# Clinical Policy: Temsirolimus (Torisel)

Reference Number: CP.PHAR.324
Effective Date: 03/17
Last Review Date: 03/17

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for temsirolimus for injection (Torisel®).

**Policy/Criteria**
It is the policy of health plans affiliated with Centene Corporation® that Torisel is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Renal Cell Carcinoma** (must meet all):

1. Diagnosis of advanced renal cell carcinoma (RCC) (i.e., relapsed, metastatic or stage IV disease; clear cell or non-clear cell histology);
2. Prescribed dose does not exceed 25 mg once a week (50 mg once a week if used with a strong CYP3A4 inducer [e.g. dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampacin, phenobarbital]);
3. Not prescribed concurrently with live vaccines (e.g., intranasal influenza, measles, mumps, rubella, oral polio, BCG [tuberculosis vaccine], yellow fever, varicella, TY21a typhoid vaccines);
4. Member does not have a bilirubin > 1.5 times the upper limit of normal (ULN).

**Approval duration: 3 months**

**B. Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.

1. The following NCCN recommended uses for Torisel, meeting NCCN categories 1, 2a, or 2b, are approved per the CP.PHAR.57 Global Biopharm Policy:
   a. The following soft tissue sarcomas:
      i. Perivascular epitheloid cell tumor;
      ii. Recurrent angiomyolipoma;
      iii. Lymphangioleiomyomatosis;
   b. Endometrial carcinoma.

**II. Continued Approval**

**A. All Indications** (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Member has none of the following reasons to discontinue:
   a. Disease progression or unacceptable toxicity;
   b. Bilirubin > 1.5 times ULN.

**Approval duration: 6 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
2. Refer to CP.PHAR.57 - Global Biopharm Policy**.**

**Background**
*Description/Mechanism of Action:*
Temsirolimus is an inhibitor of mTOR (mammalian target of rapamycin). Temsirolimus binds to an intracellular protein (FKBP-12), and the protein-drug complex inhibits the activity of mTOR that controls cell division. Inhibition of mTOR activity resulted in a G1 growth arrest in treated tumor cells. When mTOR was inhibited, its ability to phosphorylate p70S6k and S6 ribosomal protein, which are downstream of mTOR in the PI3 kinase/AKT pathway was blocked. In *in vitro* studies using renal cell carcinoma cell lines, temsirolimus inhibited the activity of mTOR and resulted in reduced levels of the hypoxia-inducible factors HIF-1 and HIF-2 alpha, and the vascular endothelial growth factor.

*Formulations:*
Torisel (temsirolimus) injection, 25 mg/mL:
- Each kit is supplied in a single carton containing:
  - One single-use vial of 25 mg/mL of temsirolimus; and
  - One diluent vial which includes a deliverable volume of 1.8 mL.

*FDA Approved Indications:*
Torisel is a kinase inhibitor/intravenous formulation indicated for:
- Treatment of advanced renal cell carcinoma.

**Appendices**
**Appendix A: Abbreviation Key**
BCG: Bacille Calmette-Guerin
HIF: Hypoxia-inducible factors
RCC: Renal cell carcinoma
ULN: Upper limit of normal

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9330 | Injection, temsirolimus, 1 mg |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Policy split from CP.PHAR.182 Excellus Oncology. | 02/17 | 03/17 |

**References**

1. Torisel prescribing information. Philadelphia, PA: Pfizer, Inc.; July 2016. Available at http://labeling.pfizer.com/showlabeling.aspx?id=490. Accessed January 30, 2017.
2. Temsirolimus. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at NCCN.org. Accessed January 30, 2017.
3. Kidney cancer (Version 2.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 30, 2017.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.