

# Torisel (temsirolimus)

Override	Approval Duration
Prior Authorization	1 year

Medication
Torisel (temsirolimus)

## **APPROVAL CRITERIA**

Requests for Torisel (temsirolimus) may be approved if the following criteria are met:

- I. Individual has a diagnosis of advanced Renal Cell Carcinoma and the following are met (Label, NCCN 1, 2A):
  - A. Temsirolimus is used as a single agent (monotherapy) in non-clear cell histology RCC 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* three (3) of the following (a. through f.) (Hudes 2007, NCCN Kidney Cancer Guidelines):
      - 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 60 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. Individual has a diagnosis of Soft Tissue Sarcoma and the following are met (NCCN 2A):
  - A. Temsirolimus is used as a single agent (monotherapy) for sarcoma including, but not limited to, PEComa, recurrent angiomyolipoma, and lymphangi leiomyomatosis; **OR**
  - B. Temsirolimus is used in combination with cyclophosphamide and vinorelbine for non-pleomorphic rhabdomyosarcoma;

**OR**

- III. Individual has a diagnosis of Endometrial Adenocarcinoma or Uterine Perivascular Epithelioid Cell neoplasm (PEComa) and the following are met (NCCN 2A):

- A. Temsirolimus is used as a single agent (monotherapy); **AND**
- B. Individual has unresectable, recurrent or metastatic disease.

Torisel (temsirolimus) may not be approved for the following:

- I. Bilirubin greater than 1.5 times the upper limit of normal (ULN); **OR**
- II. When criteria are not met and for all other indications.

#### **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 19, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Hudes GR, Carducci MA, Choueiri TK, et al. Temsirolimus, Interferon Alfa, or both for advanced renal-cell carcinoma. N Engl J Med. 2007; 356:2271-2281.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 19, 2024
  - a. Kidney Cancer. V3.2024. Revised March 11, 2024.
  - b. Soft Tissue Sarcoma. V3.2023. Revised December 12, 2023.
  - c. Uterine Neoplasms. V2.2024. Revised March 6, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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