DRUG QUANTITY MANAGEMENT POLICY – PER RX

POLICY: Oncology –Sunitinib Drug Quantity Management Policy – Per Rx
- Sutent® (sunitinib malate capsules – Pfizer, generic)

REVIEW DATE: 05/02/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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.

CIGNA NATIONAL FORMULARY COVERAGE:

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 tumor**, 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 (bone cancer, central nervous system cancers, myeloid/lymphoid neoplasms with eosinophilia and

tyrosine kinase fusion genes, neuroendocrine tumors, 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.

Off-Label Dosing

For bone cancer, soft tissue sarcoma, and neuroendocrine tumors sunitinib has been used at a dose of 37.5 mg QD.[3,8,12,13] 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.[4,14,15] In thyroid cancer, sunitinib has been used at a dose of 37.5 mg or 50 mg QD.[16,17]

Dose Modifications

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]

POLICY STATEMENT

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	Retail Maximum Quantity per Rx	Home Delivery Maximum Quantity per Rx
Sutent® (sunitinib capsules, generic)	12.5 mg capsules	90 capsules	270 capsules
	25 mg capsules	30 capsules	90 capsules
	37.5 mg capsules	30 capsules	90 capsules
	50 mg capsules	30 capsules	90 capsules

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Sunitinib (Sutent, generic) 12.5 mg capsules

1. If the patient 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 210 capsules per dispensing at retail or 630 capsules per dispensing at home delivery.
Note: This is a quantity sufficient to provide a daily dose of up to 87.5 mg (12.5 mg x 7 capsules).

Sunitinib (Sutent, generic) 25 mg capsules

1. If the patient is taking a concomitant strong cytochrome P450(CYP) 3A4 inducer AND has end-stage renal disease on hemodialysis, approve the requested quantity, not to exceed 210 capsules per dispensing at retail or 630 capsules per dispensing at home delivery.
Note: This quantity allows for the highest recommended daily dose for use with strong CYP3A4 inducer in a patient 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 patient has end-stage renal disease on hemodialysis and needs to increase the daily dose to 100 mg daily, approve 60 capsules per dispensing at retail or 180 capsules per dispensing at home delivery.

REFERENCES

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Policy was updated to reflect the existing quantity limits when a product is obtained via home delivery. No changes to criteria.	05/25/2023
Annual Revision	No criteria changes.	05/29/2024
Annual Revision	No criteria changes.	05/02/2025