



CIGNA PHARMACY COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

Effective Date 5/15/2011
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Coverage Policy Number 6111

Subject **Sunitinib (Sutent®)**

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), 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 supercedes** 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. 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. Proprietary information of CIGNA. Copyright ©2011 CIGNA

Coverage Policy

CIGNA covers sunitinib (Sutent®) as medically necessary for treatment of ANY of the following:

- advanced renal cell carcinoma (RCC)
- angiosarcoma
- gastrointestinal stromal tumor (GIST) when there is failure or intolerance to imatinib (Gleevec®)
- hemangiopericytoma
- islet cell tumors
- thyroid carcinoma

FDA Approved Indications

Sutent is indicated for the treatment of GIST after disease progression on or intolerance to imatinib mesylate. Sutent is indicated for the treatment of advanced RCC.

FDA Recommended Dosing

The recommended dose of Sutent for GIST and RCC is one 50 mg oral dose taken once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off.

Drug Availability

12.5 mg capsules - hard gelatin capsule with orange cap and orange body, printed with white ink "Pfizer" on the cap, "STN 12.5 mg" on the body; available in bottles of 28. 25 mg capsules - hard gelatin capsule with caramel cap and orange body, printed with white ink "Pfizer" on the cap, "STN 25 mg" on the body; available in bottles of 28. 50 mg capsules - hard gelatin capsule with caramel cap and caramel body, printed with white ink "Pfizer" on the cap, "STN 50 mg" on the body available in bottles of 28.

General Background

Pharmacology

Sunitinib is the second multiple tyrosine kinase inhibitor labeled for the treatment of gastrointestinal stromal tumor (GIST) and for metastatic renal cell carcinoma (MRCC). Sunitinib is recommended as a second-line agent in treating GIST that is resistant to the other tyrosine kinase inhibitor, imatinib (Gleevec). Both forms of cancer have few treatment options and limited effect with traditional chemotherapy or cytokine-based therapy.

Sunitinib inhibits several receptor tyrosine kinases that are involved in tumor growth, angiogenesis and metastatic progression. Sunitinib inhibits phosphorylation of platelet-derived growth factor receptor (PDGFR), vascular endothelial growth factor receptor (VEGFR), and stem cell factor receptor (KIT) resulting in tumor regression, slowed growth or inhibited metastases in cancer models. Sunitinib is orally absorbed 90% protein-bound in plasma. Both sunitinib and its active metabolite are substrates of cytochrome P450 enzyme 3A4 (CYP3A4). Approximately 61% of a sunitinib dose is eliminated in feces and another 16% in urine. Sunitinib's terminal half-life is 40 to 60 hours, and its active metabolite's half-life is 80 to 110 hours.

Guidelines

That National Comprehensive Cancer Network (NCCN) recommends sunitinib as follows:

Angiosarcoma

Grade 2A

May be useful as a single agent for angiosarcoma.

Gastrointestinal Stromal Tumor (GIST)

Grade 2A

Treatment for patients with life-threatening side effects on imatinib therapy who have documented GIST that is marginally resectable; resectable with risk of significant morbidity; unresectable; recurrent; metastatic disease. Treatment for unresectable or metastatic disease following failure of imatinib.

Hemangiopericytoma

Grade 2A

Single-agent therapy for the treatment of solitary fibrous tumor and hemangiopericytoma

Pancreatic Endocrine Tumors (Islet Cell Tumors)

Grade 2A

Management of unresectable locoregional disease and/or distant metastatic disease in patients with symptoms, clinically significant tumor burden, or clinically significant progression

Renal Cell Carcinoma (RCC)

Grade 1

First-line therapy as a single agent for relapsed or medically unresectable stage IV disease. Subsequent therapy as a single agent for relapsed or medically unresectable stage IV disease with predominant clear cell histology in patients who have progressed on prior first-line therapy.

Thyroid Carcinoma

Grade 2A

Follicular carcinoma

Consider for treatment of clinically progressive or symptomatic metastatic disease in patients with nonradioiodine-responsive tumors at sites other than central nervous system

Hürthle cell carcinoma

Consider for treatment of clinically progressive or symptomatic metastatic disease in patients with nonradioiodine-responsive tumors at sites other than central nervous system

Medullary carcinoma

Consider for treatment of disseminated symptomatic disease

Papillary carcinoma

Consider for treatment of clinically progressive or symptomatic metastatic disease in patients with nonradioiodine-responsive tumors at sites other than central nervous system

Adverse Reactions

The most common adverse reactions are fatigue, asthenia, diarrhea, nausea, mucositis/stomatitis, vomiting, dyspepsia, abdominal pain, constipation, hypertension, rash, hand-foot syndrome, skin discoloration, altered taste, anorexia, and bleeding.

Both sunitinib and its primary active metabolite are substrates of CYP3A4 only. Potent inhibitors of CYP3A4 may substantially increase concentrations of both molecules. Potent CYP3A4 inducers decrease sunitinib concentrations. Patients should avoid grapefruit and St. John's Wort.

Coding/Billing Information

Note: This section is not in use.

References

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12. Wilhelm SM, Carter C, Tang L, et al. BAY 43-9006 exhibits broad spectrum oral antitumor activity and targets the RAF/MEK/ERK pathway and receptor tyrosine kinases involved in tumor progression and angiogenesis. Cancer Res. Oct 1 2004;64(19):7099-7109.

Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	6111	Sunitinib (Sutent [®])
Great-West Healthcare	8/2007	P06.109	Sutent

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