Reference number
2022-A

SPECIALTY GUIDELINE MANAGEMENT

SUTENT (sunitinib)
sunitinib

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Gastrointestinal Stromal Tumor (GIST)
   Sutent is indicated for the treatment of adult patients with gastrointestinal stromal tumor after disease progression on or intolerance to imatinib mesylate.
2. Advanced Renal Cell Carcinoma (RCC)
   Sutent is indicated for the treatment of adult patients with advanced renal cell carcinoma.
3. Adjuvant Treatment of Renal Cell Carcinoma (RCC)
   Sutent is indicated for the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.
4. Advanced Pancreatic Neuroendocrine Tumors (pNET)
   Sutent is indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors in adult patients with unresectable locally advanced or metastatic disease.

B. Compendial Uses
1. Relapsed or stage IV RCC
2. Soft tissue sarcoma subtypes:
   a. Angiosarcoma
   b. Solitary fibrous tumor
   c. Alveolar soft part sarcoma
   d. Extraskeletal myxoid chondrosarcoma
3. Gastrointestinal stromal tumors
4. Thymic carcinomas
5. Differentiated thyroid carcinoma (papillary, oncocytic/Hürthle cell, or follicular)
6. Medullary thyroid carcinoma
7. Meningioma
8. Recurrent chordoma
9. Lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in chronic or blast phase
10. Pheochromocytoma/Paraganglioma

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Testing or analysis confirming FLT3 rearrangement (if applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma

1. Authorization of 12 months may be granted for treatment of relapsed, advanced, or stage IV renal cell carcinoma as a single agent.

2. Authorization of up to 54 weeks total may be granted for adjuvant treatment of members who are at high risk of recurrent renal cell carcinoma following nephrectomy.

B. Soft Tissue Sarcoma

Authorization of 12 months may be granted for treatment of the following subtypes of soft tissue sarcoma as single-agent therapy: alveolar soft-part sarcoma (ASPS), angiosarcoma, solitary fibrous tumor or extraskeletal myxoid chondrosarcoma.

C. Gastrointestinal Stromal Tumor (GIST)

Authorization of 12 months may be granted for treatment of gastrointestinal stromal tumor when any of the following criteria are met:

1. The requested medication will be used for treatment of residual, unresectable, tumor rupture or recurrent/metastatic GIST after failure of imatinib due to disease progression or intolerable side effects as a single agent.
2. The requested medication will be used for treatment of residual, unresectable, recurrent, or metastatic/tumor rupture GIST in combination with everolimus for disease progression after the member has failed at least four FDA-approved therapies (e.g., imatinib, avapritinib, regorafenib and ripretinib).
3. The requested medication will be used for treatment of residual, unresectable, tumor rupture or recurrent/metastatic succinate dehydrogenase (SDH)-deficient GIST as a single agent.
4. The requested medication will be used for neoadjuvant therapy as a single agent to decrease surgical morbidity of SDH-deficient GIST.

D. Pancreatic Neuroendocrine Tumor

Authorization of 12 months may be granted for treatment of pancreatic neuroendocrine tumors.

E. Pheochromocytoma/Paraganglioma

Authorization of 12 months may be granted for treatment of locally unresectable or metastatic pheochromocytoma or paraganglioma as a single agent.

F. Thymic Carcinoma

Authorization of 12 months may be granted for treatment of thymic carcinoma with failure or intolerance of one previous chemotherapy regimen as a single agent.

G. Papillary, Oncocytic/Hürthle cell, or Follicular Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of progressive and/or symptomatic papillary, oncocytic/Hürthle cell, or follicular thyroid carcinoma not amenable to radioactive iodine (RAI) therapy.

H. Medullary Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of recurrent or metastatic medullary thyroid carcinoma when either of the following criteria are met:

1. Member has a contraindication or intolerance to FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]); OR
2. Member has disease progression while on FDA approved systemic therapy options (e.g., vandetanib [Caprelsa], cabozantinib [Cometriq]).

I. Meningioma
Authorization of 12 months may be granted for treatment of surgically inaccessible recurrent or progressive meningioma for which radiation is not possible.

J. Chordoma
Authorization of 12 months may be granted for treatment of recurrent chordoma as single-agent therapy.

K. Myeloid/Lymphoid Neoplasms with Eosinophilia
Authorization of 12 months may be granted for treatment of myeloid and/or lymphoid neoplasms with eosinophilia and FLT3 rearrangement in the chronic phase or blast phase.

IV. CONTINUATION OF THERAPY

A. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen for the specified indications below:
   1. Relapsed, advanced, or stage IV renal cell carcinoma
   2. Soft tissue sarcoma
   3. Pancreatic neuroendocrine tumor
   4. Thymic carcinoma
   5. Papillary, Oncocytic/Hürthle cell, or Follicular thyroid carcinoma
   6. Medullary thyroid carcinoma
   7. Meningioma
   8. Chordoma
   9. Myeloid and/or lymphoid neoplasms with eosinophilia
   10. Pheochromocytoma/Paraganglioma

B. Authorization of up to 54 weeks total may be granted for continued treatment in members requesting reauthorization for adjuvant treatment of renal cell carcinoma when the following criteria are met:
   1. Disease is not recurrent; AND
   2. Member has not exceeded a maximum of nine 6 week cycles.

C. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for treatment of GIST when there is no evidence of unacceptable toxicity while on the current regimen.

V. REFERENCES

1. Sutent [package insert]. New York, NY: Pfizer Labs.; August 2021.
2. Sunitinib [package insert]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; September 2021.
3. The NCCN Drugs & Biologics Compendium 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 2, 2024.
4. Kaley TJ, Web P, Schiff D, et al. Phase II Trial of Sunitinib for Recurrent and Progressive Atypical and Anaplastic Meningioma. *Neuro Oncol.* 2015:17(1):116-21.

5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Thyroid Carcinoma. Version 2.2024. Accessed May 2, 2024.