Reference number(s)
4501-A

SPECIALTY GUIDELINE MANAGEMENT

UKONIQ (umbralisib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Marginal Zone Lymphoma (MZL)
      Ukoniq is indicated for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior anti-CD20-based regimen.

   2. Follicular Lymphoma (FL)
      Ukoniq is indicated for the treatment of adult patients with relapsed or refractory FL who have received at least three prior lines of systemic therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

A. Marginal Zone Lymphoma (MZL)
Authorization of 12 months may be granted for treatment of relapsed or refractory MZL in members who have received at least one prior anti-CD20-based regimen (e.g., rituximab, obinutuzumab) when the requested medication is used as a single agent.

B. Follicular Lymphoma (FL)
Authorization of 12 months may be granted for treatment of relapsed or refractory FL in members who have received at least three prior lines of systemic therapy when the requested medication is used as a single agent.

III. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section II when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

IV. REFERENCES

1. Ukoniq [package insert]. Edison, NJ: TG Therapeutics, Inc.; February 2021.