POLICY: Oncology – Torisel (temsirolimus injection for intravenous use – Wyeth Pharmaceuticals)

APPROVAL DATE: 10/16/2019

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for kidney cancer (Version 2.2020 – August 5, 2019) recommend Torisel as a single agent for the treatment of relapsed or stage IV renal cell carcinoma.[2,3]

The NCCN guidelines for soft tissue sarcoma (Version 4.2019 – September 12, 2019) recommend Torisel for the treatment of perivascular epithelioid cell tumors (PEComas), and lymphangioleiomyomatosis or angiomyolipomas.[2,4]

The NCCN guidelines for uterine neoplasms (Version 4.2019 – September 16, 2019) 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 indication(s). 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).

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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** The patient has relapsed, advanced, or metastatic disease; AND
   - **B)** Torisel will be used as a single-agent; AND
   - **C)** Torisel 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

2. Soft Tissue Sarcoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
- **A)** The patient has one of the following (i, ii, or iii):
  - **i.** Perivascular epithelioid cell tumors (PEComas); OR
  - **ii.** Lymphangioleiomyomatosis; OR
  - **iii.** Recurrent angiomyolipoma; AND
- **B)** Torisel will be used as a single-agent; AND
- **C)** Torisel 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]

3. Endometrial Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
- **A)** The patient has recurrent, metastatic or high-risk disease; AND
- **B)** Torisel will be used as a single-agent; AND
- **C)** Torisel 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]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Torisel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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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4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 4.2019 – September 12, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 24, 2019.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (Version 4.2019 – September 16, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on September 24, 2019.
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	Approval Date
New Policy	--	10/16/2019