Specialty Guideline Management

Torisel (temsirolimus)

POLICY

A. INDICATIONS

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

FDA-Approved Indication
• Torisel is indicated for the treatment of advanced renal cell carcinoma

Compendial Indications
• Endometrial carcinoma
• Soft tissue sarcoma subtypes:
  o Perivascular epithelioid cell tumors (PEComa)
  o Recurrent angiomyolipoma
  o Lymphangioleiomyomatosis

All other indications are considered experimental/investigational and are not covered benefits.

B. INITIAL CRITERIA FOR APPROVAL

1. Renal Cell Carcinoma (RCC)
   Authorization of 12 months may be granted to members who are prescribed Torisel as a single agent for the treatment of relapsed or medically unresectable RCC.

2. Endometrial Carcinoma
   Authorization of 12 months may be granted to members who are prescribed Torisel as a single agent for the treatment of recurrent or metastatic endometrial carcinoma that has progressed after prior cytotoxic chemotherapy.

3. Soft Tissue Sarcoma
   Authorization of 12 months may be granted to members prescribed Torisel as a single agent for the treatment of any of the following subtypes of soft tissue sarcoma:
   a. Perivascular epithelioid cell (PEComa)
   b. Angiomyolipoma
   c. Lymphangioleiomyomatosis

C. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

D. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. Dosing Limits
   The following dosing limit applies:
   • All indications: 25 mg/week

REFERENCES


