

CALQUENCE[®] (acalabrutinib)

Digital Access and Reimbursement Guide



*Helping Patients
Access the Care
They Need*

INDICATIONS AND USAGE

CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor 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.

CALQUENCE is also indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

Please see Important Safety Information on pages 18-19 and full [Prescribing Information](#), including [Patient Information](#).

Welcome to the AstraZeneca Access 360™ Program!

The AstraZeneca Access 360™ program provides personal support to help streamline access and reimbursement for CALQUENCE. Access 360 provides:

- ✓ Assistance with understanding patient insurance coverage and pharmacy options
- ✓ Prior authorization (PA) support
- ✓ Claims and appeals process support
- ✓ Eligibility requirements and enrollment assistance with AstraZeneca's Co-pay Savings Programs
- ✓ Access to the AZ&Me™ Prescription Savings Program, AstraZeneca's patient assistance program
- ✓ Information about independent charitable patient assistance foundations

This guide contains information to help you and your office staff understand the access and reimbursement process and provides links to additional Access 360 resources.

This description of the Access 360 program is for informational purposes only. Access 360 does not file claims or appeals on behalf of healthcare providers (HCPs) or patients and makes no representation or guarantee concerning reimbursement or coverage for any service or item.

Your Field Reimbursement Manager

AstraZeneca Field Reimbursement Managers (FRMs) are a resource for patients, HCPs, and office staff. FRMs provide regional, patient-specific support and have extensive expertise that can help streamline access and reimbursement for select AstraZeneca medicines.

Your FRM can provide:



Access and reimbursement support for providers and office staff, onsite or via telephone*



Personalized support to help connect patients to affordability programs



Resources to educate providers and office staff about support services offered by AstraZeneca Access 360™



Timely responses to questions about access and reimbursement



Access to innovative technology resources such as the Access 360™ Provider Portal

For more information, call AstraZeneca Access 360™ at **1-844-ASK-A360**, Monday through Friday, 8 AM to 6 PM ET.



1-844-ASK-A360 (1-844-275-2360)



www.MyAccess360.com



1-844-FAX-A360 (1-844-329-2360)



Access360@AstraZeneca.com



One MedImmune Way, Gaithersburg, MD 20878

*Please note that FRMs are not able to file claims on behalf of providers or office staff.

HCP=healthcare provider.

Contents of This Guide and Overview of Key Steps*

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CALQUENCE Enrollment Form

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Access 360 conducts benefits investigation and completes PA research

CALQUENCE Affordability Resources



Access 360 submits prescription to SPP

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HCP submits PA

Prior Authorization and Appeal Checklists



SPP supports office with submitted PA

Peer-to-Peer Resource



SPP communicates approval†



Authorization/Delivery

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SPP contacts patient to discuss co-pay, if applicable

CALQUENCE Distribution Card



Payment authorization; SPP schedules delivery



Medication is delivered to patient

*Please note that patient and/or HCP attestation/consent may be required.

†If PA is denied, Access 360 can assist with appeals support.

HCP=healthcare provider; PA=prior authorization.

CALQUENCE[®] (acalabrutinib) Enrollment Form



The CALQUENCE Enrollment Form is used to capture necessary patient, provider, and prescription information to start a new request for support from Access 360. We recommend that you and your patient fill out this form so your patient can enroll in Access 360. The patient and the provider are each responsible for completing their designated sections of this form.

To download the Enrollment Form from [MyAccess360.com](https://myaccess360.com), click [here](#).

SERVICES REQUESTED

This section allows the office to specify which services Access 360 completes.

PATIENT SIGNATURE

This section is for the patient to complete in the office. The first signature will progress the level of support Access 360 can provide. The second signature allows Access 360 to enroll the patient into the Co-Pay Savings Program (eligibility rules apply) and send the patient treatment information.

HCP SIGNATURE

This signature allows Access 360 to complete initial research for the requested services. The signature can be provided by the prescribing physician, office staff, or practice manager.

