**Drug Therapy Guidelines**

**Applicable**

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<th>Medical Benefit</th>
<th>Applicable*</th>
<th>Effective: 1/1/21</th>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 9/21</td>
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<td>Pharmacy- Formulary 2</td>
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<td>Date of Origin: 3/08</td>
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I. Medication Description

Temsirolimus is an inhibitor of mTOR (mammalian target of rapamycin). Temsirolimus binds to an intracellular protein (FKBP-12), and the protein-drug complex inhibits the activity of mTOR that controls cell division. Inhibition of mTOR activity resulted in a G1 growth arrest in treated tumor cells. When mTOR was inhibited, its ability to phosphorylate p70S6k and S6 ribosomal protein, which are downstream of mTOR in the PI3 kinase/AKT pathway was blocked. In in vitro studies using renal cell carcinoma cell lines, temsirolimus inhibited the activity of mTOR and resulted in reduced levels of the hypoxia-inducible factors HIF-1 and HIF-2 alpha, and the vascular endothelial growth factor.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every claim.

III. Policy

Coverage of Torisel or temsirolimus is available when the following criteria have been met:
- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

4 Torisel or temsirolimus kits per 30 days—each kit contains one 25mg/mL vial of temsirolimus.

V. Coverage Duration

Coverage is provided for up to 6 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread **AND**
- Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

- Pertinent diagnoses:
VIII. Summary of Policy Changes

- 9/1/11: Addition of Warnings/Contraindications and billing/coding information
- 9/15/12: Second-line therapy only applies to predominantly clear cell histology based on NCCN Compendia recommendations
- 9/15/13: Addition of related guidelines and removal of exclusions from policy criteria
- 9/15/14: Addition of coverage for endometrial adenocarcinoma and update of ICD10 coding
- 4/30/15: addition of criteria for coverage for soft tissue sarcomas
- 7/1/15: formulary distinctions made
- 12/15/15: updated coverage for endometrial cancers in accordance with current NCCN treatment guidelines
- 9/15/16: no policy changes
- 10/16/17: coverage criteria updated to allow use as supported by current NCCN guidelines
- 11/1/18: no policy changes
- 11/15/19: no policy changes
- 1/1/21: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.