PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Ukoniq Prior Authorization Policy
- Ukoniq™ (umbralisib tablets – TG Therapeutics)

REVIEW DATE: 02/02/2022

OVERVIEW

Ukoniq, a phosphoinositide 3-kinase delta and casein kinase inhibitor, is indicated for the following uses:[1]

- **Follicular lymphoma**, in adults with relapsed or refractory disease who have received at least three prior lines of systemic therapy.
- **Marginal zone lymphoma**, in adults with relapsed or refractory disease who have received at least one prior anti-CD20-based regimen.

Both indications have been approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Guidelines

The National Comprehensive Cancer Network B-Cell Lymphomas treatment guidelines (version 5.2021 – September 22, 2021) recommend Ukoniq for the treatment of relapsed/refractory follicular lymphoma after three prior therapies.[2,3] NCCN also recommends Ukoniq for relapsed/refractory marginal zone lymphoma, and gastric and non-gastric mucosa-associated lymphoid tissue (MALT) lymphoma after at least one prior anti-CD20 monoclonal antibody-based regimen.

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Follicular Lymphoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has received at least three prior lines of systemic therapy.
     Note: Examples of systemic therapy include bendamustine + rituximab, CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CVP (cyclophosphamide, vincristine, prednisone), and Revlimid (lenalidomide capsules) + rituximab.

2. **Marginal Zone Lymphoma.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND

B) Patient has received at least one prior anti-CD20-based regimen.
Note: Examples of anti-CD20-based therapy include rituximab, rituximab + Revlimid (lenalidomide capsules), and Gazyza (obinutuzumab intravenous infusion) + bendamustine.

Other Uses with Supportive Evidence

3. Mucosa-Associated Lymphoid Tissue (MALT) Lymphoma. Approve for 3 years if the patient meets the following criteria (A, B, and C):
A) Patient is ≥ 18 years of age; AND
B) Patient meets one of the following (i or ii):
i. Patient has gastric MALT; OR
ii. Patient has non-gastric/non-cutaneous MALT; AND
C) Patient has received at least one prior anti-CD20-based regimen.
Note: Examples of anti-CD20-based therapy include rituximab, rituximab + Revlimid (lenalidomide capsules), and Gazyza (obinutuzumab intravenous infusion) + bendamustine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ukoniq 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. Ukoniq™ tablets [prescribing information]. Edison, NJ: TG Therapeutics; February 2021.
2. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2021 – September 22, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 24, 2022.
3. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed January 24, 2022. Search term: umbralisib.