AstraZeneca Access 360[™] Enrollment Form

Services Requested (check only those that apply)

☐ Benefit Investigation, Prior Authorization Support, and Pharmacy Coordination (Please check "On-Site Dispensing" in Section 5 if the prescription will be filled at an in-office pharmacy)

☐ Co-Pay Support (Note: You may also visit www.calquenceaccess360.com for direct enrollment into the CALQUENCE Patient Savings Program) (Eligibility rules apply)

☐ Appeals Support (Please attach a copy of the denial letter)

To enroll in AZMe[™] (Patient Assistance Program), visit www.azandmeapp.com. (Eligibility rules apply)

Please complete form, sign, and fax all pages to 1-844-329-2360.
For questions or assistance, please call Access 360, Monday through Friday, 8 a.m. – 8 p.m. at 1-844-275-2360.

1 Patient Information

First Name: _____ Last Name: _____ Patient DOB: ____/____/____ Gender: ☐ M ☐ F

Street: _____ City: _____ State: _____ ZIP: _____

Preferred Phone #: ☐ Home ☐ Mobile _____ Patient Email: _____

Alternate Contact Name: _____ Relationship to Patient: _____

Alternate Contact Phone #: _____ Patient preferred language (if other than English): _____

Okay to contact patient? ☐ Yes ☐ No Okay to leave a detailed voicemail? ☐ Yes ☐ No

Patient Authorization
I have read and agree to the Patient Authorization included on page 2

Support Programs (Savings Program and Additional Services)
I have read and agree to the Support Programs Authorization included on page 2

Patient Signature/Legal Representative MM DD YYYY
Printed Name/Relationship to Patient (if applicable) _____

Patient Signature/Legal Representative MM DD YYYY
Printed Name/Relationship to Patient (if applicable) _____

2 Insurance Information Please include front and back copies of all medical and pharmacy cards or complete this section.

☐ Commercial/Private Insurance ☐ Medicare/Medicaid/Tricare ☐ No Insurance

	Pharmacy Insurance	Primary Medical Insurance	Secondary Medical Insurance
Insurance Provider			
Insurance Phone #			
Cardholder Name (if not the patient)			
Cardholder DOB			
Policy #			
Group #			
BNVPCN		X	X

By signing this form, I certify that (1) I have received the necessary authorization to release the information included on this form and other related Protected Health Information (as defined by HIPAA) to AstraZeneca Access 360 including employees, contractors, or affiliates of AstraZeneca, and health care plans for programs, dispensing pharmacy(ies) or other entities for the purposes of treatment and payment support, and (2) I have obtained any necessary authorization to allow AstraZeneca Access 360 to contact the patient or caregiver, if not included with this submission to obtain a signed Patient Authorization.

HCP Name: _____

HCP Signature: _____ Date: _____

Please complete form, sign, and fax all pages to 1-844-329-2360.

All sections of the enrollment form, with the exception of the patient authorization, can be completed by an authorized HCP who can either:

- Download and print the enrollment form [here](#). Once signed, fax the document to Access 360. This form will also need to be signed by the patient.
- Complete the form electronically through the HCP portal [here](#).

HCP=healthcare provider.

If patient or legally authorized representative is unable to sign the enrollment form, they can instead:

- Submit signature electronically at www.MyAccess360.com.
- Download and print the patient authorization form [here](#). Once signed, fax the document to Access 360.
- Call Access 360 to provide verbal authorization (1-844-275-2360).

CALQUENCE[®] (acalabrutinib) Enrollment Form (cont'd)



To download the Enrollment Form from MyAccess360.com, click [here](#).

PATIENT AUTHORIZATION AND SUPPORT PROGRAMS (PAGE 2)

This page outlines the authorization of the patient to release specific personal information to Access 360 and explains available support options for covering the cost of their medication, if necessary.

