Torisel (temsirolimus)

**Line(s) of Business:**
- HMO; PPO; QUEST Integration
- Akamai Advantage

**Original Effective Date:** 10/01/2015

**Current Effective Date:** 03/01/2017

**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 Uses**
- Renal cell carcinoma
  - First-line therapy as a single agent for relapse or for surgically unresectable stage IV disease for patients with poor prognosis
  - First-line therapy as a single agent for relapse or for surgically unresectable stage IV disease for patients with non-clear cell histology
  - Subsequent therapy following prior cytokine therapy as a single agent for relapse or for surgically unresectable stage IV disease with predominant clear cell histology
- Soft tissue sarcoma
  - Single-agent therapy for the treatment of PEComa, recurrent angiomyolipoma, and lymphangioleiomyomatosis
- Endometrial carcinoma
  - Endometrial adenocarcinoma
    - Primary therapy as a single agent with radiation therapy (RT) for disease not suitable for primary surgery in patients with suspected or gross cervical involvement
    - Preoperative primary therapy as a single agent for intra-abdominal disease
    - Primary therapy as a single agent with or without radiation therapy/brachytherapy for extrauterine pelvic disease
    - Primary therapy with or without RT and/or hormonal therapy for extra-abdominal or liver disease
    - Therapy for surgically staged patients as a single agent (with or without RT) for stage IIIA, IIIB, IIEC, or IV disease
    - Single agent therapy for disseminated metastatic disease that has progressed on hormonal therapy
- Single agent therapy for symptomatic, grade 2-3, or large volume disseminated metastatic disease
- Single agent therapy with sequential tumor-directed radiation therapy for local recurrence confined to the vagina, or the pelvic, para-aortic, or common iliac lymph nodes
- Single agent therapy for microscopic upper abdominal or peritoneal recurrences
- Single agent for local/regional recurrence in patients who have received prior external beam radiation therapy to the site of recurrence
  - Serous or clear cell adenocarcinoma
    - Adjuvant therapy as a single agent
  - Carcinosarcoma
    - Adjuvant therapy as a single agent

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- The patient’s treatment plan with treatment regimen including dose, frequency, length of each cycle, number of cycles, and additional therapies (e.g., other medications, radiation) must be documented.
- Cancer type/location, tumor histology and grade, staging, new cancer/recurrence, metastases, prior treatments, treatment intent (e.g., initial chemotherapy, neoadjuvant, adjuvant, or palliative), pertinent laboratory and imaging reports
- Relevant laboratory reports, imaging studies, and office notes to substantiate status and progression of disease

C. PRESCRIBER RESTRICTION
The medication must be prescribed by, or in conjunction with, an oncologist.

D. CRITERIA FOR APPROVAL
1. Renal cell carcinoma
   a. Authorization of 3 months may be granted for members prescribed Torisel as first line therapy as a single agent for clear cell renal cell carcinoma which is stage I-IV and has relapsed after primary treatment (e.g., partial or radical nephrectomy) OR is stage IV and is unresectable when ANY of the following criteria for poor prognosis are met:
      i. Hemoglobin less than the lower limit of normal
      ii. Serum corrected calcium greater than the upper limit of normal
      iii. Karnofsky performance status less than 80%
      iv. Time from initial diagnosis to medication therapy is greater than 1 year
      v. Absolute neutrophil count greater than the upper limit of normal
      vi. Platelet count greater than the upper limit of normal
   b. Authorization of 3 months may be granted for members prescribed Torisel as a single agent as subsequent therapy after cytokine therapy for clear cell renal cell carcinoma which is stage I-IV and has relapsed after primary treatment (e.g., partial or radical nephrectomy) OR is stage IV and is unresectable
   c. Authorization of 3 months may be granted for members prescribed Torisel as a single agent for non-clear cell renal cell carcinoma which is stage I-IV and has relapsed after primary treatment (e.g., partial or radical nephrectomy) OR is stage IV and is unresectable
Soft-tissue sarcoma
a. Authorization of 3 months may be granted for members prescribed Torisel as a single agent for the treatment of perivascular epithelioid cell tumor (PEComa), recurrent angiomyolipoma, or recurrent lymphangioleiomyomatosis

3. Endometrial carcinoma
a. Authorization of 3 months may be granted for members prescribed Torisel as a single agent as adjuvant therapy for the treatment of endometrial carcinoma which expresses serious cell adenocarcinoma, clear cell adenocarcinoma, or carcinosarcoma histology

b. Authorization of 3 months may be granted for members prescribed Torisel as primary therapy as a single agent with radiation therapy (RT) for disease not suitable for primary surgery in members with suspected or gross cervical involvement

c. Authorization of 3 months may be granted for members with intra-abdominal disease prescribed Torisel as a single agent as primary preoperative therapy for the treatment of endometrial carcinoma which expresses endometrioid adenocarcinoma histology

d. Authorization of 3 months may be granted for members with extrauterine pelvic disease prescribed Torisel as a single agent (with or without radiation therapy/brachytherapy) as primary therapy for the treatment of endometrial carcinoma which expresses endometrioid adenocarcinoma histology

e. Authorization of 3 months may be granted for members with extra-abdominal or liver disease and who are prescribed Torisel as a single agent (with or without RT and/or hormonal therapy) as primary therapy for the treatment of endometrial carcinoma which expresses endometrioid adenocarcinoma histology

f. Authorization of 3 months may be granted for members prescribed Torisel as a single agent (with or without RT) for the treatment of endometrial carcinoma which expresses endometrioid adenocarcinoma histology which has been surgically staged as IIIA, IIIB, IIIC, or IV

g. Authorization of 3 months may be granted for members prescribed Torisel as a single agent for the treatment of microscopic upper abdominal or peritoneal recurrences of endometrial carcinoma which expresses endometrioid adenocarcinoma histology

h. Authorization of 3 months may be granted for members prescribed Torisel as a single agent in combination with sequential tumor-directed radiation therapy for the treatment of recurrences of endometrial carcinoma which expresses endometrioid adenocarcinoma histology which are confined to the vagina, or the pelvic, para-aortic, or common iliac lymph nodes

i. Authorization of 3 months may be granted for members prescribed Torisel as a single agent for the treatment of other local or regional recurrences of endometrial carcinoma which expresses endometrioid adenocarcinoma histology and has received prior external beam radiation therapy at the site of the recurrence
j. Authorization of 3 months may be granted for members prescribed Torisel as a single agent for the treatment of disseminated metastatic endometrial carcinoma which expresses endometrioid adenocarcinoma histology when ANY of the following criteria are met:
   i. The patient has previously failed hormonal therapy for metastatic disease
   ii. The patient has symptomatic disease
   iii. The patient has grade 2 or 3 disease
   iv. The patient has large volume metastases

E. CONTINUATION OF THERAPY
   All members, including new members, requesting authorization for therapy must meet ALL initial authorization criteria.

   Members who were previously approved for Torisel by HMSA may request reauthorizations after their initial approval. Approval for an additional 3 months may be granted if the following information is supplied and the member has not demonstrated evidence of disease progression:
   • A current oncology notes documenting the patient’s response to treatment showing no progression of disease
   • Current imaging studies and other objective measures showing no progression of disease when compared with previous results

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

G. ADMINISTRATIVE GUIDELINES
   Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER
   The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

   Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

   This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

Revised: June 2016.