

Reference number
2081-A

SPECIALTY GUIDELINE MANAGEMENT

TORISEL (temsirolimus)

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

Advanced renal cell carcinoma

B. Compendial Uses

1. Relapsed or surgically unresectable stage IV kidney cancer
2. Endometrial carcinoma
3. Soft tissue sarcoma subtypes:
 - a. Perivascular epithelioid cell tumors (PEComa)
 - b. Recurrent angiomyolipoma
 - c. Lymphangioleiomyomatosis

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Renal Cell Carcinoma (RCC)**

Authorization of 12 months may be granted for treatment of relapsed, metastatic, or unresectable RCC.

B. **Endometrial Carcinoma**

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

C. **Soft Tissue Sarcoma**

Authorization of 12 months may be granted for treatment of soft tissue sarcoma with any of the following subtypes: perivascular epithelioid cell tumor (PEComa), angiomyolipoma, or lymphangioleiomyomatosis.

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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2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed May 18, 2018.

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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®): Uterine Neoplasms. Version 1.2018. Accessed May 22, 2018. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf.
5. Oza AM, Elit L, Tsao MS, et al. Phase II study of temsirolimus in women with recurrent or metastatic endometrial cancer: a trial of the NCIC Clinical Trials Group. *J Clin Oncol*. 2011;29(24):3278-85.
6. 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.
7. Benson C, Vitfell-Rasmussen J, Maruzzo M, et al. A retrospective study of patients with malignant PEComa receiving treatment with sirolimus or temsirolimus: the Royal Marsden Hospital experience. *Anticancer Res* 2014;34:3663-8.