

# Clinical Criteria

**Subject:** Torisel (temsirolimus)

**Document #:** ING-CC-0101 **Publish Date:** ~~06/21/2021~~06/20/2022

**Status:** ~~Reviewed~~Revised **Last Review Date:** ~~05/21/2021~~05/20/2022

## Table of Contents

[Overview](#) [Coding](#) [References](#)

[Clinical criteria](#) [Document history](#)

## Overview

This document addresses the use of Torisel (temsirolimus). Torisel is an inhibitor of mammalian target of rapamycin (mTOR) primarily used to treat renal cell carcinoma.

Torisel is FDA approved for advanced renal cell carcinoma (RCC). It was approved based on results from a phase 3 trial of patients with previously untreated advanced RCC (clear cell and non-clear cell histologies) (Hudes 2007). Patients in this study had 3 or more of 6 pre-selected prognostic risk factors (less than one year from time of initial renal cell carcinoma diagnosis to randomization, Karnofsky performance status of 60 or 70, hemoglobin less than the lower limit of normal, corrected calcium of greater than 10 mg/dL, lactate dehydrogenase >1.5 times the upper limit of normal, more than one metastatic organ site).

The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Torisel. These include its use in relapsed or stage IV RCC for patients who are at poor/intermediate risk as defined by prognostic risk factors used in the previously mentioned study. NCCN also recommends Torisel in certain types of soft tissue sarcoma (PEComa, recurrent angiomyolipoma, and lymphangioleiomyomatosis, rhabdomyosarcoma) and for advanced, recurrent, or metastatic endometrial carcinoma.

### Definitions and Measures

**Angiomyolipoma:** A neoplasm with perivascular epithelioid cell differentiation (PEComa) often associated with tuberous sclerosis. It is characterized by a mixture of epithelioid cells, smooth muscle, vessels, and mature adipose tissue. The kidney is the most common site of involvement. Other sites of involvement include the liver, lung, lymph nodes, and retroperitoneum. The vast majority of cases follow a benign clinical course. However, cases of metastatic angiomyolipomas with sarcomatoid features have been described.

**Endometrial Adenocarcinoma:** An adenocarcinoma arising from the uterine body cavity. This is the most frequent malignant tumor affecting the uterine body, and is linked to estrogen therapy. Most individuals present with uterine bleeding and are over age 40 at the time of diagnosis. The prognosis depends on the stage of the tumor, the depth of the uterine wall invasion, and the histologic subtype. Endometrioid adenocarcinoma is the most frequently seen morphologic variant of endometrial adenocarcinoma (NCI, 2015).

**Karnofsky Performance Status (KPS):** A standard way of measuring the ability of individuals with cancer to perform ordinary tasks. The KPS scores range from 0 to 100. A higher score means the person is better able to carry out daily activities. The KPS may be used to determine an individual's prognosis, to measure changes in the ability to function, or to decide if an individual could be included in a clinical trial (NCI, 2015).

### Line of Therapy:

- **First-line therapy:** The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- **Second-line therapy:** Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- **Third-line therapy:** Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

**Lymphangioleiomyomatosis:** A multifocal neoplasm with perivascular epithelioid cell differentiation (PEComa) affecting almost exclusively females of child-bearing age. It is characterized by the presence of smooth muscle and epithelioid cells and by the proliferation of lymphatic vessels. Sites of involvement include the lungs, mediastinum, and the retroperitoneum. It usually presents with chylous pleural effusion or ascites (NCI, 2015).

Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.

One line of therapy: Single line of therapy.

PEComa: A soft tissue mesenchymal tumor with perivascular epithelioid cell differentiation (PEComa). Representative examples include angiomyolipoma, clear cell-sugar-tumor of the lung, and lymphangioleiomyomatosis.

Refractory Disease: Illness or disease that does not respond to treatment.

Relapse or recurrence: After a period of improvement, during which time a disease (for example, cancer) could not be detected, the return of signs and symptoms of illness or disease. For cancer, it may come back to the same place as the original (primary) tumor or to another place in the body.

Unresectable: Unable to be removed with surgery.

## Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

### Torisel (temsirolimus)

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:
  - 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 10mg/dL (2.5mmol/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. Temsirolimus is used 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**
  - A-B. Temsirolimus is used in combination with cyclophosphamide and vinorelbine for non-pleomorphic rhabdomyosarcoma;
- OR**
- III. Individual has a diagnosis of Endometrial Adenocarcinoma 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 the above criteria are not met and for all other indications.

## Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Formatted: Font: Not Bold

#### HCPCS

**J9330** Injection, temsirolimus, 1 mg [Torisel]

#### ICD-10 Diagnosis

**C49.0-C49.9** Malignant neoplasm of other connective and soft tissue  
**C54.1** Malignant neoplasm of endometrium  
**C64.1-C64.9** Malignant neoplasm of kidney, except renal pelvis  
**C65.1-C65.9** Malignant neoplasm of renal pelvis  
**D30.00-D30.02** Benign neoplasm of kidney  
**D30.10-D30.12** Benign neoplasm of renal pelvis  
**J84.81** Lymphangioleiomyomatosis  
**Z85.528** Personal history of other malignant neoplasm of kidney

## Document History

Revised 05/20/2022

Document History:

- 05/20/2022 – Annual Review: Update clinical criteria for use in Rhabdomyosarcoma. Coding Reviewed: No changes.
- 05/21/2021 – Annual Review: No changes. Coding Reviewed: No changes.
- 05/15/2020 – Annual Review: Add labeled contraindications to temsirolimus criteria. Wording and formatting changes. Coding review: No changes
- 05/17/2019 – Annual Review: Initial review of temsirolimus clinical criteria. Minor wording and formatting changes. Coding Reviewed: No changes.

## References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2022. 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, 2022.
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.; 2021; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 7, 2022
  - a. Kidney Cancer. V4.2022. Revised December 21, 2021.
  - b. Soft Tissue Sarcoma. V1.2022. Revised March 29, 2022.
  - c. Uterine Neoplasms. V1.2022. Revised November 4, 2021.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.

© CPT Only – American Medical Association