PHARMACY COVERAGE GUIDELINES	
SECTION: DRUGS	
ORIGINAL EFFECTIVE DATE:	**1/01/2016**
LAST REVIEW DATE:	**2/17/2022**
LAST CRITERIA REVISION DATE:	**2/17/2022**
ARCHIVE DATE:	

Sunitinib oral
SUTENT® (sunitinib) oral

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.**

Sunitinib oral
SUTENT® (sunitinib) oral

Criteria:

- **Criteria for initial therapy:** Sutent (sunitinib) or generic 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 in patient at high risk of recurrent RCC following nephrectomy

    d. Progressive, well-differentiated Pancreatic neuroendocrine tumor (pNET) with 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

4. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
    a. Liver function tests
    b. Left ventricular ejection fraction (LVEF)
    c. Electrocardiogram (EKG)
    d. Blood pressure
    e. Thyroid function tests
    f. A routine oral examination performed by a medical provider or dentist and individuals with risk factors for ONJ (see Definition section) should receive appropriate preventive dentistry prior to initiation of sunitinib
    g. Negative pregnancy test in a woman of childbearing potential
    h. Eastern Cooperative Oncology Group (ECOG) Performance Status of 0-2

5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

6. There are no significant interacting drugs

Initial approval duration: 6 months

Sunitinib oral
SUTENT® (sunitinib) oral

- **Criteria for continuation of coverage (renewal request):** Sutent (sunitinib) or generic 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. Individual's condition has responded while on therapy
     a. Response is defined as:
        i. Documented evidence of efficacy, disease stability and/or improvement
        ii. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

  3. Individual has been adherent with the medication

  4. Individual has not developed any significant adverse drug effects that may exclude continued use
     a. Significant adverse effect such as:
        i. Life-threatening or severe hepatotoxicity that does not resolve after dose modification
        ii. Clinical manifestations of congestive heart failure
        iii. Life-threatening hypertension
        iv. Life-threatening or severe hemorrhage that does not resolve after dose modification
        v. Thrombotic microangiopathy
        vi. Nephrotic syndrome or recurrent episodes of 24-hour protein of 3 or more grams despite dose modification
        vii. Dermatologic toxicities such as Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme or necrotizing fasciitis
        viii. Reversible posterior leukoencephalopathy syndrome (RPLS)
        ix. Osteonecrosis of the jaw

  5. Individual does not have severe hepatic impairment (Child-Pugh Class C)

  6. There are no significant interacting drugs

  Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

  1. **Off-Label Use of Non-cancer Medications**

  2. **Off-Label Use of Cancer Medications**

Sunitinib oral
SUTENT® (sunitinib) oral

Description:

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*.

Definitions:

Osteonecrosis of the jaw (ONJ):
According to the American College of Rheumatology, ONJ can be diagnosed by the presence of exposed bone on oral examination that has lasted more than eight weeks.

ONJ risk factors include:
- Invasive dental procedures (e.g. tooth extraction, dental implants, oral surgery)
- Poor oral hygiene
- A diagnosis of cancer
- Co-morbid disorders (e.g. periodontal and/or other pre-existing dental disease, anemia, coagulopathy, infection, ill-fitting dentures)
- Use of concomitant therapies (e.g. angiogenesis inhibitors, bisphosphonates, chemotherapy, corticosteroids, denosumab, radiotherapy)

Resources:

Sutent (sunitinib) product information, revised by Pfizer Laboratories Div Pfizer, Inc. 08-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 10, 2021.

Sunitinib product information, revised by Sun Pharmaceutical Industries, Inc. 09-2021. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed December 10, 2021.

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National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Gastrointestinal Stromal Tumors (GISTs) Version 1.2021 – Updated October 30, 2020. Available at https://www.nccn.org. Accessed December 10, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer Version 3.2022 – Updated November 04,021. Available at https://www.nccn.org. Accessed December 09, 2021.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Neuroendocrine and Adrenal Tumors Version 3.2021 – Updated August 13, 2021. Available at https://www.nccn.org. Accessed December 10, 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.