VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

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

REVIEW DATE: 11/03/2021

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 2.2022 – September 8, 2021) recommend Torisel as a single agent for the treatment of relapsed or stage IV renal cell carcinoma.[2,3]
- **Soft tissue sarcoma:** Guidelines (version 2.2021 – April 28, 2021) recommend Torisel as a single agent for the treatment of perivascular epithelioid cell tumors (PEComas), lymphangioleiomyomatosis and angiomyolipomas.[2,4]
- **Uterine neoplasms:** Guidelines (version 4.2021 – September 3, 2021) recommend Torisel as a single-agent for the treatment of recurrent, metastatic, or high-risk 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 Indications

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1. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed, advanced, or metastatic 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.[1]

Other Uses with Supportive Evidence

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2. Endometrial Carcinoma. Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has recurrent, metastatic or high-risk 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.[9,10]

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3. Soft Tissue Sarcoma. Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has one of the following (i, ii, or iii):
  - **i.** Perivascular epithelioid cell tumors (PEComas); OR
  - **ii.** Lymphangioleiomyomatosis; OR
  - **iii.** Recurrent angiomyolipoma; 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.[6-8]

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

1. Torisel® intravenous infusion [prescribing information]. Philadelphia, PA: Wyeth; March 2018.
2. The NCCN Drugs and Biologics Compendium. © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 29, 2021.
3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (Version 2.2022 – September 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 29, 2021.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 2.2021 – April 28, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 29, 2021.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (Version 4.2021 – September 3, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 29, 2021.
6. Italiano A, Delcambre C, Hostein I, et al. Treatment with the mTOR inhibitor temsirolimus in patients with malignant PEComa. *Ann Oncol*. 2010;5:1135-1137.
7. Benson C, Vitfell-Rasmussen J, Maruzzo M, et al. A retrospective study of patients with malignant PEComa receiving treatment with sirolimus or temsirolumis: The Royal Marsden Hospital experience. *Anticancer Res*. 2014;34:3663-3668.

8. Starbuck KD, Drake RD, Budd GT, Rose PG. Treatment of advanced malignant uterine perivascular epithelioid cell tumor with mTOR inhibitors: Single-institution experience and review of the literature. *Anticancer Res*. 2016;36:6161-6164.
9. Oza AM, Elit L, Tsao MS, et al. Phase II study of temsirolimus in women with recurrent or metastatic endometrial cancer: A trial of the NCIC Clinical Trials Group. *J Clin Oncol*. 2011;24:3278-3285.
10. Fleming GF, Filiaci VL, Marzullo B, et al. Temsirolimus with or without megestrol acetate and tamoxifen for endometrial cancer: A Gynecologic Oncology Group study. *Gynecol Oncol*. 2014;132:585-592.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/28/2020
Annual Revision	**Renal Cell Carcinoma:** A requirement was added that the patient is ≥ 18 years of age. **Endometrial Carcinoma:** A requirement was added that the patient is ≥ 18 years of age. **Soft Tissue Sarcoma:** A requirement was added that the patient is ≥ 18 years of age.	11/03/2021