OVERVIEW
Torisel, an inhibitor of mammalian target of rapamycin (mTOR), is indicated for the treatment of advanced renal cell carcinoma.¹

Guidelines

The NCCN guidelines for soft tissue sarcoma (Version 4.2019 – September 12, 2019) recommend Torisel for the treatment of perivascular epithelioid cell tumors (PEComas), and lymphangioleiomyomatosis or angiomyolipomas.²⁴


POLICY STATEMENT
Prior authorization is recommended for medical benefit coverage of Torisel. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist).

Because of the specialized skills required for evaluation and diagnosis of patients treated with Torisel as well as the monitoring required for adverse events and long-term efficacy, approval requires Torisel to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Torisel is recommended in those who meet the following criteria:

FDA-Approved Indications

1. Renal Cell Carcinoma. Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) The patient has relapsed, advanced, or metastatic disease; AND
   B) Torisel will be used as a single-agent; AND
   C) Torisel is prescribed by or in consultation with an oncologist.

   Dosing. Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.¹

Other Uses with Supportive Evidence
2. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) The patient has one of the following (i, ii, or iii):
      i. Perivascular epithelioid cell tumors (PEComas); OR
      ii. Lymphangioleiomyomatosis; OR
      iii. Recurrent angiomyolipoma; AND
   B) Torisel will be used as a single-agent; AND
   C) Torisel is prescribed by or in consultation with an oncologist.

   **Dosing.** Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.\(^5\)\(^-\)\(^8\)

3. **Endometrial Carcinoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   A) The patient has recurrent, metastatic or high-risk disease; AND
   B) Torisel will be used as a single-agent; AND
   C) Torisel is prescribed by or in consultation with an oncologist.

   **Dosing.** Each individual dose must not exceed 25 mg administered by intravenous infusion no more frequently than once a week.\(^5\)\(^,\)\(^10\)

### CONDITIONS NOT RECOMMENDED FOR APPROVAL
Torisel has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

### REFERENCES

### HISTORY

10/16/2019
<table>
<thead>
<tr>
<th>Type of Revision</th>
<th>Summary of Changes</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Policy</td>
<td>--</td>
<td>10/16/2019</td>
</tr>
</tbody>
</table>