SPECIALTY GUIDELINE MANAGEMENT

VOTRIENT (pazopanib)

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. Votrient is indicated for the treatment of advanced renal cell carcinoma (RCC)
2. Votrient is indicated for the treatment of advanced soft tissue sarcoma (STS) in patients who have received prior chemotherapy

B. Compendial Uses
1. Relapsed or unresectable RCC
2. Uterine sarcoma
3. Soft tissue sarcoma of one of the following subtypes:
   a. Gastrointestinal stromal tumors (GIST)
   b. Angiosarcoma
   c. Pleomorphic rhabdomyosarcoma
   d. Retroperitoneal/intra-abdominal sarcoma
   e. Extremity/superficial trunk sarcoma
4. Papillary, Hürthle cell, or follicular thyroid carcinoma:
   a. Unresectable recurrent or persistent locoregional disease
   b. Distant metastatic disease
5. Medullary thyroid carcinoma:
   a. Progressive disease
   b. Symptomatic distant metastatic disease
6. Metastatic dermatofibrosarcoma protuberans (DFSP)

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

II. CRITERIA FOR INITIAL APPROVAL

A. Dermatofibrosarcoma Protuberans (DFSP)
Authorization of 12 months may be granted to members prescribed Votrient for the treatment of metastatic DFSP.

B. Renal Cell Carcinoma
Authorization of 12 months may be granted to members prescribed Votrient for the treatment of relapsed or unresectable renal cell carcinoma.

C. Soft Tissue Sarcoma (STS)
Authorization of 12 months may be granted to members prescribed Votrient for the treatment of soft tissue sarcoma (STS) that is not an adipocytic sarcoma and the member has ONE of the following subtypes of STS:
a. Gastrointestinal stromal tumor (GIST)
b. Pleomorphic rhabdomyosarcoma
c. Angiosarcoma.
d. Retroperitoneal/intra-abdominal sarcoma

e. Extremity/superficial trunk sarcoma

D. Thyroid Carcinoma

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

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

E. Uterine Sarcoma
Authorization of 12 months may be granted to members prescribed Votrient for the treatment of uterine sarcoma.

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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4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma. Version 2.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf.
5. Ganjoo KN, Villalobos VM, Kamaya A, et al. A multicenter phase II study of pazopanib in patients with advanced gastrointestinal stromal tumors (GIST) following failure of at least imatinib and sunitinib. *Ann Oncol* 2014;25(1):236-40.
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7. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms. Version 2.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf.
8. National Comprehensive Cancer Network. 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/
9. Bible KC, Suman VJ, Molina JR, et al. Efficacy of pazopanib in progressive, radioiodine-refractory, metastatic differentiated thyroid cancers: results of a phase 2 consortium study. *Lancet Oncol* 2010;11(10):962-72.
10. Bible KC, Suman VJ, Molina JR, et al. A multicenter phase 2 trial of pazopanib in metastatic and progressive medullary thyroid carcinoma: MC057H. *J Clin Endocrinol Metab* 2014;99(5):1687-93.