Clinical Policy Title:	acalabrutinib
Policy Number:	RxA.054
Drug(s) Applied:	Calquence®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Clinical Policy

I. Initial Approval Criteria

A. Mantle Cell Lymphoma (MCL) (must meet all)**:**

1. Diagnosis of MCL;
2. Used as a single-agent, second-line therapy;
3. Member has received at least 1 prior therapy;
4. If refractory to Imbruvica® (member previously used Imbruvica® and remission was not achieved or disease stopped responding), member does not have a BTK C481S mutation.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (must meet all):

1. Diagnosis of CLL or SLL;
2. Calquence® is prescribed in one of the following ways (a or b):*
   a. First-line therapy as a single agent or in combination with Gazyva®;
   b. Subsequent therapy as a single agent for relapsed or refractory disease, and (i and ii):
      i. Member has received ≥ 1 prior therapy;
      ii. If refractory to Imbruvica (member previously used Imbruvica and remission was not achieved or disease stopped responding), member does not have a BTK C481S mutation.

   *Prior authorization may be required.

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma (off-label use) (must meet all):

1. Diagnosis of Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma;
2. Prescribed as a single agent therapy as alternative therapy for previously treated disease that does not respond to primary therapy or for progressive or relapsed disease.

Approval Duration

All Lines of Business (except Medicare): 6 months

D. B-Cell Lymphomas (off-label use) only for capsule (must meet all):

1. Diagnosis of one of the following (a, b, c or d):
   a. Nodal Marginal Zone Lymphoma;

b. Gastric MALT Lymphoma;
c. Splenic Marginal Zone Lymphoma;
d. Non-gastric MALT Lymphoma (non-cutaneous).
2. Disease is recurrent, relapsed, refractory, or progressive;
3. Member has received at least 1 prior therapy;
4. Patient has an intolerance or contraindication to Imbruvica®.

Approval Duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**
1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. B-cell Lymphomas Version 3.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. CLL/SLL. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title Table updated. 2. Line of Business Policy Applies to was updated to “All lines of business”. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance”. 4. References were reviewed and updated. 5. Added initial approval criteria for Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma per NCCN 2A recommendation.	10/26/2020	12/07/2020
Policy was reviewed: 1. Initial Approval Criteria I.A.5.a and I.B.6.a was updated from “400 mg (4 capsules)” to “200 mg (2 capsules)”. 2. Initial Approval Criteria I.B.4 was updated to include new criteria “ Member meets one of the following..”. 3. Initial Approval Criteria I.D was updated to include a new off label indication “B-Cell Lymphomas”. 4. Continued Therapy Approval II.3.a was updated from	09/25/2021	12/07/2021

"400 mg (4 capsules)" to "200 mg (2 capsules)". 5. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria I.A.1.: Updated diagnosis criteria from Diagnosis of MCL as a single-agent, second line therapy to Diagnosis of MCL. 2. Initial Approval Criteria I.A.2.: Updated to include therapy criteria 'Used as a single-agent, second-line therapy' which is separated from I.A.1. 3. Initial Approval Criteria, I.A.7.a, I.B.5.a: Updated dosing criteria from dose does not exceed 200 mg (2 capsules) per day to dose does not exceed 400 mg per day. 4. Initial Approval criteria I.A.6: Updated to include criteria for mutation 'If refractory to Imbruvica® (member previously used Imbruvica and remission was not achieved or disease stopped responding), member does not have a BTK C481S mutation'. 5. Initial Approval Criteria I.B.2 removed and merged with I.B.5 as Calquence® is prescribed in one of the following ways (a or b):* a. First-line therapy as a single agent or in combination with Gazyva®; b. Subsequent therapy as a single agent for relapsed or refractory disease, and (i and ii): i. Member has received ≥ 1 prior therapy (see Appendix B); ii. If refractory to Imbruvica (member previously used Imbruvica and remission was not achieved or disease stopped responding), member does not have a BTK C481S mutation; *Prior authorization may be required 6. Initial Approval Criteria, I.D.5: Updated to include new prior treatment criteria Member has received ≥ 1 prior therapy. 7. Initial Approval Criteria, I.C.5.a and I.D.6.a: Updated to include new dosing criteria dose does not exceed 400 mg per day. 8. Continued Therapy Approval Crtieria, II.A.3.a: Updated dosing criteria from new dose does not exceed 200 mg (2 capsules) per day to dose does not exceed 400 mg per day. 9. References were reviewed and updated.	09/15/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023

Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024