Clinical Policy: Temsirolimus (Torisel)

Reference Number: PA.CP.PHAR.324
Effective Date: 01/18
Last Review Date: 10/18

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®).

FDA Approved Indication(s)
Torisel is indicated for the treatment of advanced renal cell carcinoma (RCC).

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 RCC (i.e., relapsed, metastatic or stage IV disease);
2. Prescribed by or in consultation with an oncologist;
3. Use is as a single agent;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

B. Endometrial Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of endometrial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Request meets one of the following (a or b):
   a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*).
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

C. Soft Tissue Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of PEComa, recurrent angiomyolipoma, or lymphangioleiomyomatosis;
2. Prescribed by or in consultation with an oncologist;
3. Use is as a single agent;
4. Request meets one of the following (a or b):

a. Dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

Approval duration: 6 months

D. Other diagnoses/indications: Refer to PA.CP.PMN.53

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 is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 25 mg per week (*50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital*);
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 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.PMN.53

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.

Appendices

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
PEComas: perivascular epithelioid cell tumors
RCC: renal cell carcinoma

Appendix B: Therapeutic Alternatives

Not applicable.

Appendix C: Contraindications/Black Box Warnings

- Contraindication(s): bilirubin >1.5 times the upper limit of normal
- Boxed warning(s): none reported

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
4Q 2018 annual review: no significant changes; specialist involvement in care and continuation of care added; references reviewed and updated.	08/18	

References

1. Torisel Prescribing Information. Philadelphia, PA: Pfizer, Inc.; March 2018. Available at http://labeling.pfizer.com/showlabeling.aspx?id=490. Accessed July 19, 2018.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 19, 2018.
3. National Comprehensive Cancer Network. Soft tissue sarcoma. Version 2.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 19, 2018.
4. National Comprehensive Cancer Network. Uterine neoplasms. Version 2.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 19, 2018.
5. National Comprehensive Cancer Network. Uterine neoplasms. Version 2.2018. Available at: http://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Accessed July 19, 2018.
6. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2018. Available at: http://www.clinicalpharmacology-ip.com/.