

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. Lymphangiomyomatosis

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 lymphangiomyomatosis.

##### III. CONTINUATION OF THERAPY

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

##### IV. REFERENCES

1. Torisel [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; March 2018.
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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](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](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.