AstraZeneca Access 360[™] Enrollment Form

Patient Authorization

I authorize my health care providers (HCPs) and staff, my health plan, and my pharmacies to use and share Protected Health Information (my "Information") with AstraZeneca (including AstraZeneca Access 360) and its affiliates, as well as its contractors ("AstraZeneca"). My Information includes my prescription-related health records, Information about my health care plan benefits, demographic, contact, and any other Information bearing on my health. My Information may be used to verify treatment and payment.

AstraZeneca Access 360[™] Enrollment Form

Patient First Name: _____ Patient Last Name: _____ Patient DOB: ____/____/____

3 Provider Information Prescriber Name: _____ Specialty: _____
Practice Name: _____ Office Contact Name: _____
Street: _____ City: _____ State: _____ ZIP: _____
Phone #: _____ Fax #: _____ Email: _____
Prescriber NPI #: _____ Tax ID #: _____
PTAN: _____ Other Provider ID (if applicable): _____ Alternate Office Contact Name: _____
Alternate Office Contact Phone #: _____ Alternate Office Contact Email: _____

4 Clinical Information

Diagnosis ICD-10-CM code(s): _____
Description: _____

5 Acquisition Information (Choose One)

☐ On-Site Dispense (Prescription information does not need to be completed)
☐ Specialty Pharmacy Provider (SPP) (Please select preferred SPP and complete prescription below)

Specialty Pharmacy Provider (SPP)

☐ BIOLOGICS ☐ ONCO360 ☐ No Preference¹

¹If you have questions about in-network SPP(s) for your patient, contact Access 360 at 1-844-275-2360. By choosing "No Preference," the SPP will be chosen based on the results of a Benefit Investigation.

CALQUENCE[®] (acalabrutinib)

100-mg tablets Quantity: _____
Refills: _____
Dose instructions: _____

☐ **Optional: Free Limited Supply (FLS) Request**
Free Limited Supply is available for eligible patients who face a delay in approval by their insurance company for CALQUENCE.

CALQUENCE[®] (acalabrutinib)

100-mg tablets Quantity: _____
Dose instructions: _____

I authorize Access 360 program to convey the attached prescription on my behalf to the pharmacy chosen above and to receive information on the status and related matters. By signing below, I certify that the medicine prescribed on this form is medically necessary based on my independent medical judgment, and I have received the necessary authorization to release the information included on this form and other Protected Health Information (as defined by HIPAA) to Access 360, the dispensing pharmacy, or other contractors for the purpose of seeking reimbursement or assisting in initiating or continuing therapy. Each practitioner is solely responsible for ensuring the accuracy of the information submitted.

Prescriber Name: _____
Prescriber Signature: _____ Date: _____

Once completed and signed, fax this form to 1-844-329-2360. You may need to provide additional information depending on the type of support requested.

1-844-ASK-A360 (1-844-275-2360) 1-844-FAX-A360 (1-844-329-2360) www.MyAccess360.com
Access360@AstraZeneca.com One Medimmune Way, Gaithersburg, MD 20878

AstraZeneca

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PROVIDER INFORMATION

The phone number, fax number, and email can refer directly to the office contact's information. Providing this information may help facilitate communications with Access 360.

PRESCRIPTION INFORMATION

This section requires you to provide detailed information about the prescription, such as product dose.

This section may also include information regarding the **Free Limited Supply (FLS) Request**, which applies to select AstraZeneca medications. If applicable, completing this section may allow a limited supply of free medication for patients (eligibility rules apply).

PRESCRIBER SIGNATURE

This section must be signed by the prescriber if this form is being used to fill a prescription. For faxing purposes, this page can be detached from the form.

CALQUENCE[®] (acalabrutinib) Coding Resource



It is important to note that the codes identified in this resource are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of these codes does not guarantee reimbursement.

To download the Coding Resource from MyAccess360.com, click [here](#).

National Drug Code (NDC)¹

10-digit NDC

Dosage	Code
100 mg TABLETS – 60 ct bottle	0310-3512-60

11-digit NDC

Dosage	Code
100 mg TABLETS – 60 ct bottle	00310-3512-60

Mantle Cell Lymphoma Diagnosis Codes²

ICD-10-CM	Description
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face, and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

CALQUENCE® (acalabrutinib) Coding Resource (cont'd)



▼ To download the Coding Resource from MyAccess360.com, click [here](#).

