Torisel® (temsirolimus)

Medical Guideline Disclaimer

All rights reserved. The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member’s benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and website links are accurate at time of publication. EmblemHealth Services Company LLC, (“EmblemHealth”) has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definition

Torisel (temsirolimus) binds with specific and high affinity to immunophilin FKBP-12. This complex inhibits the mammalian target of rapamycin (mTOR) kinase, which leads to G1 phase cell cycle arrest and significant reductions in tumor size, as well as preventing the enhanced angiogenesis that is associated with sporadic renal cell carcinoma and loss of von Hippel Lindau function.

Torisel (temsirolimus) is FDA approved for the treatment of advanced renal cell carcinoma. Non-FDA labeled indications include: Endometrial Cancer.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:
- 25 billable units per 7 days

I. INITIAL APPROVAL CRITERIA

TORisel may be considered medically necessary when any of the following selection criteria is met:

1. Renal Cell Carcinoma (RCC)
   a. First-line or subsequent therapy as a single agent for relapsed or medically unresectable stage IV clear cell histology disease AND with ≥3 high risk factors:
      i. Serum lactate dehydrogenase level (LDH) >1.5 times the upper limit of normal
      ii. Hemoglobin level below normal
      iii. Corrected serum calcium >10milligrams/deciliter (mg/dL)
      iv. Interval of less than a year from initial diagnosis
v. Karnovsky performance status of 60 or 70 (for ECOG conversion status, please see Appendix A).
vi. 2 or greater metastatic sites.

OR
b. First line or subsequent therapy as a single agent for relapsed or medically unresectable stage IV disease with non-clear cell histology

Limitations/Exclusions
Torisel is not considered medically necessary for when any of the following selection criteria is met:
1. The member has moderate to severe liver disease, bilirubin greater than 1.5 x ULN.
2. Torisel (temsirolimus) is being used without pretreatment medications (i.e. diphenhydramine).
3. Member has disease progression while taking Torisel (temsirolimus).
4. Torisel (temsirolimus) is being used concurrently with other chemotherapy.
5. Dosing exceeds single dose limit of Torisel (temsirolimus) 25 mg.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA
Patient continues to meet criteria in INITIAL APPROVAL CRITERIA.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal cell carcinoma, Advanced</td>
<td>25mg IV infused over 30 to 60 minutes once weekly until disease progression or unacceptable toxicity; premedicate with diphenhydramine 25 to 50mg IV 30 minutes prior to each dose</td>
</tr>
</tbody>
</table>

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9330</td>
<td>Injection, temsirolimus, 1 mg, 1 billable unit = 1 mg</td>
</tr>
</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>00008-1179-xx</td>
<td>Torisel 25 mg/ml injection</td>
</tr>
</tbody>
</table>

Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C49.8</td>
<td>Malignant neoplasm of overlapping sites of connective and soft tissue</td>
</tr>
<tr>
<td>C49.9</td>
<td>Malignant neoplasm of connective and soft tissue, unspecified</td>
</tr>
<tr>
<td>C54.0</td>
<td>Malignant neoplasm of isthmus uteri</td>
</tr>
<tr>
<td>C54.1</td>
<td>Malignant neoplasm of endometrium</td>
</tr>
<tr>
<td>C54.2</td>
<td>Malignant neoplasm of myometrium</td>
</tr>
<tr>
<td>C54.3</td>
<td>Malignant neoplasm of fundus uteri</td>
</tr>
<tr>
<td>C54.8</td>
<td>Malignant neoplasm of overlapping sites of corpus uteri</td>
</tr>
</tbody>
</table>
C54.9  Malignant neoplasm of corpus uteri, unspecified
C55  Malignant neoplasm of uterus, part unspecified
C64.1  Malignant neoplasm of right kidney, except renal pelvis
C64.2  Malignant neoplasm of left kidney, except renal pelvis
C64.9  Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1  Malignant neoplasm of right renal pelvis
C65.2  Malignant neoplasm of left renal pelvis
C65.9  Malignant neoplasm of unspecified renal pelvis
D49.2  Neoplasm of unspecified behavior of bone, soft tissue, and skin
Z80.49  Family history of malignant neoplasm of other genital organs
Z85.528  Personal history of other malignant neoplasm of kidney
Z85.831  Personal history of malignant neoplasm of soft tissue

References

2) Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) temsirolimus. National Comprehensive Cancer Network, 2019. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2019.