 87.5 mg QD on a 4/2 schedule.
- Pancreatic cancer: 62.5 mg QD.

For patients with end-stage renal disease on hemodialysis, no dose adjustment is required for the starting dose. However, due to decreases exposure, subsequent doses may be increased gradually up to 2-fold based on safety and tolerability.

Availability
Sunitinib (Sutent, generic) is available as 12.5 mg, 25 mg, 37.5 mg, and 50 mg capsules in bottles of 28 capsules.[1]

References

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Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Sunitinib (generic to Sutent) was added to the policy. Approval duration was changed to 1 year, previously 3 years. **Sunitinib 25 mg capsules**: Override criteria were added to approve up to 210 capsules per dispensing for patients taking a concomitant cytochrome P450(CYP) 3A inducer AND with end-stage renal disease on hemodialysis. Previously, the 25 mg capsules had no overrides.	05/25/2022