BlueCross BlueShield of Arizona
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| **PHARMACY COVERAGE GUIDELINES** | **ORIGINAL EFFECTIVE DATE: 1/01/16** |
| **SECTION: DRUGS** | **LAST REVIEW DATE: 3/15/18** |
| | **LAST CRITERIA REVISION DATE: 3/15/18** |
| | **ARCHIVE DATE:** |

# SUTENT® (sunitinib malate) 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 malate) oral capsule (cont.)

**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*.

# Sutent (sunitinib)

**Medication class:**
Tyrosine kinase inhibitor, vascular endothelial growth factor (VEGF) inhibitor

**FDA-approved indication(s):**
- Treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib
- Treatment of advanced renal cell carcinoma (RCC)
- The adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.
- Treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) in patients with unresectable locally advanced or metastatic disease

**Recommended Dose:**
Dosage:
- GIST: 50 mg orally once daily, 4 weeks on treatment followed by 2 weeks off
- RCC: 50 mg orally once daily, 4 weeks on treatment followed by 2 weeks off
- Adjuvant RCC: 50 mg orally once daily, with or without food, 4 weeks on treatment followed by 2 weeks off for nine 6-week cycles.
- pNET: 37.5 mg orally once daily, continuously without a scheduled off-treatment period

***Maximum dosage***
- GIST and RCC: 87.5 mg once daily when used with CYP3A4 inducers
- pNET: 50 mg once daily, 62.5 mg once daily when used with CYP3A4 inducers

**Available Dosage Forms:**
- 12.5 mg, 25 mg, 37.5 mg, 50 mg capsules

**Warnings and Precautions:**

## SUTENT® (sunitinib malate) oral capsule (cont.)

- Sutent has not been studied in patients with severe hepatic impairment (Child-Pugh Class C)
- Avoid use with CYP3A4 inducers that decrease Sutent levels, consider an increase in dose of Sutent if unavoidable
- Avoid use with CYP3A4 inhibitors that increase Sutent levels, consider a decrease in dose of Sutent if unavoidable
- Woman of child bearing potential should use effective contraception
- Woman breast feeding an infant or child should stop breast feeding
- Hepatotoxicity or impairment (Child-Pugh Class C) or pancreatitis
  - Some sign & symptoms may include: yellow eyes, or skin, itching, dark urine, right sided abdominal pain, confusion
- Congestive heart failure, MI
  - Some sign & symptoms may include: edema, shortness of breath, weight gain, chest pain, shortness of breath
- Hemorrhage or significant bleeding
  - Some sign & symptoms may include rectal bleeding, bleeding gums, GI bleed, blood in urine, blood in stools, nose bleeds
- Nephrotic syndrome or moderate to severe proteinuria
  - Some signs & symptom may include: repeat episodes of 24-hour protein $\geq$ 3g protein
- Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme or necrotizing fasciitis
  - Some sign & symptoms may include progressive skin rash, blistering, oral ulcers

**Criteria:**

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

  1. Provider is an Oncologist

  2. Individual is 18 years of age or older

  3. A confirmed diagnosis of **ONE** of the following:
     - Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib
     - Advanced Renal Cell Carcinoma (RCC)
     - Adjuvant treatment of patients at high risk of recurrent RCC following nephrectomy
     - Pancreatic neuroendocrine tumor (pNET) that is progressive, well-differentiated unresectable locally advanced or metastatic disease

  **Initial approval duration:** 6 months

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

  1. Continues to be seen by an Oncologist

## SUTENT® (sunitinib malate) oral capsule (cont.)

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:
   - Cardiovascular events like heart failure, cardiomyopathy, myocardial infarction etc.
   - QTc prolongation and torsades de pointes
   - Severe hypertension
   - Hemorrhage like epistaxis, GI hemorrhage, hymoptysis pulmonary hemorrhage etc.
   - Hepatotoxicity or impairment (Child-Pugh Class C) or pancreatitis
   - Tumor lysis syndrome
   - Thrombotic microangiopathy
   - Proteinuria or nephrotic syndrome
   - Dermatologic toxicities like Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme or necrotizing fasciitis
   - GI complications like GI perforation or pancreatitis
   - Symptomatic hypoglycemia
   - Osteonecrosis of the jaw

5. There are no significant interacting drugs

**Renewal duration:** 6 months

**Resources:**

Sutent. Package Insert. Revised by manufacturer 11/20117. Accessed 02-23-2018.

Sutent. Package Insert. Revised by manufacturer 4/2015. Accessed 08-04-2015, 08-28-2017

NCCN Clinical Practice Guidelines in Oncology: Kidney cancer. Version 2.2017, Oct 31, 2016. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf

NCCN Clinical Practice Guidelines in Oncology: Soft tissue sarcoma. Version 2.2017, Feb 8, 2017. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf

NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine tumors. Version 3.2017, June 13, 2017. https://www.nccn.org/professionals/physician_gls/PDF/neuroendocrine.pdf

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.

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**Fax completed prior authorization request form to 602-864-3126** or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

# Pharmacy Prior Authorization Request Form

**Do not copy for future use. Forms are updated frequently.**
**REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.**

## Member Information

| Member Name (first & last): | Date of Birth: | Gender: | BCBSAZ ID#: |
|---|---|---|---|
| Address: | City: | State: | Zip Code: |

## Prescribing Provider Information

| Provider Name (first & last): | Specialty: | NPI#: | DEA#: |
|---|---|---|---|
| Office Address: | City: | State: | Zip Code: |
| Office Contact: | Office Phone: | Office Fax: | |

## Dispensing Pharmacy Information

| Pharmacy Name: | Pharmacy Phone: | Pharmacy Fax: |
|---|---|---|

## Requested Medication Information

| Medication Name: | Strength: | Dosage Form: |
|---|---|---|
| Directions for Use: | Quantity: / Refills: | Duration of Therapy/Use: |

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

## Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

## Clinical Information

1. **What is the diagnosis? Please specify below.**

   **ICD-10 Code:** _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

| Medication Name, Strength, Frequency | Dates started and stopped or Approximate Duration | Describe response, reason for failure, or allergy |
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5. **Are there any supporting labs or test results? Please specify below.**

| Date | Test | Value |
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# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature: Date:

**Please note**: Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.