Clinical Policy Title:	acalabrutinib
Policy Number:	RxA.054
Drug(s) Applied:	Calquence®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of MCL;
2. Used as a single-agent, second-line therapy;
3. Prescribed by or in consultation with an oncologist or a hematologist;
4. Age ≥ 18 years;
5. Previously received at least one prior therapy;
6. 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;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 400 mg per day;
   b. 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

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

1. Diagnosis of CLL or SLL;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. 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
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 400 mg per day;
   b. 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

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

1. Diagnosis of Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma;
2. Prescribed by or in consultation with an oncologist or a hematologist;
3. Age ≥ 18 years;
4. 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;
5. Request meets one of the following (a or b):*
   a. Dose does not exceed 400 mg per day;
   b. Dose is within FDA-approved maximum limit for an FDA approved indication or 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

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. Prescribed by or in consultation with an oncologist or a hematologist;
4. Age ≥ 18 years;
5. Member has received ≥ 1 prior therapy;
6. Patient has an intolerance or contraindication to Imbruvica®;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 400 mg per day;
   b. Dose is within FDA-approved maximum limit for an FDA approved indication or 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

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving acalabrutinib (Calquence®) for a covered indication and has received this medication for at least 30 days;

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 400 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: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. B-cell Lymphomas Version 5.2021. Available at https://www.nccn.org/professionals/physician_gls/pdf/b-cell_blocks.pdf. Accessed September 15, 2022.
2. National Comprehensive Cancer Network. Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf. Accessed September 15, 2022.
3. National Comprehensive Cancer Network. CLL/SLL. Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf . Accessed September 15, 2022.

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 "400 mg (4 capsules)" to "200 mg (2 capsules)". 5. References were reviewed and updated.	09/25/2021	12/07/2021

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