Generic Name: Umbralisib

Therapeutic Class or Brand Name: Ukoniq®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 21533080400320

Preferred: N/A

Non-preferred: N/A

Date of Origin: 3/8/2021

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I-IV are met)

I. Documented diagnosis of one of the following conditions A or B and must meet criteria listed under applicable diagnosis:

A. Marginal Zone Lymphoma

1. Adult patients with a diagnosis of relapsed or refractory marginal zone lymphoma.
2. Received at least one prior anti-CD20-based regimen.

B. Follicular Lymphoma

1. Adult patients with a diagnosis of relapse or refractory follicular lymphoma
2. Received at least three prior lines of systemic therapy.

II. Received prophylaxis for Pneumocystis jirovecii pneumonia (PJP) during treatment with UKONIQ

III. Age ≥ 18 years old.

IV. Prescribed by or in consultation with an oncologist.

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Consider prophylactic antivirals during treatment with UKONIQ to prevent cytomegalovirus (CMV) infection, including CMV reactivation.
- Provide prophylaxis for Pneumocystis jirovecii pneumonia (PJP) during treatment with UKONIQ. Withhold UKONIQ in patients with suspected PJP (Pneumocystis jirovecii pneumonia) of any grade and permanently discontinue in patients with confirmed PJP.
- Infections: Monitor for fever and any new or worsening signs and symptoms of infection. Evaluate promptly and treat as needed.

- Neutropenia: Monitor neutrophil counts at least every 2 weeks for the first 2 months of UKONIQ and at least weekly in patients with neutrophil counts <1 ×109/L (Grade 3-4). Withhold, reduce dose, or discontinue UKONIQ depending on the severity and persistence of neutropenia.
- Diarrhea or Non-infectious colitis: Monitor for the development of diarrhea or colitis and provide supportive care as appropriate.
- Hepatotoxicity: Monitor hepatic function at baseline and during treatment with UKONIQ. For ALT/AST greater than 5 to less than 20 times ULN, withhold UKONIQ until return to less than 3 times ULN, then resume at a reduced dose. For ALT/AST elevation greater than 20 times ULN, discontinue UKONIQ.
- Severe cutaneous reactions: Withhold treatment, reduce dose, or discontinue treatment depending on severity and persistence of severe cutaneous reaction.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 200 mg tablets: Up to 120 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** 1 year, an updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

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REFERENCES

1. Ukoniq® (umbralisub) [package insert]. Edison, NJ: TG Therapeutics, Inc., February 2021. Available at: https://tgtherapeutics.com/prescribing-information/uspi-ukon.pdf.
2. Medispan.
3. NCCN Guidelines Version 2.2021 – B-Cell Lymphoma https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf.