Clinical Policy: Temsirolimus (Torisel)

Reference Number: LA.PHAR.324
Effective Date: 11.04.23
Last Review Date: ~~04.22.24~~12.03.24 Coding Implications
Line of Business: Medicaid Revision Log

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

Please note: This policy is for medical benefit

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 Louisiana Healthcare Connections 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. Prescribed as a single agent;
5. Member has at least 3 prognostic risk factors (*Appendix D*);
6. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
7. 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~~Uterine Neoplasms (off-label) (must meet all)**:**

1. Diagnosis of one of the following (a or b):
   a. Endometrial carcinoma;
   b. Uterine Sarcoma;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
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

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

1. Diagnosis of one of the following soft tissue sarcomas (a, b, c, or d):
   a. Locally advanced, unresectable, or metastatic malignant perivascular epithelioid cell tumor (PEComa);
   b. Recurrent angiomyolipoma;
   c. Lymphangioleiomyomatosis;
   d. Non-pleomorphic rhabdomyosarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed in one of the following ways (a or b):
   a. For non-pleomorphic rhabdomyosarcoma: In combination with cyclophosphamide and vinorelbine;
   b. For all other indications: As a single agent;
5. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
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

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections 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. For brand Torisel requests, member must use generic temsirolimus injection, unless contraindicated or clinically significant adverse effects are experienced;
4. 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. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: LA.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 policy – LA.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 inclusion criteria in 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 < 13.5 g/dL, women < 12 g/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.; April 2023. Available at https://www.pfizermedicalinformation.com/en-us/torisel. Accessed ~~August 7, 2023~~July 15, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August ~~7, 2023.~~ 22, 2024.
3. National Comprehensive Cancer Network. Kidney Cancer Version 1.~~2024~~2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed August ~~7, 2023~~22, 2024.

4. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.~~2023~~2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed August ~~7, 2023~~22, 2024.
5. National Comprehensive Cancer Network. Uterine Neoplasms Version 2.~~2023~~2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed August ~~7, 2023~~22, 2024.
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	LDH Approval Date
Converted corporate to local policy.	06.16.23	10.05.23
Annual review: per NCCN, added "uterine sarcoma" under Uterine Neoplasms criteria; references reviewed and updated.	04.22.24	07.10.24
Updated "Endometrial Carcinoma" indication to "Uterine Neoplasms" per NCCN compendium as Uterine Neoplasms include both endometrial carcinoma and uterine sarcoma; references reviewed and updated.	12.03.24	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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