Temsirolimus (Torisel®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

POLICY

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
Treatment of advanced renal cell carcinoma (RCC).

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

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

COVERAGE CRITERIA

Renal Cell Carcinoma (RCC)

Authorization of 12 months may be granted for treatment of advanced RCC.

Endometrial Carcinoma

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

Mantle Cell Lymphoma (MCL)

Authorization of 12 months may be granted for treatment of relapsed or refractory MCL.

Soft Tissue Sarcoma

Authorization of 12 months may be granted for treatment of any of the following soft tissue sarcoma subtypes as single agent:

- Locally advanced unresectable or metastatic perivascular epithelioid cell tumor (PEComa)
- Recurrent angiomyolipoma, or recurrent lymphangioleiomyomatosis.

Authorization of 12 months (maximum 12 cycles) may be granted for treatment of rhabdomyosarcoma in combination with cyclophosphamide and vinorelbine.

Uterine Sarcoma

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

CONTINUATION OF THERAPY

Rhabdomyosarcoma

Authorization of 12 months (maximum 12 cycles) may be granted for continued treatment in members requesting reauthorization for rhabdomyosarcoma when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

All Other Indications

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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Torisel [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; April 2023.
2. Temsirolimus [package insert]. Raleigh, NC: Accord Healthcare, Inc.; December 2023.
3. The NCCN Drugs & Biologics Compendium® © 2026 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 13, 2026.
4. Temsirolimus. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed May 13, 2026.
5. Temsirolimus. Clinical Pharmacology powered by ClinicalKey. Philadelphia (PA). Elsevier. c2026. Available at: https://www.clinicalkey.com. Accessed May 13, 2026.

This document has been classified as public information

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(23):3822-29.

EFFECTIVE DATE 1/30/2027

ID_CHS_20812026_1126