Reference number
2081-A

SPECIALTY GUIDELINE MANAGEMENT

TORISEL (temsirolimus)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication
Advanced renal cell carcinoma (RCC)

B. Compendial Uses
1. Relapsed or stage IV renal cell carcinoma
2. Endometrial carcinoma
3. Soft tissue sarcoma subtypes:
   a. Perivascular epithelioid cell tumors (PEComa)
   b. Rhabdomyosarcoma
   c. Angiomyolipoma
   d. Lymphangioleiomyomatosis
5. Mantle cell lymphoma (MCL)
6. Uterine Sarcoma

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Renal Cell Carcinoma
Authorization of 12 months may be granted as a single agent for treatment of advanced, relapsed, or stage IV renal cell carcinoma.

B. Endometrial Carcinoma
Authorization of 12 months may be granted as a single agent for subsequent treatment of recurrent endometrial carcinoma.

C. Soft Tissue Sarcoma
1. Authorization of 12 months may be granted for treatment of any of the following subtypes of soft tissue sarcoma as single agent therapy: locally advanced unresectable or metastatic perivascular epithelioid cell tumor (PEComa), recurrent angiomyolipoma, or recurrent lymphangioleiomyomatosis.
2. Authorization of 12 months may be granted for treatment of rhabdomyosarcoma in combination with cyclophosphamide and vinorelbine.

D. Mantle Cell Lymphoma
Authorization of 12 months may be granted for treatment of relapsed or refractory mantle cell lymphoma.

E. Uterine Sarcoma
Authorization of 12 months may be granted as a single agent for subsequent treatment of advanced, recurrent/metastatic or inoperable PEComa.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Torisel [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; March 2018.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed May 5, 2023.
3. Clinical Pharmacology. Elsevier Inc. Available at: https://www.clinicalkey.com/pharmacology/. Accessed May 8, 2023.
4. Hess G, Herbrecht R, Romaguerra J, et al. Phase III study to evaluate temsirolimus compared with investigator's choice therapy for the treatment of relapsed or refractory mantle cell lymphoma. *J Clin Oncol.* 2009;27:3822-29.