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. Sutent is indicated for the treatment of advanced renal cell carcinoma (RCC)
2. Sutent is indicated for the treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib
3. Sutent is indicated for the treatment of progressive, well-differentiated pancreatic neuroendocrine tumors (PNETs) in patients with unresectable, locally advanced or metastatic disease

B. Compendial Uses
1. Chordoma
2. Relapsed or unresectable RCC
3. Lung neuroendocrine tumors
4. Soft tissue sarcoma subtypes:
   - Angiosarcoma
   - Solitary fibrous tumor
   - Hemangiopericytoma
5. Papillary, Hürthle cell, or follicular thyroid carcinoma:
   - Unresectable recurrent or persistent locoregional disease
   - Distant metastatic disease
6. Medullary thyroid carcinoma:
   - Progressive disease
   - Symptomatic distant metastatic disease
7. Thymic carcinoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Chordoma
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of chordoma.

B. Gastrointestinal Stromal Tumor (GIST)
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of GIST.

C. Renal Cell Carcinoma
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of relapsed or unresectable RCC.

D. Lung Neuroendocrine Tumor

Authorization of 12 months may be granted to members prescribed Sutent for the treatment of lung neuroendocrine tumors.

E. Pancreatic Neuroendocrine Tumor
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of pancreatic tumors.

F. Soft Tissue Sarcoma
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of the following subtypes of STS:
1. Angiosarcoma
2. Solitary Fibrous Tumor
3. Hemangiopericytoma

G. Thymic Carcinoma
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of thymic carcinoma.

H. Thyroid Carcinoma

1. Papillary, Hurthle Cell, or Follicular Thyroid Carcinoma
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of unresectable or metastatic papillary, Hurthle cell, or follicular thyroid carcinoma.

2. Medullary Thyroid Carcinoma
Authorization of 12 months may be granted to members prescribed Sutent for the treatment of progressive or metastatic medullary thyroid carcinoma.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

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6. The NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 1.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf/.
7. The NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas. Version 3.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/thymic.pdf.
8. Thomas A, Rajan A, Berman AW, et al. Phase II trial of sunitinib in patients with thymic epithelial tumors (TET) [abstract]. *J Clin Oncol* 2014;32(suppl 5): Abstract 7525.

9. Carr LL, Mankoff DA, Goulart BH, et al. Phase II study of daily sunitinib in FDG-PET-positive, iodine-refractory differentiated thyroid cancer and metastatic medullary carcinoma of the thyroid with functional imaging correlation. *Clin Cancer Res* 2010;16(21):5260-8.
10. Kulke MH, Lenz HJ, Meropol NJ, et al. Activity of sunitinib in patients with advanced neuroendocrine tumors. *J Clin Oncol* 2008;26:3403-10.
11. George S, Merriam P, Maki RG, et al. Multicenter phase II trial of sunitinib in the treatment of nongastrointestinal stromal tumor sarcomas. *J Clin Oncol* 2009;27:3154-60.