

## Temsirolimus (Torisel®)

Place of Service  
Office Administration  
Outpatient Facility Infusion  
Administration  
Infusion Center Administration

HCPCS: J9330 per 1 mg

### Conditions listed in policy (see criteria for details)

- [Renal cell carcinoma](#)
- [Endometrial carcinoma](#)
- [Soft tissue sarcoma](#)
- [Uterine sarcoma](#)

AHFS therapeutic class: Antineoplastic Agents

Mechanism of action: mTOR kinase inhibitor

### **(1) Special Instructions and pertinent Information**

**Covered under the Medical Benefit**, please submit clinical information for prior authorization review via fax.

### **(2) Prior Authorization/Medical Review is required for the following condition(s)**

All requests for Torisel® (temsirolimus) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

#### Renal cell carcinoma - advanced (aRCC)

1. Used as a single agent

##### **Covered Doses**

Up to 25 mg IV once weekly

##### **Coverage Period**

Indefinite

##### **ICD-10:**

C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, Z85.528

#### Endometrial Cancer

1. Used as a single agent, **AND**
2. **Effective 10/30/2023 and after**: Second line or subsequent therapy, **AND**
3. **Effective 10/30/2023 and after**: Recurrent disease

##### **Covered Doses**

Up to 25 mg IV once weekly

##### **Coverage Period**

Indefinite

**ICD-10:**

C54.0-C54.3, C54.8, C54.9, C55, Z80.49

**Soft tissue sarcoma**

1. Either of the following:

a. Being used as a single agent for one of the following types of soft tissue sarcoma:

- i. Malignant perivascular epithelioid cell tumors (PEComas), and **effective 10/30/2023 and after**. will require disease to be locally advanced unresectable, or metastatic, OR
- ii. Angiomyolipoma that is recurrent, OR
- iii. Lymphangiomyomatosis

**OR**

b. Being used in combination with cyclophosphamide and vinorelbine for non-pleomorphic rhabdomyosarcoma

**Covered Doses**

Up to 25 mg IV once weekly

**Coverage Period**

Indefinite

**ICD-10:**

C48.0-C48.2, C48.8, C49.4, C49.5, C49.8, C49.9, D49.2, Z85.831

**Uterine sarcoma**

- 1. Patient has perivascular epithelioid cell tumor (PEComa), **AND**
- 2. Advanced, recurrent, metastatic or inoperable disease, **AND**
- 3. Second-line or subsequent therapy, **AND**
- 4. Being used as a single agent

**Covered Doses**

Up to 25 mg IV once weekly

**Coverage Period**

Indefinite

**ICD-10:**

C54.0-C54.3, C54.8, C54.9, C55, Z85.42

**(3) The following condition(s) DO NOT require Prior Authorization/Preservice**

**All requests for Torisel® (temsirolimus) must be sent for clinical review and receive authorization prior to drug administration or claim payment.**

**(4) This Medication is NOT medically necessary for the following condition(s):**

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

## (5) Additional Information

How supplied:

25 mg/mL (single-use vial)

## (6) References

- AHFS®. Available by subscription at <http://www.lexi.com>
- Atkins, et al. Randomized phase II study of multiple dose levels of CCI-779, a novel mammalian target of rapamycin kinase inhibitor, in patients with advanced refractory renal cell carcinoma. *J Clin Oncol* 2004; 22(5): 909-917.
- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Hudes, et al. Temsirolimus, interferon Alfa or both for advanced renal cell carcinoma. *NEJM* 2007;356:2271-81
- Oza AM, Elit L, Tsao MS, Kamel-Reid S, 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;20;29(24):3278-85.
- National Comprehensive Cancer Network Drugs and Compendium (Version 2023). Available at: [www.nccn.org](http://www.nccn.org).
- National Comprehensive Cancer Network. Kidney Cancer (Version 4.2023). Available at: [www.nccn.org](http://www.nccn.org).
- National Comprehensive Cancer Network. Soft Tissue Sarcoma (Version 2.2023). Available at: [www.nccn.org](http://www.nccn.org)
- National Comprehensive Cancer Network (NCCN). Uterine Neoplasms (Version 2.2023). Available at: [www.nccn.org](http://www.nccn.org)
- Torisel® (temsirolimus) [Prescribing information]. Philadelphia, PA: Wyeth Pharmaceuticals; 4/2023.

## (7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- New indication in Section (2): Added coverage for Uterine sarcoma  
*Rationale: NCCN category 2A support*
- Section (2): Soft tissue sarcoma: **Effective 10/30/2023 and after**, will add requirement for malignant perivascular epithelioid cell tumors (PEComas) to be locally advanced unresectable, or metastatic  
*Rationale: NCCN category 2A support*
- Section (2): Endometrial carcinoma: **Effective 10/30/2023 and after**, will add requirement for endometrial carcinoma to be used as second line or subsequent therapy for recurrent disease  
*Rationale: NCCN category 2A support*

*BSC Drug Coverage Criteria to Determine Medical Necessity  
Reviewed by P&T Committee*