

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. Advanced renal cell carcinoma (RCC)
2. Adult patients at high risk of recurrent RCC following nephrectomy
3. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib
4. Progressive, well-differentiated pancreatic neuroendocrine tumors (PNETs) in patients with unresectable, locally advanced or metastatic disease

B. Compendial Uses

1. Relapsed or surgically unresectable stage IV RCC
2. Soft tissue sarcoma subtypes:
 - a. Angiosarcoma
 - b. Solitary fibrous tumor
 - c. Hemangiopericytoma
3. Thymic carcinoma
4. Thyroid carcinoma (medullary, papillary, Hürthle cell, or follicular)
5. Chordoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Renal Cell Carcinoma**

Authorization of 12 months may be granted for treatment of RCC when either of the following criteria is met:

1. Disease is relapsed, metastatic or unresectable
2. Member is at high risk of recurrent RCC following nephrectomy

B. **Soft Tissue Sarcoma**

Authorization of 12 months may be granted for treatment of the following subtypes of STS: gastrointestinal stromal tumor, angiosarcoma, solitary fibrous tumor, and hemangiopericytoma.

C. **Pancreatic Neuroendocrine Tumor**

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

D. **Thymic Carcinoma**

Authorization of 12 months may be granted for treatment of thymic carcinoma.

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E. Thyroid Carcinoma

Authorization of 12 months may be granted for treatment of medullary, papillary, Hurthle cell, or follicular thyroid carcinoma.

F. Chordoma

Authorization of 12 months may be granted for treatment of chordoma.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Sutent [package insert]. New York, NY: Pfizer Labs.; November 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 18, 2018.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Kidney Cancer. Version 4.2018. Accessed May 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Soft Tissue Sarcoma. Version 2.2018. Accessed May 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.
5. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Neuroendocrine and Adrenal Tumors. Version 2.2018. Accessed May 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf.
6. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thymomas and Thymic Carcinomas. Version 2.2018. Accessed May 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf.
7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Thyroid Carcinoma. Version 1.2018. Accessed May 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf.