Temsirolimus (Torisel®)

NDC CODE(S) 00008-1179-XX TORISEL 25MG/ML Solution (PFIZER U.S.)
16729-0221-XX TEMSIROLIMUS 25MG/ML Solution (ACCORD HEALTHCARE)
16729-0223-XX TEMSIROLIMUS 25MG/ML Solution (ACCORD HEALTHCARE)
72611-0780-XX TEMSIROLIMUS 25MG/ML Solution (ALMAJECT)
72611-0785-XX TEMSIROLIMUS 25MG/ML Solution (ALMAJECT)

DESCRIPTION

Temsirolimus is an inhibitor of mTOR, mammalian target of rapamycin. Temsirolimus is a kinase inhibitor used as an antineoplastic agent. The mTOR kinase plays a role in activating a cascade that induces cell division, tumor growth and angiogenesis. Temsirolimus binds to an intracellular protein (FKBP-12) blocking the action of mTOR to activate the cascade. The result is in growth arrest in treated tumor cells and reduced levels of the vascular endothelial growth factor or VEGF.

POLICY

- Temsirolimus for the treatment of the following is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**
  - Renal cell carcinoma (kidney cancer)
  - Soft tissue sarcoma
  - Uterine neoplasms
- Temsirolimus for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- 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

- Patient has advanced disease

Soft Tissue Sarcoma (PEComa/Recurrent angiomyolipoma/Lymphangioleiomyomatosis)

Uterine Neoplasm - Endometrial Carcinoma

RENEWAL CRITERIA

- Patient continues to meet the universal and other indication-specific relevant criteria identified in the Initial Approval Criteria; **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.

DOSAGE/ADMINISTRATION

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

LENGTH OF AUTHORIZATION

Coverage will be provided for six months and may be renewed

DOSING LIMITS

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

- 25 billable units every 7 days

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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
9. Lexi-Comp Online. (2019, February). AHFS DI. *Temsirolimus*. Retrieved April 22, 2019 from Lexi-Comp Online with AHFS.
10. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2019, April). *Temsirolimus*. Retrieved April 22, 2019 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

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