Personal History of Drug Therapy²

ICD-10-CM	Description
Z92.21	Personal history of antineoplastic chemotherapy
Z92.22	Personal history of monoclonal drug therapy

Chronic Lymphocytic Leukemia Diagnosis Codes²

ICD-10-CM	Description
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse

Small Cell B-cell Lymphoma Diagnosis Codes²

ICD-10-CM	Description
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites

ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

It is important to note that the codes identified in this resource are examples only. Each provider is responsible for ensuring all coding is accurate and documented in the medical record based on the condition of the patient. The use of these codes does not guarantee reimbursement.

CALQUENCE[®] (acalabrutinib) Affordability Resources

One of the goals of Access 360 is to connect patients to appropriate affordability programs. Below is information regarding the Patient Savings Program and other independent foundations, including eligibility requirements.



 To learn more about affordability options for patients who are prescribed CALQUENCE, click here.

Co-pay Savings Program

For eligible commercially insured patients

CALQUENCE Co-pay Savings Program

The goal of the CALQUENCE Co-pay Savings Program is to assist eligible commercially insured patients with their out-of-pocket costs for CALQUENCE.

Most eligible patients will pay as little as \$0 per month to assist with CALQUENCE out-of-pocket costs. There are no income requirements to participate in the program.

For additional information, please visit www.azpatientsupport.com or call Access 360 at **1-844-ASK-A360** (1-844-275-2360).

Eligibility Requirements:

- Must be a resident of the United States or Puerto Rico
- Patients must have commercial health insurance that covers medication costs for CALQUENCE, but not the full cost to the patient

Patients are ineligible if prescriptions are paid for by any state or other federally funded programs, including, but not limited to, Medicare Part B, Medicare Part D, Medicaid, Medigap, VA or TRICARE, or where prohibited by law. Eligibility rules apply. Additional restrictions may apply.

The CALQUENCE Co-pay Savings Program covers the cost of the drug and administration, but does not cover costs for office visits or any other associated costs.

Offer is invalid for claims and transactions more than 365 days from the date of service.

CALQUENCE[®] (acalabrutinib) Affordability Resources (cont'd)

AZ&Me[™]

The AZ&Me Prescription Savings Program provides AstraZeneca medicines at no cost to qualifying patients.



Who can apply?

- People without health insurance
- Medicare Part D and/or B recipients
- Those who have recently experienced a financial crisis
- Residents of the United States



<https://www.azandmeapp.com/>



Other Resources for Patients Requiring Additional Assistance

AstraZeneca Access 360[™] can provide information about independent foundations that may be able to assist with out-of-pocket costs.

- Access 360 does not guarantee support by independent foundations. Each foundation sets its own eligibility requirements and support determinations



To learn more about this affordability option, click [here](#).



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Technology Resources

These technology resources are designed to help you manage your patients' care and may help streamline access to CALQUENCE. Below is an overview of the different portals that are available to you (including the Access 360 Provider Portal).

Dial by Extension and Access 360 Email



Dial by Extension allows providers to connect directly with their Access 360 Reimbursement Counselors. Currently, the dial-in line may result in some delays for providers and/or patients.

- Skip the phone menu and speak to or leave a message for the same Reimbursement Counselor every time you call by dialing **1-844-275-2360** and selecting your counselor's extension



Access 360 Email allows HCPs to send emails directly to Access 360.

- Send questions to the Access 360 team via email at **Access360@AstraZeneca.com***
- We will respond to your email promptly

Access 360 Provider Portal



The Access 360 Provider Portal simplifies the process for providers to manage access to select AstraZeneca medicines for patients online.

