Reference number(s)
2081-A

Specialty Guideline Management temsirolimus-Torisel

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Torisel	temsirolimus

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.

FDA-Approved Indications[1-2]

Advanced renal cell carcinoma (RCC)

Compendial Uses[3-6]

- Endometrial carcinoma
- Soft tissue sarcoma subtypes:
  - Perivascular epithelioid cell tumors (PEComa)
  - Rhabdomyosarcoma
  - Angiomyolipoma
  - Lymphangioleiomyomatosis
- Mantle cell lymphoma (MCL)
- Uterine Sarcoma

All other indications are considered experimental/investigational and not medically necessary.

Coverage Criteria

Renal Cell Carcinoma[1]

Authorization of 12 months may be granted for treatment of advanced renal cell carcinoma.

Endometrial Carcinoma[3,4]

Authorization of 12 months may be granted as a single agent for subsequent treatment of locally advanced, recurrent, or metastatic endometrial carcinoma.

Soft Tissue Sarcoma[3]

Authorization of 12 months may be granted for treatment of any of the following subtypes of soft tissue sarcoma as single agent therapy: locally advanced unresectable or metastatic perivascular epithelioid cell tumor (PEComa), recurrent angiomyolipoma, or recurrent lymphangioleiomyomatosis.

Authorization of 12 months may be granted for treatment of non-pleomorphic rhabdomyosarcoma in combination with cyclophosphamide and vinorelbine.

Mantle Cell Lymphoma[5,6]

Authorization of 12 months may be granted for treatment of relapsed or refractory mantle cell lymphoma.

Uterine Sarcoma[3]

Authorization of 12 months may be granted as a single agent for subsequent treatment of advanced, recurrent/metastatic or inoperable PEComa.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in the Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Torisel [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; April 2023.
2. Temsirolimus [package insert]. Raleigh, NC: Accord Healthcare, Inc.; December 2023.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed May 20, 2025.
4. Temsirolimus. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed May 20, 2025.
5. Clinical Pharmacology. Elsevier Inc. Available at: https://www.clinicalkey.com/pharmacology/. Accessed May 20, 2025.
6. Hess G, Herbrecht R, Romaguerra J, et al. Phase III study to evaluate temsirolimus compared with investigator's choice therapy for the treatment of relapsed or refractory mantle cell lymphoma. J Clin Oncol. 2009;27:3822-29.