

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. Gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib
3. Progressive, well-differentiated pancreatic neuroendocrine tumors (PNETs) in patients with unresectable, locally advanced or metastatic disease

B. Compendial Uses

1. Relapsed or stage IV RCC
2. Soft tissue sarcoma subtypes:
 - Angiosarcoma
 - Solitary fibrous tumor
 - Hemangiopericytoma
3. Thymic carcinoma
4. Medullary, papillary, Hürthle cell, or follicular thyroid carcinoma
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 relapsed, metastatic or unresectable RCC.

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.

E. **Thyroid Carcinoma**

Authorization of 12 months may be granted for treatment of thyroid carcinoma with any of the following histologies: papillary, Hurthle cell, follicular, or medullary.

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

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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.
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