Torisel (temsirolimus)

Line(s) of Business:  
HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 11/1/2017

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
  o Systemic therapy as a single agent for relapse or for stage IV disease with non-clear cell histology
  o First-line or subsequent therapy as a single agent for relapse or for stage IV disease with predominant clear cell histology
• Soft tissue sarcoma
  o Single-agent therapy for the treatment of PEComa, recurrent angiomyolipoma, and lymphangioleiomyomatosis
• Endometrial carcinoma
  o Endometrial adenocarcinoma
    ▪ Primary therapy as a single agent 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 external beam radiation therapy (EBRT) and/or brachytherapy for extrauterine pelvic disease
    ▪ Primary therapy with or without EBRT and/or hormonal therapy for extra-abdominal or liver disease
    ▪ Adjuvant therapy for surgically staged patients as a single agent (with or without EBRT/brachytherapy) for stage III 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 or without sequential EBRT/brachytherapy for local/regional recurrence in patients with gross upper abdominal residual disease, disease in vagina or pelvic lymph nodes, disease in para-aortic or common iliac lymph nodes, or microscopic residual upper abdominal or peritoneal disease

- 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 a single agent as first-line or subsequent therapy for clear cell renal cell carcinoma which is stage I-III and has relapsed after primary treatment (eg, partial or radical nephrectomy) OR is stage IV.

   b. 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-III and has relapsed after primary treatment (eg, partial or radical nephrectomy) OR is stage IV.

2. 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 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 extraterine pelvic disease prescribed Torisel as a single agent (with or without EBRT/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 EBRT 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 EBRT/brachytherapy) for the adjuvant treatment of endometrial carcinoma which expresses endometrioid adenocarcinoma histology which has been surgically staged as III or IV.

g. Authorization of 3 months may be granted for members prescribed Torisel as a single agent (with or without EBRT) 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 (with or without EBRT/brachytherapy) for the treatment of recurrences of endometrial carcinoma which expresses endometrioid adenocarcinoma histology which are confined to the vagina; the pelvic, para-aortic, or common iliac lymph nodes; or gross upper abdominal residual disease.

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 EBRT 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
   1. No previous authorization/precertification:
      All members (including new members and members currently receiving treatment without prior
      authorization) must meet criteria for initial approval in section D.
   2. Reauthorization:
      Authorization of 3 months may be granted to members requesting authorization for
      continuation of therapy if Torisel was previously authorized by HMSA/CVS and the member has
      not demonstrated evidence of disease progression:
      a. A current oncology note documenting no progression of disease
      b. 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

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