

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

Torisel is indicated for the treatment of advanced renal cell carcinoma

B. Compendial Uses

1. Endometrial carcinoma
2. Soft tissue sarcoma subtypes:
 - Perivascular epithelioid cell tumors (PEComa)
 - Recurrent angiomyolipoma
 - 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 to members who are prescribed Torisel for the treatment of relapsed or unresectable RCC.

B. **Endometrial Carcinoma**

Authorization of 12 months may be granted to members who are prescribed Torisel for the treatment of endometrial carcinoma.

C. **Soft Tissue Sarcoma**

Authorization of 12 months may be granted to members prescribed Torisel for the treatment of any of the following subtypes of soft tissue sarcoma:

1. Perivascular epithelioid cell (PEComa)
2. Angiomyolipoma
3. Lymphangioleiomyomatosis

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.; February 2015.
2. The NCCN Drugs & Biologics Compendium™ © 2016 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed June 28, 2016. https://www.nccn.org/professionals/drug_compendium/content/contents.asp.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. Version 3.2016. Accessed August 2, 2016. https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf.

4. 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.
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. 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.
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.