PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 1/01/2016
LAST REVIEW DATE: 2/18/2021
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SUTENT® (sunitinib) oral capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

SUTENT® (sunitinib) oral capsule

Criteria:

- **Criteria for initial therapy:** Sutent (sunitinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Nephrologist, or Gastroenterologist depending upon indication or use

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     a. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib

     b. Advanced Renal Cell Carcinoma (RCC)

     c. Adjuvant treatment following nephrectomy in a patient at high risk of recurrent RCC

     d. Pancreatic neuroendocrine tumor (pNET) that is progressive, well-differentiated unresectable locally advanced or distant metastatic disease

     e. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Sutent (sunitinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist, Nephrologist, or Gastroenterologist depending upon indication or use
  2. The cancer has not worsened while on therapy

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use, such as:
     a. Cardiovascular events like heart failure, cardiomyopathy, myocardial infarction etc.
     b. QTc prolongation and torsades de pointes
     c. Severe hypertension
     d. Hemorrhage like epistaxis, GI hemorrhage, hymoptysis pulmonary hemorrhage etc.
     e. Hepatotoxicity or impairment (Child-Pugh Class C) or pancreatitis
     f. Tumor lysis syndrome
     g. Thrombotic microangiopathy
     h. Proteinuria or nephrotic syndrome

SUTENT® (sunitinib) oral capsule

i. Dermatologic toxicities like Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme or necrotizing fasciitis
j. GI complications like GI perforation or pancreatitis
k. Symptomatic hypoglycemia
l. Osteonecrosis of the jaw

5. There are no significant interacting drugs

Renewal duration: 6 months

Description:

Sutent (sunitinib) is a kinase inhibitor that is indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib; advanced renal cell carcinoma (RCC); the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy; and progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease.

Sunitinib is an inhibitor of multiple receptor tyrosine kinases (RTK), some of which are implicated in tumor growth, pathologic angiogenesis, and metastatic progression of cancer. It inhibits platelet-derived growth factor receptors (PDGFRα and PDGFRβ), vascular endothelial growth factor receptors (VEGFR1, VEGFR2 and VEGFR3), stem cell factor receptor (KIT), Fms-like tyrosine kinase-3 (FLT3), colony stimulating factor receptor type 1 (CSF-1R), and the glial cell-line derived neurotrophic factor receptor (RET). Sunitinib inhibition of the activity of these RTK and inhibition of function has been demonstrated in cell proliferation assays. It has demonstrated inhibition of tumor growth or tumor regression and/or inhibited metastases in some experimental models of cancer. Sunitinib demonstrated the ability to inhibit growth of tumor cells expressing dysregulated target RTKs (PDGFR, RET, or KIT) *in vitro* and to inhibit PDGFRβ- and VEGFR2-dependent tumor angiogenesis *in vivo*.

Resources:

Sutent (sunitinib) product information, revised by Pfizer Laboratories Div Pfizer, Inc. 08-2020, at DailyMed http://dailymed.nlm.nih.gov. Accessed January 31, 2021.

Sutent (sunitinib). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: http://www.nccn.org. Accessed January 31, 2021.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.