Reference number
2022-A

SPECIALTY GUIDELINE MANAGEMENT

SUTENT (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 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 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 patients with unresectable locally advanced or metastatic disease.

B. Compendial Uses
1. Relapsed or stage IV RCC
2. Soft tissue sarcoma subtypes:
   a. Angiosarcoma; as single-agent therapy
   b. Solitary fibrous tumor; as single-agent therapy
   c. Alveolar soft part sarcoma; as single-agent therapy
3. Gastrointestinal stromal tumors
   a. Primary treatment for patients with life-threatening side effects on imatinib therapy who have documented GIST that is resectable with risk of significant morbidity, unresectable, recurrent, or metastatic, or continue for limited progression.
   b. Preferred second-line treatment for unresectable or metastatic disease with limited or generalized (widespread, systemic) progression on primary treatment with imatinib.
   c. Fourth-line therapy in combination with everolimus for unresectable or metastatic disease progressive after single-agent therapy with imatinib, sunitinib, and regorafenib.
   d. Consider as adjuvant treatment for patients who have life-threatening side effects on imatinib therapy following complete resection of primary GIST with no preoperative imatinib for patients with significant risk of recurrence, or with persistent microscopic residual disease (R1 resection) or gross residual disease (R2 resection).
4. Thymic carcinomas, second-line therapy as a single agent
5. Differentiated thyroid carcinoma (papillary, Hürthle cell, or follicular), progressive and/or symptomatic iodine-refractory
6. Medullary thyroid carcinoma
   a. Clinical trials, vandetanib, or cabozantinib are not available or appropriate
   b. Disease progression on vandetanib or cabozantinib

7. Meningioma; surgically inaccessible recurrent or progressive disease for which radiation is not possible
8. Recurrent chordoma; as single-agent therapy
9. Myeloid/lymphoid neoplasms with eosinophilia and FLT3 rearrangement in chronic phase
10. Lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and FLT3 rearrangement in blast phase

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, angiosarcoma, or solitary fibrous tumor.

C. Gastrointestinal Stromal Tumor (GIST)

1. Authorization of 12 months may be granted for treatment of gastrointestinal stromal tumor after failure of imatinib due to progression or intolerable side effects.

2. Authorization of 12 months may be granted for treatment of gastrointestinal stromal tumor in combination with everolimus for disease progression after single-agent therapy with imatinib, sunitinib, and regorafenib.

D. Pancreatic Neuroendocrine Tumor

Authorization of 12 months may be granted for treatment of pancreatic neuroendocrine tumors as a single agent.

E. Thymic Carcinoma

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

F. Papillary, Hürthle cell, or Follicular Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of progressive and/or symptomatic radioiodine refractory papillary, Hürthle cell, or follicular thyroid carcinoma.

G. Medullary Thyroid Carcinoma

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

1. Member has a contraindication or intolerance to vandetanib (Caprelsa) AND cabozantinib (Cometriq); OR
2. Disease progression occurred while on vandetanib (Caprelsa) OR cabozantinib (Cometriq)

H. Meningioma

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

I. Chordoma

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

J. 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. Gastrointestinal stromal tumor
   4. Pancreatic neuroendocrine tumor
   5. Thymic carcinoma
   6. Papillary, Hürthle cell, or Follicular thyroid carcinoma
   7. Medullary thyroid carcinoma
   8. Meningioma
   9. Chordoma
   10. Myeloid and/or lymphoid neoplasms with eosinophilia

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.

V. REFERENCES

1. Sutent [package insert]. New York, NY: Pfizer Labs.; May 2019.
2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed August 18, 2020.
3. 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.