VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Torisel Utilization Management Medical Policy
- Torisel® (temsirolimus intravenous infusion – Wyeth)

REVIEW DATE: 12/11/2024

OVERVIEW

Torisel, an inhibitor of mammalian target of rapamycin (mTOR), is indicated for the treatment of **advanced renal cell carcinoma**.[1]

Guidelines

Torisel is addressed in National Comprehensive Cancer Network guidelines:

- **Kidney cancer:** Guidelines (version 2.2025 – September 6, 2024) no longer recommend Torisel for the treatment of relapsed or stage IV renal cell carcinoma.[2,3]
- **Soft tissue sarcoma:** Guidelines (version 4.2024 – November 21, 2024) recommend Torisel as a single agent for the treatment of perivascular epithelioid cell tumors (PEComas), lymphangioleiomyomatosis and angiomyolipomas; and in combination with cyclophosphamide and vinorelbine for non-pleomorphic rhabdomyosarcoma.[2,4]
- **Uterine neoplasms:** Guidelines (version 3.2024 – September 20, 2024) recommend Torisel as a single-agent for the treatment of advanced, recurrent, metastatic, or inoperable endometrial cancer.[2,5]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Torisel. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Torisel as well as the monitoring required for adverse events and long-term efficacy, approval requires Torisel to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Torisel is recommended in those who meet one of the following criteria:

FDA-Approved Indication

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1. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced disease; AND
   - **C)** Torisel will be used as a single-agent; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.

Other Uses with Supportive Evidence

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2. **Endometrial Carcinoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has advanced, recurrent, metastatic, or inoperable disease; AND
   - **C)** Patient has ONE of the following (i or ii):
     - **i.** Endometrial carcinoma; OR
     - **ii.** Uterine perivascular epithelioid cell tumor (PEComa); AND
   - **D)** Torisel will be used as a single-agent; AND
   - **E)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.

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3. **Soft Tissue Sarcoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has ONE of the following (i, ii, iii, or iv):
     - **i.** Perivascular epithelioid cell tumors (PEComas); OR
     - **ii.** Recurrent lymphangioleiomyomatosis; OR
     - **iii.** Recurrent angiomyolipoma; OR
     - **iv.** Non-pleomorphic rhabdomyosarcoma; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Torisel will be used as a single-agent; OR
     - **ii.** Torisel will be used in combination with cyclophosphamide and vinorelbine: AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Torisel is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

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3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – September 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 5, 2024.

4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 4.2024 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 5, 2024.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 3.2024 – September 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 5, 2024.
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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Endometrial Carcinoma:** Added requirement that the patient has either endometrial carcinoma or uterine perivascular epithelioid cell tumor (PEComa).	12/13/2023
Annual Revision	**Renal Cell Carcinoma:** Removed relapsed and metastatic from requirement that the patient has advanced disease. **Endometrial Carcinoma:** Added advanced and inoperable, and removed high-risk from requirement that the patient has advanced, recurrent, metastatic, or inoperable disease.	12/11/2024