

Specialty Pharmacy Program

Sutent[®] (sunitinib)

DESCRIPTION

Sutent is an oral multiple tyrosine kinase inhibitor indicated for the treatment of renal cell carcinoma and for the treatment of gastrointestinal stromal tumor after disease progression or intolerance to prior Gleevec (imatinib) therapy.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. The treatment of gastrointestinal stromal tumor (GIST) after disease progression on imatinib mesylate.
2. The treatment of GIST after intolerance to imatinib mesylate.
3. The treatment of advanced renal cell carcinoma.

Off-Label Indication(s)

Requests for off-label use of Sutent will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS[®] Drug Information, Thomson Micromedex[®], National Comprehensive Cancer Network Drugs and Biologics Compendium[™], and Clinical Pharmacology.