

Torisel® (temsirolimus) (Intravenous)

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I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Torisel 25 mg/mL vial: 1 vial every 7 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 25 billable units every 7 days

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria

- Therapy will not be administered concurrently with live vaccines and close contact with individuals who have received live vaccines will be avoided; **AND**
- Confirmation that patient does not have bilirubin >1.5 times the upper limit of normal (ULN); **AND**
- Used as single agent therapy; **AND**

Renal Cell Carcinoma † ⊕ ¹⁻³

- Patient has advanced disease

Soft Tissue Sarcoma (PEComa/Recurrent angiomyolipoma/Lymphangioliomyomatosis) ‡ ^{2,6,7}

Uterine Neoplasm - Endometrial Carcinoma ‡ ^{2,5,8}

† FDA-labeled indication; ‡ Compendia approved indication(s); ⊕ Orphan Drug

IV. Renewal Criteria ^{1-3,5-8}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hypersensitivity/infusion reactions, hepatic impairment, hyperglycemia/glucose intolerance, infections, interstitial lung disease, hyperlipidemia, bowel perforation, renal failure, wound healing complications, intracerebral hemorrhage, proteinuria/nephrotic syndrome, etc.

V. Dosage/Administration ^{1,5-8}

Indication	Dose
All indications	Administer 25 mg intravenously over a 30-60 minute period once every 7 days (weekly)

VI. Billing Code/Availability Information

HCPCS Code:

- J9330 - Injection, temsirolimus, 1 mg: 1 billable unit = 1 mg

NDC:

- Torisel 25 mg/mL injection, single-use vial*: 00008-1179-xx*
* (Note: available generically through various manufacturers)

VII. References

1. Torisel [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals Inc; March 2018. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) temsirolimus. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.
3. Hudes G, Carducci M, Tomczak P, et al. Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma. *N Engl J Med.* 2007 May 31;356(22):2271-81.
4. Dutcher JP, de Souza P, McDermott D, et al. Effect of temsirolimus versus interferon-alpha on outcome of patients with advanced renal cell carcinoma of different tumor histologies. *Med Oncol.* 2009;26(2):202-9.
5. 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;29(24):3278-3285. [PubMed 21788564]
6. Italiano A, Delcambre C, Hostein I, et al. Treatment with the mTOR inhibitor temsirolimus in patients with malignant PEComa. *Ann Oncol* (2010) 21 (5): 1135-1137. [PubMed 20215136]

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 Jul;34(7):3663-8. PMID: 24982384
8. 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 Mar;132(3):585-92. doi: 10.1016/j.ygyno.2014.01.015. Epub 2014 Jan 20

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, unspecified
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
D49.2	Neoplasm of unspecified behavior of bone, soft tissue, and skin
Z85.831	Personal history of malignant neoplasm of soft tissue

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC