Clinical Policy: Temsirolimus (Torisel)

Reference Number: PA.CP.PHAR.324
Effective Date: 01/18
Last Review Date: 11/17

Coding Implications
Revision Log

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

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® 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 PA.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 PA.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 Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.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

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.