PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

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CALQUENCE® (acalabrutinib) oral capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

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Criteria:

- **Criteria for initial therapy:** Calquence (acalabrutinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of **ONE** of the following:
     a. Mantle cell lymphoma (MCL) in those who have received at least one therapy
     b. Chronic Lymphocytic Leukemia (CLL) or Small Lymphocytic Lymphoma (SLL)
     c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Calquence (acalabrutinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist
  2. Individual's condition has not worsened while on therapy
     a. Worsening is defined as:
        i. Cancer progression
  3. Individual has been adherent with the medication
  4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
     a. Significant adverse effect such as:
        i. Hemorrhage
        ii. Thrombocytopenia/neutropenia
        iii. Progressive multifocal leukoencephalopathy (PML)
  5. There are no significant interacting drugs

  Renewal duration: 12 months

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Description:

Calquence (acalabrutinib) is a bruton tyrosine kinase inhibitor (BTKI) indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Bruton tyrosine kinase (BTK) is a signaling molecule that activates B-cell proliferation, trafficking, chemotaxis, and adhesion. Calquence (acalabrutinib) binds with BTK active site, leading to inhibition of BTK enzymatic activity.

Background:

- Mantle cell lymphoma (MCL) is a rare, fast growing form of mature B-cell non-Hodgkin lymphomas (NHL)
- MCL has been previously referred to as intermediate lymphocytic lymphoma, mantle zone lymphoma, centrocytic lymphoma, and lymphocytic lymphoma of intermediate differentiation
- MCL encompasses approximately 3-10% of adult NHLs in the US
- The histologic pattern of MCL may be diffuse, nodular, or mantle zone, or a combination
- The course of MCL is moderately aggressive and variable
- Most patients present with advanced stage disease with disease spread to lymph nodes, bone marrow, and other organs
- Combination chemotherapy plus immunotherapy remains the main treatment modality with or without high-dose therapy and autologous hematopoietic cell transplantation
- Initially, all patients with MCL should receive rituximab in addition to chemotherapy
- A number of treatment regimens have been evaluated in patients with recurrent or refractory MCL
- Choice is primarily made based on the patient's prior treatment, comorbidities and performance status, expected toxicities, and the clinician's experience with the regimens.

Usual Therapy:

National Comprehensive Cancer Network Guideline: B-Cell Lymphoma version 7.2017 (12/05/2017)
Category 2A suggested regimens, unless otherwise stated (alphabetical order)

Aggressive therapy:

- CALGB (treatment 1, 2, 2.5: rituximab, methotrexate with augmented CHOP, treatment 3: etoposide, cytarabine, rituximab, treatment 4: carmustine, etoposide, cyclophosphamide/autologous stem cell rescue, treatment 5: rituximab maintenance) Treatment 2.5 is given if the pre-treatment bone marrow biopsy contains > 15% MCL)

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- HyperCVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone alternating with high-dose methotrexate and cytarabine) + rituximab
- NORDIC (dose-intensified induction immunochemotherapy with rituximab, cyclophosphamide, vincristine, doxorubicin, prednisone [maxi-CHOP]) alternating with rituximab, high-dose cytarabine)
- Alternating RCHOP / RDHAP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) / (rituximab, dexamethasone, cisplatin, cytarabine)
- RDHAP (oxaliplatin or carboplatin can be used instead of cisplatin)
- Sequential RCHOP / RICE (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) / (rituximab, ifosfamide, carboplatin, etoposide)

Less aggressive therapy:
- Bendamustine + rituximab
- VR-CAP (bortezomib, rituximab, cyclophosphamide, doxorubicin, prednisone)
- CHOP + rituximab
- Lenalidomide + rituximab
- Modified rituximab-HyperCVAD in patients > 65 years (rituximab + ibrutinib can be used as a pre-treatment to limit the number of cycles of RHyperCVAD/rituximab maintenance)

First-line consolidation candidate for HDT/ASCR:
- High-dose therapy with autologous stem cell rescue + rituximab maintenance (category 1 for rituximab maintenance)

First-line consolidation not a candidate for HDT/ASCR:
- Rituximab maintenance (category 1 following RCHOP)

Second-line therapy:
- Acalabrutinib
- Bendamustine ± rituximab
- Bortezomib ± rituximab
- Cladribine + rituximab
- Ibrutinib
- Lenalidomide ± rituximab
- Venetoclax

Second-line consolidation:
- Allogeneic stem cell transplant (non-myeloablative or myeloablative)

Resources:

Calquence (acalabrutinib) product information, revised by AstraZeneca Pharmaceuticals, LP. 11-2019, at DailyMed http://dailymed.nlm.nih.gov accessed January 30, 2021.

Calquence (acalabrutinib). National Comprehensive Cancer Network (NCCN). NCCN Drugs & Biologics Compendium. 2021; Available at: http://www.nccn.org. Accessed January 30, 2021.

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Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.