

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Torisel Prior Authorization Policy

- Torisel® (temsirolimus intravenous infusion – Wyeth)

REVIEW DATE: 12/11/2024

OVERVIEW

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

Guidelines

Torisel is addressed in National Comprehensive Cancer Network guidelines:

- **Kidney cancer:** Guidelines (version 2.2025 – September 6, 2024) no longer recommend Torisel for the treatment of relapsed or stage IV renal cell carcinoma.^{2,3}
- **Soft tissue sarcoma:** Guidelines (version 4.2024 – November 21, 2024) recommend Torisel as a single agent for the treatment of perivascular epithelioid cell tumors (PEComas), lymphangiomyomatosis, and angiomyolipomas; and in combination with cyclophosphamide and vinorelbine for non-pleomorphic rhabdomyosarcoma.^{2,4}
- **Uterine neoplasms:** Guidelines (version 3.2024 – September 20, 2023) recommend Torisel as a single-agent for the treatment of advanced, recurrent, metastatic, or inoperable endometrial cancer.^{2,5}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Torisel. All approvals are provided for the duration noted below. 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.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Torisel is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Renal Cell Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has advanced disease; AND
 - C) Torisel will be used as a single-agent; AND
 - D) The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

12/11/2024

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2. **Endometrial Carcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has advanced, recurrent, metastatic, or inoperable disease; AND
 - C) Patient has ONE of the following (i or ii):
 - i. Endometrial carcinoma; OR
 - ii. Uterine perivascular epithelioid cell tumor (PEComa); AND
 - D) Torisel will be used as a single-agent; AND
 - E) The medication is prescribed by or in consultation with an oncologist.

3. **Soft Tissue Sarcoma.** Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has ONE of the following (i, ii, iii, or iv):
 - i. Perivascular epithelioid cell tumors (PEComas); OR
 - ii. Lymphangiomyomatosis; OR
 - iii. Recurrent angiomyolipoma; OR
 - iv. Non-pleomorphic rhabdomyosarcoma; AND
 - C) Patient meets ONE of the following (i or ii):
 - i. Torisel will be used as a single-agent; OR
 - ii. Torisel will be used in combination with cyclophosphamide and vinorelbine; AND
 - D) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Torisel is not recommended in the following situations:

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

1. Torisel[®] intravenous infusion [prescribing information]. Philadelphia, PA: Wyeth; April 2023.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2024.
3. The NCCN Kidney Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – September 6, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2024.
4. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (version 4.2024 – November 21, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2024.
5. The NCCN Uterine Neoplasms Clinical Practice Guidelines in Oncology (version 3.2024 – September 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 5, 2024.