

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Torisel (temsirolimus)

CG-DRUG-52

Override	Approval Duration
Prior Authorization	1 year

Medication	Quantity Limit
Torisel (temsirolimus)	N/A

APPROVAL CRITERIA

Requests for Torisel (temsirolimus) injection **may be approved** for any of the following conditions (I. through III.) when criteria are met:

- I. Advanced renal cell carcinoma for either of the following (A. or B.):
 - A. As first-line therapy as a single agent (monotherapy) for (either 1. or 2.):
 1. Relapsed metastatic disease; **OR**
 2. Surgically unresectable stage IV renal carcinoma in individuals with a poor prognosis as manifested by having at least 3 of the following (a. through f.):
 - a. Lactate dehydrogenase greater than 1.5 times the upper limit of normal; **OR**
 - b. Hemoglobin less than the lower limit of normal; **OR**
 - c. Corrected calcium level greater than 10 mg/dL (2.5 mmol/liter); **OR**
 - d. Interval of less than a year from original diagnosis to the start of systemic therapy; **OR**
 - e. Karnofsky performance status less than or equal to 70 or ECOG performance score of 2, 3, or 4; **OR**
 - f. Greater than or equal to 2 sites of metastases;
 - OR**
 - B. For subsequent (second-line) therapy as a single agent (monotherapy) for relapsed metastatic or for surgically unresectable stage IV disease;
- OR**
- II. Soft tissue sarcoma as single agent therapy (monotherapy) for sarcoma including, but not limited to, PEComa, recurrent angiomyolipoma, and lymphangi leiomyomatosis;
- OR**
- III. Endometrial adenocarcinoma as a single agent (monotherapy) for unresectable, recurrent or metastatic disease.

Torisel (temsirolimus) injection **may not be approved** when criteria are not met and for all other indications.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Flaherty KT, Manola JB, Pins M, et al. BEST: A randomized phase II study of vascular endothelial growth factor, RAF kinase, and mammalian target of rapamycin combination targeted therapy with bevacizumab, sorafenib, and temsirolimus in advanced renal cell carcinoma--A trial of the ECOG-ACRIN Cancer Research Group (E2804). J Clin Oncol. 2015; 33(21):2384-2391.
2. National Cancer Institute (NCI). Listing of active or planned clinical trials of Temsirolimus. Available at: <http://www.cancer.gov/about-cancer/treatment/clinical-trials/search/results?protocolsearchid=6151697>. Accessed on September 20, 2016.
3. National Cancer Institute (NCI). Temsirolimus. Updated October 28, 2011. Available at: <http://www.cancer.gov/about-cancer/treatment/drugs/temsirolimus>. Accessed on September 20, 2016.
4. National Comprehensive Cancer Network®. NCCN Drugs & Biologic Compendium® (electronic version). For additional information see the NCCN website: <http://www.nccn.org>. Accessed on September 20, 2016.
5. NCCN Clinical Practice Guidelines in Oncology™ (NCCN). © 2016 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website at: <http://www.nccn.org/index.asp>. Accessed on September 20, 2016.
 - Kidney cancer (V3.2016). Revised 05/26/2016.
 - Soft tissue sarcoma (V2.2016). Revised 02/19/2016.
 - Uterine neoplasm (V2.2016). Revised 11/20/2015.
6. NCCN Task Force Report (National Comprehensive Cancer Network, Inc.): Optimizing treatment of advanced renal cell carcinoma with molecular targeted therapy. JNCCN. 2011; 9(1):S1-29.
7. Torisel® (Temsirolimus injection) [Prescribing Information], Madison, NJ. Wyeth Pharmaceuticals, Inc. February 2015. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/022088s018lbl.pdf. Accessed on September 20, 2016.
8. Temsirolimus. In: DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated February 27, 2016. Available at: <http://www.micromedexsolutions.com>. Accessed on September 20, 2016.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.