

## Clinical Policy: Temsirolimus (Torisel)

Reference Number: PA.CP.PHAR.324

Effective Date: 01/2018

Last Review Date: 10/2025

### Description

Temsirolimus for injection (Torisel<sup>®</sup>) is a kinase inhibitor.

### FDA Approved Indication(s)

Torisel is indicated for the treatment of advanced renal cell carcinoma (RCC).

### Policy/Criteria

It is the policy of PA Health & Wellness<sup>®</sup> that Torisel and temsirolimus are **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Renal Cell Carcinoma (must meet all):

1. Diagnosis of advanced RCC (i.e., relapsed, metastatic or stage IV disease);
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed as a single agent;
5. Member has at least 3 prognostic risk factors (*Appendix D*);
6. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
7. Request meets one of the following (a or b):
  - a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

##### B. Uterine Neoplasms (off-label) (must meet all):

1. Diagnosis of one of the following (a or b):
  - a. Endometrial carcinoma;
  - b. Uterine Sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed as a single agent;
5. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
  - a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);

- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**C. Soft Tissue Sarcoma (off-label) (must meet all):**

1. Diagnosis of one of the following soft tissue sarcomas (a, b, c, or d):
  - a. Locally advanced, unresectable, or metastatic malignant perivascular epithelioid cell tumor (PEComa);
  - b. Recurrent angiomyolipoma;
  - c. Lymphangiomyomatosis;
  - d. Non-pleomorphic rhabdomyosarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age  $\geq$  18 years;
4. Prescribed in one of the following ways (a or b):
  - a. For non-pleomorphic rhabdomyosarcoma: In combination with cyclophosphamide and vinorelbine;
  - b. For all other indications: As a single agent;
5. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
  - a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**D. Other diagnoses/indications:** Refer to PA.CP.PMN.53

**II. Continued Approval**

**A. All Indications in Section I (must meet all):**

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
4. Request meets one of the following (a or b):
  - a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);
  - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications (must meet 1 or 2):**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.PHARM.01) applies; or
2. Refer to PA.CP.PMN.53

### III. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration  
 NCCN: National Comprehensive Cancer Network  
 PEComa: perivascular epithelioid cell tumor  
 RCC: renal cell carcinoma

*Appendix B: Therapeutic Alternatives*

Not applicable

*Appendix C: Contraindications/Black Box Warnings*

- Contraindication(s): bilirubin >1.5 times the upper limit of normal
- Boxed warning(s): none reported

*Appendix D: General Information*

- At least 3 of the following 6 prognostic risk factors (based on the inclusion criteria in the Torisel pivotal trial):
  - Interval of less than 1 year from time of RCC diagnosis to start of systemic therapy
  - Karnofsky performance status score of 60 or 70
  - Hemoglobin level below normal (e.g., men < 13.5g/dL, women <12g/dL)
  - Corrected serum calcium level > 10 mg/dL (2.5 mmol per liter)
  - Serum lactate dehydrogenase level > 1.5 times the upper limit of normal
  - More than one metastatic organ site

### IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RCC	25 mg administered as an IV infusion over a 30-60 minute period once a week.  Consider 50 mg once a week if concomitant strong CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital).	50 mg/week

### V. Product Availability

Kit: single-use vial 25 mg/mL temsirolimus; diluent vial 1.8 mL

### VI. References

1. Torisel Prescribing Information. Philadelphia, PA: Pfizer, Inc.; April 2023. Available at <http://www.pfizermedicalinformation.com/en-us/torisl>. Accessed July 10, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed August 31, 2025.

3. National Comprehensive Cancer Network. Kidney Cancer Version 1.2026. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/kidney.pdf](https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf). Accessed August 31, 2025.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 1.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/sarcoma.pdf](https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf). Accessed August 31, 2025.
5. National Comprehensive Cancer Network. Uterine Neoplasms Version 3.2025. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/uterine.pdf](https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf). Accessed August 31, 2025.
6. Hudes G, Carducci M, Tomczak P, et al. Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma. N Eng J Med 2007; 356:2271-2281.

**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9330	Injection, temsirolimus, 1 mg

Reviews, Revisions, and Approvals	Date
4Q 2018 annual review: no significant changes; specialist involvement in care and continuation of care added; references reviewed and updated.	08/2018
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019
4Q 2020 annual review: Added age limit; updated appendices; references reviewed and updated.	8/2020
4Q 2021 annual review: Use as single agent added to Endometrial Carcinoma section; references reviewed and updated.	10/2021
4Q 2022 annual review: per NCCN, added disease qualifiers for PEComa and added non-pleomorphic rhabdomyosarcoma as a coverable off-label diagnosis; added redirection to generic product; references reviewed and updated.	10/2022
4Q 2023 annual review: per NCCN, added “uterine sarcoma” under Uterine Neoplasms criteria; references reviewed and updated.	10/2023
4Q 2024 annual review: updated “Endometrial Carcinoma” indication to “Uterine Neoplasms” per NCCN compendium as Uterine Neoplasms include both endometrial carcinoma and uterine sarcoma; references reviewed and updated.	10/2024
4Q 2025 annual review: no significant changes; added temsirolimus to medically necessary statement as generic requires prior authorization; for initial approval criteria, extended approval duration from 6 months to 12 months; references reviewed and updated.	10/2025