# 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 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* three (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. 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 lymphangioleiomyomatosis; **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.: 2023. 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: April 7, 2023.
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.; 2023; 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 April 7, 2023
    a. Kidney Cancer. V4.2023. Revised January 18, 2023.
    b. Soft Tissue Sarcoma. V2.2023. Revised April 25, 2023.
    c. Uterine Neoplasms. V2.2023. Revised April 28, 2023.