Clinical Policy Bulletin: Temsirolimus (Torisel)

Number: 0873

Policy

Aetna considers temsirolimus (Torisel) medically necessary for the following indications:

- advanced (metastatic or unresectable) renal cell carcinoma; or
- endometrioid adenocarcinoma; or
- endometrial carcinosarcoma or serous or clear cell endometrial carcinoma; or
- PEComa, recurrent angiomyolipoma, or lymphangioleiomyomatosis.

Temsirolimus is considered experimental and investigational for all other indications.

Background

Temsirolimus (Torisel) is an intravenous chemotherapeutic agent in the class mTOR inhibitor for the treatment of renal cell carcinoma. It was approved by the U.S. Food and Drug Administration (FDA) in May 2007 for the treatment of advanced renal cell carcinoma in adults.

Current guidelines from the National Comprehensive Cancer Network (NCCN, 2013) recommend use of temsirolimus in kidney cancer for the following indications: 1) first-line therapy as a single agent for relapsed or surgically unresectable stage IV disease (clear cell or non-clear cell); 2) subsequent therapy as a single agent for relapsed or surgically unresectable stage IV disease with predominant clear cell histology.

NCCN Guidelines (2014) recommend temsirolimus for endometrioid adenocarcinoma:
Primary treatment as a single agent
may be considered preoperatively for intra-abdominal disease
with sequential radiation therapy (RT) and brachytherapy with or
without surgery for extrauterine pelvic disease
may be considered following palliative hysterectomy with bilateral
salpingo-oophorectomy with or without RT and/or hormonal therapy
for extra-abdominal or liver disease

For surgically staged patients as a single agent
with sequential pelvic radiation therapy (RT) and/or vaginal
brachytherapy in patients with stage IB disease with histologic grade
3 tumors and adverse risk factors
with sequential pelvic RT and vaginal brachytherapy in patients with
stage II disease with histologic grade 3 tumors
with sequential tumor-directed RT for stage IIIA disease
with or without sequential tumor-directed RT for stage IIIB and IIIC
disease
with or without sequential RT for stage IIIA and IV disease

Single agent
for disseminated metastases that have progressed on hormonal
therapy
with or without sequential palliative radiation therapy (RT) for
symptomatic, grade 2–3, or large-volume disseminated metastases
may be considered for isolated metastases
with sequential tumor-directed RT with or without brachytherapy for
local recurrence in patients with disease confined to the vagina or in
pelvic, para-aortic, or common iliac lymph nodes
with or without sequential tumor-directed RT for microscopic upper
abdominal or peritoneal recurrences
for local/regional recurrence in patients who have received prior
external beam RT to site of recurrence

NCCN guidelines (2014) recommend temsirolimus for endometrial carcinosarcoma
or serous or clear cell endometrial carcinoma as adjuvant therapy as a single
agent with or without: 1) vaginal brachytherapy for stage IA disease with no
myometrial invasion; or 2) sequential tumor-directed radiation therapy for stage IA
disease with myometrial invasion or stage IB-IV disease.

NCCN guidelines (2015) on soft tissue sarcoma recommend temsirolimus as
single-agent therapy for the treatment of PEComa, recurrent angiomyolipoma, and
lymphangioleiomyomatosis.

Appendix

Continued use beyond 3 months (12 weeks) is considered medically necessary for
persons with stable disease (tumor size within 25% of baseline). Continued use is
considered not medically necessary when there is evidence of disease
progression or unacceptable toxicity occurs.
CPT Codes / HCPCS Codes / ICD-9 Codes

Other CPT codes related to the CPB:

96409  Chemotherapy administration; intravenous, push technique,
       single or initial substance/drug

96413 - 96417  Chemotherapy administration; intravenous infusion technique

HCPCS codes covered if selection criteria are met:

J9330  Injection, temsirolimus, 1 mg (Torisel)

ICD-9 codes covered if selection criteria are met:

182.0  Malignant neoplasm of corpus uteri, except isthmus

189.0 - 189.1  Malignant neoplasm of kidney and renal pelvis

The above policy is based on the following references:

2.  Wyeth Pharmaceuticals, Inc. Torisel Kit (temsirolimus) injection, for intravenous use only. Prescribing Information. Philadelphia, PA: Wyeth Pharmaceuticals; revised May 2012.