

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable – mTOR Inhibitor) – Torisel Utilization Management Medical Policy

- Torisel® (temsirolimus intravenous infusion – Wyeth)

REVIEW DATE: 12/10/2025

OVERVIEW

Torisel, an inhibitor of mammalian target of rapamycin (mTOR), is indicated for the treatment of **advanced renal cell carcinoma**.¹

Guidelines

Torisel is addressed in National Comprehensive Cancer Network (NCCN) guidelines:

- **Kidney Cancer:** NCCN guidelines (version 1.2026 – July 24, 2025) no longer recommend Torisel for the treatment of relapsed or stage IV renal cell carcinoma.^{2,3}
- **Soft Tissue Sarcoma:** NCCN guidelines (version 1.2025 – May 2, 2025) recommend Torisel as a single agent for the treatment of perivascular epithelioid cell tumors (PEComas), lymphangioliomyomatosis and recurrent angiomyolipomas; and in combination with cyclophosphamide and vinorelbine for non-pleomorphic rhabdomyosarcoma (all category 2A).^{2,4}
- **Uterine Neoplasms:** NCCN guidelines (version 2.2026 – November 14, 2025) recommend Torisel as a single-agent for the treatment of advanced, recurrent, metastatic, or inoperable endometrial cancer or PEComa as “Useful in Certain Circumstances” (category 2A).^{2,5}

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Torisel. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Torisel as well as the monitoring required for adverse events and long-term efficacy, approval requires Torisel to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Torisel is recommended in those who meet one of the following criteria:

FDA-Approved Indication

-
1. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced disease; AND
 - C) The medication will be used as a single-agent; AND
-

D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.

Other Uses with Supportive Evidence

2. **Endometrial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):

- A) Patient is ≥ 18 years of age; AND
- B) Patient has advanced, recurrent, metastatic, or inoperable disease; AND
- C) Patient has ONE of the following (i or ii):
 - i. Endometrial carcinoma; OR
 - ii. Uterine perivascular epithelioid cell tumor (PEComa); AND
- D) The medication will be used as a single-agent; AND
- E) The medication is prescribed by or in consultation with an oncologist.

Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.

3. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):

- A) Patient is ≥ 18 years of age; AND
- B) Patient has ONE of the following (i, ii, iii, or iv):
 - i. Perivascular epithelioid cell tumors (PEComas); OR
 - ii. Recurrent lymphangiomyomatosis; OR
 - iii. Recurrent angiomyolipoma; OR
 - iv. Non-pleomorphic rhabdomyosarcoma; AND
- C) Patient meets ONE of the following (i or ii):
 - i. The medication will be used as a single-agent; OR
 - ii. The medication will be used in combination with cyclophosphamide and vinorelbine: AND
- D) The medication is prescribed by or in consultation with an oncologist.

Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Torisel is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Torisel® intravenous infusion [prescribing information]. Philadelphia, PA: Wyeth; April 2023.
2. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 3, 2025. Search term: temsirolimus.

3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – July 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 3, 2025.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 1.2025 – May 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 3, 2025.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 2.2026 – November 14, 2025). © 2025 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 3, 2025.
6. Italiano A, Delcambre C, Hostein I, et al. Treatment with the mTOR inhibitor temsirolimus in patients with malignant PEComa. *Ann Oncol*. 2010;5:1135-1137.
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;34:3663-3668.
8. Starbuck KD, Drake RD, Budd GT, Rose PG. Treatment of advanced malignant uterine perivascular epithelioid cell tumor with mTOR inhibitors: Single-institution experience and review of the literature. *Anticancer Res*. 2016;36:6161-6164.
9. 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;24:3278-3285.
10. Fleming GF, Filiaci VL, Marzullo B, et al. Temsirolimus with or without megestrol acetate and tamoxifen for endometrial cancer: A Gynecologic Oncology Group study. *Gynecol Oncol*. 2014;132:585-592.
11. Mascarenhas L, Chi YY, Hingorani P, et al. Randomized Phase II trial of bevacizumab or temsirolimus in combination with chemotherapy for first relapse rhabdomyosarcoma: A report from the Children’s Oncology Group. *J Clin Oncol*. 2019;37:2866-2874.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Endometrial Carcinoma: Added requirement that the patient has either endometrial carcinoma or uterine perivascular epithelioid cell tumor (PEComa).	12/13/2023
Annual Revision	Renal Cell Carcinoma: Removed relapsed and metastatic from requirement that the patient has advanced disease. Endometrial Carcinoma: Added advanced and inoperable, and removed high-risk from requirement that the patient has advanced, recurrent, metastatic, or inoperable disease.	12/11/2024
Update	04/08/2025: The policy name was changed from “Oncology (Injectable) – Torisel UM Medical Policy” to “Oncology (Injectable – mTOR Inhibitor) – Torisel UM Medical Policy”.	N/A
Annual Revision	No criteria changes.	12/10/2025