DRUG QUANTITY MANAGEMENT POLICY - ONCOLOGY PER RX

POLICY: Sutent® (sunitinib capsules – Pfizer) Dispensing Limit

DATE REVIEWED: 05/13/2020

DESCRIPTION

Sutent 12.5 mg, 25 mg, 37.5 mg, and 50 mg capsules Maximum quantity per RX = 30 capsules

Sutent is available in 12.5 mg, 25 mg, 37.5 mg, and 50 mg capsules. The recommended dose for treatment of gastrointestinal stromal tumor (GIST) or advanced renal cell carcinoma (RCC) is one 50 mg oral dose taken once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off (Schedule 4/2). The recommended dose for treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) is 37.5 mg taken orally once daily continuously without a scheduled off-treatment period.1 Literature supports dosing up to 50 mg per day for off-label uses.[2-6]

Dose interruption and/or dose modification in 12.5 mg increments or decrements is recommended based on individual safety and tolerability. The maximum dose administered in the Phase III pNET study was 50 mg daily.

Strong CYP3A4 inhibitors such as ketoconazole may increase sunitinib plasma concentrations. Selection of an alternate concomitant medication with no or minimal enzyme inhibition potential is recommended. A dose reduction for Sutent to a minimum of 37.5 mg (GIST and RCC) or 25 mg (pNET) daily should be considered if Sutent must be co-administered with a strong CYP3A4 inhibitor.

Strong CYP3A4 inducers such as rifampin may decrease sunitinib plasma concentrations. Concurrent administration of Sutent with the strong CYP3A4 inducer, rifampin, resulted in a 46% reduction in the combined (sunitinib + primary active metabolite) area under the curve (AUC) in healthy volunteers. Selection of an alternate concomitant medication with no or minimal enzyme induction potential is recommended. A dose increase for Sutent to a maximum of 87.5 mg (GIST and RCC) or 62.5 mg (pNET) daily should be considered if Sutent must be co-administered with a CYP3A4 inducer. If dose is increased, the patient should be monitored carefully for toxicity.

For patients with End-Stage Renal Disease (ESRD) on hemodialysis, doses may be increased gradually up to 2-fold based on safety and tolerability given decreased exposure compared to patients with normal renal function.

The objective of this program is to manage potential dose escalation and to provide a sufficient quantity for indications covered by the Oncology - Sutent Prior Authorization Policy.[6]

CRITERIA

All approvals are provided for 3 years in duration unless otherwise noted below.

Sutent 12.5 mg capsules

1. Exceptions can be made when a 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 quantity requested, not to exceed a total of 210 capsules per dispensing.

Sutent 50 mg capsules

1. Exceptions can be made for patients with End-Stage Renal Disease (ESRD) on hemodialysis who need to increase the daily dose to 100 mg daily. A quantity of 60 capsules per dispensing may be approved.

Sutent 25 mg and37.5 mgcapsules

No overrides recommended.

REFERENCES

1. Sutent [prescribing information]. New York: Pfizer; May 2019.
2. Ravaud A, de la Fouchardiere C, et al. Efficacy in Advanced Medullary Thyroid Carcinoma: Intermediate Results of Phase II THYSU, *Oncologist.* 2010; 15(2):212-213.
3. George S, Merriam P, et al. Multicenter Phase II Trial of Sunitinib in the Treatment of Nongastrointestinal Stromal Tumor Sarcomas. *J Clin Oncol.* 2009*;* 27(19):3154-3160.
4. Stacchiotti s, Negri T, et al. Sunitinib malate and figitumumab in solitary fibrous tumor: patterns and molecular bases of tumor response. *Mol Cancer Ther.* 2010; 9(5): 1286-1297.
5. Stacchiotti S, Tamborini E, et al. Response to Sunitinib Malate in Advanced Alveolar Soft Part Sarcoma. Clin Cancer Res. 2009; 15:1096-1104.
6. Oncology -Sutent Prior Authorization policy.