Clinical Policy: Temsirolimus (Torisel)

Reference Number: CP.PHAR.324
Effective Date: 03.01.17
Last Review Date: 11.20
Line of Business: HIM, Medicaid

Coding Implications
Revision Log

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

Description

Temsirolimus for injection (Torisel®) is a kinase inhibitor.

FDA Approved Indication(s)

Torisel is indicated for the treatment of advanced renal cell carcinoma (RCC).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval 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 RCC (i.e., relapsed, metastatic or stage IV disease);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Use is as a single agent;
5. Member has at least 3 prognostic risk factors (*Appendix D*);
6. 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)*.

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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. Age ≥ 18 years;
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).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Soft Tissue Sarcoma (off-label) (must meet all)**:**

1. Diagnosis of perivascular epithelioid cell tumor (PEComa), recurrent angiomyolipoma, or lymphangioleiomyomatosis;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Use is as a single agent;
5. 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).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

D. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Torisel for a covered indication and has received this medication for at least 30 days;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is

NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network
PEComa: perivascular epithelioid cell tumor
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

Appendix D: General Information

- At least 3 of the following 6 prognostic risk factors (based on the Torisel pivotal trial):
  - Interval of less than 1 year from time of RCC diagnosis to start of systemic therapy
  - Karnofsky performance status score of 60 or 70
  - Hemoglobin level below normal (e.g., men < 13.5g/dL, women <12g/dL)
  - Corrected serum calcium level > 10 mg/dL (2.5 mmol per liter)
  - Serum lactate dehydrogenase level > 1.5 times the upper limit of normal
  - More than one metastatic organ site

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
RCC	25 mg administered as an IV infusion over a 30-60 minute period once a week. Consider 50 mg once a week if concomitant strong CYP3A4 inducer (e.g., dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital).	50 mg/week

VI. Product Availability

Kit: single-use vial 25 mg/mL temsirolimus; diluent vial 1.8 mL

VII. References

1. Torisel Prescribing Information. Philadelphia, PA: Pfizer, Inc.; March 2018. Available at http://labeling.pfizer.com/showlabeling.aspx?id=490. Accessed August 10, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 10, 2020.
3. National Comprehensive Cancer Network. Kidney Cancer Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August 10, 2020.
4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August 10, 2020.
5. National Comprehensive Cancer Network. Uterine Neoplasms Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed August 10, 2020.
6. Hudes G, Carducci M, Tomczak P, et al. Temsirolimus, interferon alfa, or both for advanced renal-cell carcinoma. N Eng J Med 2007; 356:2271-2281.

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	P&T Approval Date
Policy split from CP.PHAR.182 Excellus Oncology.	02.17	03.17
Policy converted to new template. Annual Review. Safety criteria was applied according to the safety guidance discussed at CPAC and endorsed by Centene Medical Affairs. Authorization limits extended from 3 and 6 months to 6 and 12 months for initial and continued approval, respectively. Added criteria for NCCN 2A and above recommended off-label uses: Endometrial cancer and soft tissue sarcoma.	08.30.17	11.17
4Q 2018 annual review: no significant changes; added HIM; specialist involvement in care and continuation of care added; references reviewed and updated.	08.07.18	11.18
4Q 2019 annual review: updated NCCN dosing per new template; added RCC prognostic risk factors; references reviewed and updated.	08.10.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	08.10.20	11.20

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.