VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 02/10/2021

OVERVIEW

Ukoniq, a phosphoinositide 3-kinase delta (PI3Kδ) and casein kinase (CK1ε) 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

Ukoniq is not addressed in the National Comprehensive Cancer Network treatment guidelines.

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 the following criteria:

FDA-Approved Indications

1. **Follicular Lymphoma.** Approve for 1 year 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 capsule) + rituximab.

2. **Marginal Zone Lymphoma.** Approve for 1 year 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 includes rituximab, rituximab + Revlimid® (lenalidomide capsule), and Gazyva® (obinutuzumab injection for intravenous use) + 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	02/10/2021