Clinical Policy Title:	umbralisib
Policy Number:	RxA.680
Drug(s) Applied:	Ukoniq™
Original Policy Date:	06/10/2021
Last Review Date:	06/10/2021
Line of Business Policy Applies to:	All lines of business

Background

Ukoniq™ is a kinase inhibitor indicated for the treatment of adult patients with:

- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen.
- Relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Umbralisib (Ukoniq™)	MZL	800 mg orally once daily with food	800 mg/day
	FL		

Dosage Forms

- Tablets: 200 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the provisions of the pharmacy benefit administer by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Marginal Zone Lymphoma (MZL) (must meet all):

1. Diagnosis of relapsed or refractory MZL;
2. Member has received at least one prior anti-CD20-based regimen (e.g. rituximab);
3. Prescribed by or in consultation with an oncologist;
4. Member age is ≥ 18 years;
5. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 800 mg per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration

Commercial: 3 months
Medicaid: 3 months

B. Follicular Lymphoma (FL) (must meet all):
1. Diagnosis of relapsed or refractory FL;
2. Member has received at least THREE prior systemic therapies, including an anti-CD20 monoclonal antibody and an alkylating agent (e.g. bendamustine + rituximab);
3. Prescribed by or in consultation with an oncologist;
4. Member age is ≥ 18 years;
5. If request is for a dose increase, request meets one of the following (a or b):*
   c. New dose does not exceed 800 mg per day;
   d. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration
Commercial: 3 months
Medicaid: 3 months

II. Continued Therapy Approval

B. All Indications in Section I (must meet all)**:**
1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 800 mg per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration
Commercial: 6 months
Medicaid: 6 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FL: follicular lymphoma
MZL: marginal zone lymphoma
NCCN: National Comprehensive Cancer Network
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
None.

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - None.
- Boxed Warning(s):
  - None.

APPENDIX D: General Information
None.

References

1. Ukoniq™ Prescribing Information. TG Therapeutics, Inc., February 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/213176s000lbl.pdf. Accessed April 26, 2021.
2. Umbralisib, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed April 26, 2021.
3. National Comprehensive Cancer Network. B-Cell Lymphomas Version 3.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Updated March 16, 2021. Accessed April 26, 2021.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	06/10/2021	06/10/2021