PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Oncology – Sunitinib Preferred Specialty Management Policy
- Sutent® (sunitinib malate capsules – Pfizer, generic)

REVIEW DATE: 01/22/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Sunitinib, a kinase inhibitor, is indicated in adults for the following uses:[1]
- **Gastrointestinal stromal tumor (GIST)**, after disease progression on or intolerance to imatinib mesylate.
- **Pancreatic neuroendocrine tumors**, that is progressive and well-differentiated in patients with unresectable locally advanced or metastatic disease.
- **Renal cell carcinoma,** advanced.
- **Renal cell carcinoma,** adjuvant treatment of patients at high risk of recurrent renal cell carcinoma following nephrectomy.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of the Preferred Product. For all medications (Preferred and Non-Preferred), the patient is required to meet the standard *Oncology – Sunitinib Prior Authorization Policy* criteria. The program also directs the patient to try the Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below).

If the patient meets the standard *Oncology – Sunitinib Prior Authorization Policy* criteria but has not tried a Preferred Product, approval for a Preferred Product will be authorized. All approvals are provided for 1 year.

Documentation: Documentation is required for use of Sutent as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to chart notes, prescription claims records, prescription receipts, and/or other information.

Preferred Products: generic sunitinib capsules
Non-Preferred Products: Sutent

Oncology – Sunitinib Preferred Specialty Management Policy non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.

NON-PREFERRED PRODUCT EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Sutent	**1.** Approve for 1 year if the patient meets ALL of the following (A, B, and C): **A)** Patient meets the standard *Oncology – Sunitinib Prior Authorization Policy* criteria; AND **B)** Patient has tried generic sunitinib capsules **[documentation required]**; AND **C)** Patient cannot take sunitinib due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the brand and bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction **[documentation required]**. **2.** If the patient has met the standard *Oncology – Sunitinib Prior Authorization Policy* criteria (1A), but has not met exception criteria (1B) and/or (1C) above for brand Sutent: approve generic sunitinib capsules.

REFERENCES

1. Sutent® capsules [prescribing information]. New York, NY: Pfizer; August 2021.

HISTORY

Type of Revision	Summary of Changes	Review Date

Annual Revision	No criteria changes.	01/17/2024
Annual Revision	No criteria changes.	01/22/2025