

Torisel® (temsirolimus)

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Date of Origin: 08/01/2013

Dates Reviewed: 11/2013, 06/2014, 6/2015, 04/2016, 04/2017, 04/2018

I. Length of Authorization

Coverage is provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 25 billable units every 7 days

III. Initial Approval Criteria

Coverage is provided in the following conditions:

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

Renal Cell Carcinoma

- Patient has advanced renal cell carcinoma †

Soft Tissue Sarcoma (PEComa/Recurrent angiomyolipoma/lymphangiomyomatosis) ‡

- Must be used as a single agent

Uterine Neoplasm - Endometrial Carcinoma ‡

- Must be used as a single agent

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

IV. Renewal Criteria

- Tumor response with 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 the following: severe infusion reactions, severe hepatic impairment; interstitial lung disease, severe hyperlipidemia, bowel perforation, renal failure, wound healing complications, intracerebral hemorrhage, etc.

V. Dosage/Administration

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

VI. Billing Code/Availability Information

Jcode:

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

NDC:

Torisel 25 mg/mL injection: 00008-1179-xx

VII. References

1. Torisel [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals Inc; July 2017. Accessed February 2018.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) temsirolimus. National Comprehensive Cancer Network, 2018. 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 February 2018.
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]

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.528	Personal history of other malignant neoplasm of kidney
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) and Local Coverage Determinations (LCDs) 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): 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions

Jurisdiction	Applicable State/US Territory	Contractor
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 Government Benefit Administrators, 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