EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Sutent® (sunitinib malate capsules – Pfizer)

TAC APPROVAL DATE: 05/08/2019

OVERVIEW

Sutent, a multi-kinase inhibitor, is indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib mesylate (Gleevec® tablets, generics); for the treatment of advanced renal cell carcinoma (RCC); for the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy; and for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (PNET) in patients with unresectable locally advanced or metastatic disease.[1]

Guidelines

Sutent features prominently in the National Comprehensive Cancer Network (NCCN) guidelines for soft tissue sarcomas, kidney cancer, neuroendocrine and adrenal tumors and others.

The NCCN soft tissue sarcoma guidelines (version 2.2019 – February 4, 2019) recommend Sutent in patients with GIST for the treatment of progressive disease (category 1).[2] It is also recommended for patients with imatinib-resistant tumors or imatinib intolerance. Sutent is also recommended for angiosarcoma, solitary fibrous tumor/hemeangiopericytoma, and alveolar soft part sarcoma.

The NCCN clinical practice guidelines on kidney cancer (version 4.2019 – April 25, 2019)[3] recommend Sutent as single-agent therapy for relapse or surgically unresectable Stage IV disease as preferred first-line therapy for clear cell histology (category 2A), as subsequent therapy for clear cell histology (category 2A), or as preferred systemic therapy for non-clear cell histology (category 2A). Sutent is also recommended as as adjuvant therapy following nephrectomy in high-risk patients (i.e., tumor stage 3 or higher, regional lymph node metastasis, or both) with predominant clear cell histology (category 2B); and for use in combination with gemcitabine for relapse or surgically unresectable Stage IV disease with predominant sarcomatoid features as subsequent therapy for clear cell histology and as systemic therapy for non-clear cell histology.

The NCCN neuroendocrine and adrenal tumors guidelines (version 1.2019 – March 5, 2019)[4] recommend Sutent as a single agent for disease progression of unresectable locoregional advanced disease and/or distant metastatic disease in patients with PNETs (category 1 for progressive disease).

The NCCN bone cancer guidelines (version 2.2019 – April 10, 2019) recommend single-agent Sutent for patients with recurrent chordoma.[5]

The NCCN thyroid carcinoma guidelines (version 1.2019 – March 28, 2019) state that in patients with medullary thyroid carcinoma, Sutent can be considered for treatment of progressive disease or symptomatic distant metastases if clinical trials, Caprelsa, or Cometriq are not available or appropriate, or if there is progression on Caprelsa or Cometriq.[6] Sutent can be considered for differentiated thyroid carcinoma if clinical trials or other systemic therapies are not available or appropriate for the treatment of progressive and/or symptomatic iodine refractory thyroid cancer that is unresectable recurrent or persistent locoregional

disease or that is distant metastatic disease.[9] This recommendation is for follicular, Hürthle cell, and papillary cancer subtypes (all category 2A).

The NCCN central nervous system cancers guidelines (version 1.2019 – March 5, 2019) recommend single-agent Sutent therapy as treatment for surgically inaccessible recurrent or progressive meningiomas when further radiation is not possible (category 2B).[7]

The NCCN thymomas and thymic carcinomas guidelines (version 2.2019 – March 11, 2019) recommend single-agent Sutent as second-line therapy for thymic carcinomas (category 2A).[8]

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Sutent. All approvals are provided for 3 years in duration.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sutent is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Gastrointestinal Stromal Tumor (GIST).** Approve for 3 years if the patient has tried imatinib (Gleevec tablets, generics).

2. **Renal Cell Carcinoma (RCC) –Clear Cell or Non-Clear Cell Histology.** Approve for 3 years if the patient meets ONE of the following criteria (A or B):
   - **A)** The patient is at high risk of recurrent clear cell RCC following nephrectomy and Sutent is used for adjuvant therapy; OR
   - **B)** The patient has relapsed or Stage IV disease.

3. **Neuroendocrine Tumors of the Pancreas.** Approve for 3 years for advanced or metastatic disease.

Other Uses with Supportive Evidence

4. **Alveolar Soft Part Sarcoma (ASPS).** Approve for 3 years.

5. **Angiosarcoma.** Approve for 3 years.

6. **Chordoma.** Approve for 3 years in patients with recurrent disease.

7. **Differentiated (i.e., papillary, follicular, and Hürthle cell) Thyroid Carcinoma.** Approve for 3 years if refractory to radioactive iodine therapy.

8. **Medullary Thyroid Carcinoma.** Approve for 3 years if the patient has tried Caprelsa® (vandetanib tablets) or Cometriq® (cabozantinib capsules).

9. **Meningioma.** Approve for 3 years if the patient has recurrent or progressive disease.

10. Solitary Fibrous Tumor/Hemangiopericytoma. Approve for 3 years.

11. Thymic Carcinoma. Approve for 3 years if the patient has tried chemotherapy (e.g., carboplatin/paclitaxel) or radiation therapy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Sutent has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Sutent® capsules [prescribing information]. New York, NY: Pfizer; November 2017.
2. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 2.2019 – February 4, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.
3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (Version 3.2018 – February 26, 2018). © 2018 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.
4. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (Version 1.2019 – March 5, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.
5. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (Version 2.2019 – April 10, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.
6. The NCCN Thyroid Cancer Clinical Practice Guidelines in Oncology (Version 1.2019 – March 28, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.
7. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (Version 1.2019 – March 5, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.
8. The NCCN Thymomas and Thymic Carcinomas Clinical Practice Guidelines in Oncology (Version 2.2019 – March 11, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on May 7, 2019.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	Renal Cell Carcinoma: Criterion were revised to add that it includes predominant clear-cell histology and non-clear cell histology. Differentiated Thyroid Carcinoma: Criteria were revised to only require that the patient's disease is refractory to radioactive iodine therapy. Medullary Thyroid Carcinoma: Criteria were revised to remove the requirement for the patient has progressive disease or symptomatic Meningioma: Criteria were added. Conditions not Recommended for Approval: Cervical Carcinoma, Chronic Lymphocytic Leukemia, Lymphoma, Myelofibrosis, and Nasopharyngeal Carcinoma were removed.	02/10/2016
Annual revision	No criteria changes.	03/08/2017
Selected revision	Renal Cell Carcinoma: Added criteria for approval in patients post-nephrectomy for adjuvant Sutent therapy based on FDA-approved new indication.	12/06/2017
Annual revision	Gastrointestinal Stromal Tumor: Added criteria for combination of Sutent with Afinitor.	04/11/2018

HISTORY (CONTINUED)

Type of Revision	Summary of Changes*	TAC Approval Date
Annual revision	• Gastrointestinal Stromal Tumors (GIST): Deleted Sutent "is used as a single agent". Deleted criteria for combination therapy with Afinitor since this is covered in the Afinitor PA policy. • Renal Cell Carcinoma: Deleted "advanced" as qualifier; instead added criteria patient has relapsed or Stage IV disease as per guidelines. Deleted"predominant" in reference to clear cell histology in line with guidelines. • Neuroendocrine Tumors of the Pancrease: Added "of the Pancreas" to condition description. Deleted "Advanced or Unresectable". Instead added "advanced or metastatic disease" in criteria. • Deleted all of the 17 conditions listed under "Conditions not Recommended for Approval".	05/08/2019

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx.