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 for Torisel® is provided for the following:

- Relapsed or medically unresectable stage IV renal cell carcinoma:
  - First line therapy as a single agent OR
  - Subsequent therapy as a single agent in disease with predominant clear cell histology
- Endometrial cancers:
  - Adenocarcinoma as a single agent
  - Serous or clear cell adenocarcinoma/carcinosarcoma: adjuvant therapy as a single agent
- Soft Tissue Sarcoma (PEComa, recurrent angiomyolipoma, lymphangioleiomyomatosis): as a single agent.

IV. Quantity Limitations

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

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:
  - Advanced Renal Cell Carcinoma: C64.1, C64.2, C64.9, C65.1, C65.2, C65.9, Z85.528
  - Endometrial carcinoma: C54.1, C54.2, C54.3, C54.9, Z80.49
  - Soft Tissue Sarcoma: C49.8, C49.9, D49.2
- J9330: 1 billable unit = 1mg of temsirolimus

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

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.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

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.