The portal:

- Makes it easy for you to enroll and track patient status from one location (only for Access 360 programs)
- Helps you access and enroll in affordability programs
- Contains advanced features, such as customizable alerts and multiple location access points
- Allows you to submit PA requests to any payer
- Notifies providers of real-time alerts and patient status updates



<https://www.myaccess360.com/calquence-acalabrutinib/access-360-portal.html>



*Protected health information should not be included in any email communications.

HCP=healthcare provider; PA=prior authorization.

Technology Resources (cont'd)

CoverMyMeds[®]

The CoverMyMeds Portal* allows pharmacists and providers to initiate, transmit, and track the status of PA requests and to enroll in drug manufacturer resources, including Access 360.

The CoverMyMeds portal offers:

- Ease in finding the correct PA request
- Ability to submit PA requests to any payer and often receive real-time determinations
- Access to drug-specific financial assistance and support programs with the enrollment process for Access 360 directly incorporated

Beyond the all-payer portal solution, CoverMyMeds is also integrated into 75% of EHR systems, offering electronic PA services within workflow.



covermymeds.com

covermymeds[®] | CoverMyMeds[®] Portal



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*Available for select AstraZeneca medicines.

EHR=electronic health record; EMR=electronic medical record; PA=prior authorization.

Technology Resources (cont'd)

AstraZeneca Specialty Savings Portal

The goal of affordability programs is to make every attempt to remove cost as a barrier for patients gaining access to necessary AstraZeneca medications.

To assist with out-of-pocket costs, Patient Savings Programs are available for eligible commercially insured patients for select AstraZeneca specialty medications.

For eligibility criteria and additional information, please visit www.azpatientsupport.com or call Access 360 at **1-844-ASK-A360** (1-844-275-2360).

The AstraZeneca Specialty Patient Savings Enrollment portal offers these benefits for providers:

- Upon successful registration into the Patient Savings Program, providers can enroll patients and have access to immediate co-pay support for eligible, commercially insured patients
- Provides product-specific online enrollment, claims submission, and reimbursement capabilities for personnel managing patient co-pay programs
- Serves as a one-stop shop for managing multiple patients, including claims status, balance information, and contact information for support



AstraZeneca Specialty Savings Portal



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Prior Authorization and Appeal Checklists

The Prior Authorization and Appeal Checklists are designed to help simplify the PA and denial/appeal processes and should be used as a reference to ensure you have all the necessary items prior to submitting a PA or an appeal. The PA Checklist should be used after you have enrolled your patient but before you have submitted the PA to their insurance. The Appeal Checklist should be used if the PA was denied.



▼ To download Prior Authorization and Appeal Checklists from MyAccess360.com, click [here](#).

PA Checklist

The items below may be necessary to obtain a PA decision from a health plan. Please ensure you have all information below prior to submitting the PA.

☐ Completed PA request form (some health plans require specific forms)

Include the following:

- ☐ Patient name, insurance policy number, and date of birth
- ☐ Patient diagnosis (ICD-10 code[s])
- ☐ Physician name and tax ID number
- ☐ Relevant procedure and HCPCS codes for services/products to be performed/provided
- ☐ Facility name and tax ID number
- ☐ Product NDC
- ☐ Date of service
- ☐ Setting of care

☐ Letter of medical necessity and relevant clinical support

- ☐ Include the Provider ID number in the letter



▼ To view a sample Letter of Medical Necessity template on MyAccess360.com, please click [here](#).

☐ Documentation that supports the treatment decision, such as:

- ☐ Previous treatments/therapies
- ☐ Patient-specific clinical notes detailing the relevant diagnosis
- ☐ Relevant laboratory results
- ☐ Product Prescribing Information

PA requirements vary by health plan and may require preapproval. Please contact the patient's health plan for specific PA requirements to ensure efficient and timely review. Failure to obtain a PA can result in nonpayment by the plan.*

Prior to submission, please keep track of dates and methods of correspondence (phone, email, and written); record the names of insurance contacts and reviewers with whom you speak; and summarize conversations and written documents issued by the insurer.

*Providers and patients are encouraged to contact the patient's insurer for detailed instructions on completing a PA or appealing/overturning a denial.

