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. Hemangiopericytoma, as single-agent therapy
   d. 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 and with disease documented as resectable with negative margins but with risk of significant morbidity, unresectable, recurrent, or metastatic
   b. Postoperative treatment for patients who have life-threatening side effects on imatinib therapy
   c. Treatment for limited or generallzed progressive disease following progression on imatinib
   d. Treatment in combination with everolimus for disease progression after single-agent therapy with imatinib, sunitinib, and regorafenib
4. Thymomas and thymic carcinomas, second-line therapy as a single agent
5. 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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma

1. Authorization of 12 months may be granted for treatment of relapsed or metastatic renal cell carcinoma when any of the following criteria are met:
   a. Sutent is given as first-line or subsequent therapy for disease with clear cell histology; OR
   b. Sutent is given as systemic therapy for disease with non-clear cell histology.

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, solitary fibrous tumor, or hemangiopericytoma.

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 unresectable locally advanced or metastatic pancreatic neuroendocrine tumors.

E. Thymoma and Thymic Carcinoma

Authorization of 12 months may be granted for treatment of thymoma or thymic carcinoma with failure of one previous chemotherapy regimen.

F. Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of progressive and/or symptomatic radioiodine refractory papillary, Hurthle 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.

III. CONTINUATION OF THERAPY

A. Authorization of 12 months may be granted for continued treatment in members requesting reauthorization who have not experienced disease progression or an unacceptable toxicity for the specified indications below:
   1. Relapsed or metastatic renal cell carcinoma
   2. Soft tissue sarcoma
   3. Gastrointestinal stromal tumor
   4. Pancreatic neuroendocrine tumor
   5. Thymoma and thymic carcinoma
   6. Thyroid carcinoma
   7. Medullary thyroid carcinoma
   8. Meningioma
   9. Chordoma

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.

IV. REFERENCES

1. Sutent [package insert]. New York, NY: Pfizer Labs.; May 2019.
2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed June 01, 2019.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Kidney Cancer. Version 4.2019. Accessed May 13, 2019. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Soft Tissue Sarcoma. Version 2.2019. Accessed May 13, 2019. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Neuroendocrine and Adrenal Tumors. Version 1.2019. Accessed June 01, 2019. https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf.
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Thymomas and Thymic Carcinomas. Version 2.2019. Accessed May 13, 2019. https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf.
7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Thyroid Carcinoma. Version 1.2019. Accessed May 13, 2019. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.