HCPCS=Healthcare Common Procedure Coding System; ICD-10=International Classification of Diseases, Tenth Revision; NDC=National Drug Code; PA=prior authorization.

Prior Authorization and Appeal Checklists (cont'd)



 To download Prior Authorization and Appeal Checklists from MyAccess360.com, click [here](#).

Denial and Appeal Checklist

If the health plan denied a PA for an AstraZeneca medicine:

- ☐ **Review the denial notification** to understand the reason and circumstances that need to be addressed and explained in the appeal letter
- ☐ **Understand the plan's most recent explanation of benefits (EOB)** or contact a representative at the insurer to verify where the appeal should be sent and any deadlines
- ☐ **Write an appeal letter.** If you need additional information regarding this process, please contact Access 360 for examples



 To view a sample Letter of Appeal template on MyAccess360.com, please click [here](#).

If you or your patient has not received a decision within 30 days:

- ☐ **Follow-up with the health plan.** Confirm the appeal letter was received and ask about its status. If the coverage denial was upheld, you could resubmit another appeal with new information or ask for a supervisor or manager to assist

If the denial is upheld again:

- ☐ **Ask for a one-time exception or a peer-to-peer medical review, or consider filing a complaint** with the state's insurance commissioner
- ☐ **If the insurer continues to deny the claim,** your patient may request an external appeal (the process varies by state law), in which an independent third party will review the claim and make a final, binding decision
- ☐ **Please contact your FRM** or Access 360 if you need additional support



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Peer-to-Peer Resource

If your patient is denied CALQUENCE, there is an option to ask for a peer-to-peer review between you and the payer. Below are some tips to help you prepare for your meeting and help you understand what to expect.



To download the Peer-to-Peer Resource from MyAccess360.com, click [here](#).

What to Prepare Before Your Meeting:

Confirm the meeting date and time, gather all required documentation, and prepare to thoroughly support your treatment decision rationale.

Please note: Your peer reviewer may work within a different specialty.

□ Gather and review documentation previously provided to payer

Include the following:

- Patient clinical documentation: Case notes, date(s) of service, treatment history, laboratory results, etc
- Claim form and EOB, if claim was submitted
- PA request
- Letter of medical necessity
- Payer denial letter(s)
- Letter of appeal

What to Expect During Your Meeting:

Prepare to provide/discuss the following resources:

□ Drug information

- Brand and established name
- Relevant NDC number(s)
- Prescribing Information
- Dosing and administration
- ICD-10-CM codes
- Relevant HCPCS code(s) – miscellaneous or permanent J-codes, depending on the medication's approval status

□ Literature supporting your decision to prescribe a medication

- Relevant clinical guidelines
- Peer-reviewed journal articles
- Comparison of listings

□ Next steps

- Confirm timing for approval
- Note any required follow-up steps

CALQUENCE® (acalabrutinib) Distribution Card



To download the Distribution Card from MyAccess360.com, click [here](#).

Specialty Pharmacy Providers (SPPs)

CALQUENCE is available to order from these authorized SPPs, who also provide support to help patients with their prescribed treatments:

Specialty Pharmacy	Phone	Fax	Website
<i>BIOLOGICS</i>	1-800-850-4306	1-800-823-4506	www.biologicsinc.com
<i>ONCO360</i>	1-877-662-6633	1-877-662-6355	www.onco360.com

Specialty Distributors

CALQUENCE is available for purchase from these authorized specialty distributors:

Specialty Distributors	Phone	Fax	Website
AMERISOURCEBERGEN			
<i>ASD Healthcare</i>	1-800-746-6273	1-800-547-9413	www.asdhealthcare.com
<i>Oncology Supply</i>	1-800-633-7555	1-800-248-8205	www.oncologysupply.com
CARDINAL HEALTH SPECIALTY DISTRIBUTION			
	1-855-740-1871	1-888-345-4916	http://specialtyonline.cardinalhealth.com
CURASCRIPT SD			
	1-877-599-7748	1-800-862-6208	www.curascriptsd.com
McKESSON SPECIALTY			
<i>McKesson Specialty Health (MD Offices)</i>	1-800-482-6700	1-800-289-9285	https://mscs.mckesson.com
<i>McKesson Plasma and Biologics (Hospitals, IDNs, VA)</i>	1-877-625-2566	1-888-752-7626	www.mckesson.com/plasmabiologics

Important Safety Information

INDICATIONS AND USAGE

CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor 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.

CALQUENCE is also indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%). These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of

hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (eg, palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The most common adverse reactions ($\geq 20\%$) of any grade in patients with relapsed or refractory MCL were anemia,* thrombocytopenia,* headache (39%), neutropenia,* diarrhea (31%), fatigue (28%), myalgia (21%), and bruising (21%). The most common Grade ≥ 3 non-hematological adverse reaction (reported in at least 2% of patients) was diarrhea (3.2%).

*Treatment-emergent decreases (all grades) of hemoglobin (46%), platelets (44%), and neutrophils (36%) were based on laboratory measurements and adverse reactions.



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Important Safety Information (cont'd)

ADVERSE REACTIONS (cont'd)

Dose reductions or discontinuations due to any adverse reaction were reported in 1.6% and 6.5% of patients, respectively. Increases in creatinine to 1.5 to 3 times the upper limit of normal (ULN) occurred in 4.8% of patients. The most common adverse reactions ($\geq 30\%$) of any grade in patients with CLL were anemia,* neutropenia,* thrombocytopenia,* headache, upper respiratory tract infection, and diarrhea.

*Treatment-emergent decreases (all grades) of hemoglobin, platelets, and neutrophils were based on laboratory measurements and adverse reactions.

In patients with previously untreated CLL exposed to CALQUENCE, fatal adverse reactions that occurred in the absence of disease progression and with onset within 30 days of the last study treatment were reported in 2% for each treatment arm, most often from infection. Serious adverse reactions were reported in 39% of patients in the CALQUENCE plus obinutuzumab arm and 32% in the CALQUENCE monotherapy arm, most often due to events of pneumonia (7% and 2.8%, respectively).

Adverse reactions led to CALQUENCE dose reduction in 7% and 4% of patients in the CALQUENCE plus obinutuzumab arm (N=178) and CALQUENCE monotherapy arm (N=179), respectively. Adverse events led to discontinuation in 11% and 10% of patients, respectively. Increases in creatinine to 1.5 to 3 times ULN occurred in 3.9% and 2.8% of patients in the CALQUENCE combination arm and monotherapy arm, respectively.

In patients with relapsed/refractory CLL exposed to CALQUENCE, serious adverse reactions occurred in 29% of patients. Serious adverse reactions in $>5\%$ of patients who received CALQUENCE included lower respiratory tract infection (6%). Fatal adverse reactions within 30 days of the last dose of CALQUENCE occurred in 2.6% of patients, including from second primary malignancies and infection.

Adverse reactions led to CALQUENCE dose reduction in 3.9% of patients (N=154), dose interruptions in 34% of patients, most often due to respiratory tract infections followed by neutropenia, and discontinuation in 10% of patients, most frequently due to second primary malignancies followed by infection. Increases in creatinine to 1.5 to 3 times ULN occurred in 1.3% of patients who received CALQUENCE.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration of CALQUENCE with a strong CYP3A inhibitor. If these inhibitors will be used short-term, interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.

Moderate CYP3A Inhibitors: Reduce the dosage of CALQUENCE to 100 mg once daily when co-administered with a moderate CYP3A inhibitor.

Strong CYP3A Inducers: Avoid co-administration of CALQUENCE with a strong CYP3A inducer. If co-administration is unavoidable, increase the dosage of CALQUENCE to 200 mg approximately every 12 hours.

SPECIFIC POPULATIONS

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women of the potential risk to a fetus. Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE.

It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Please see full [Prescribing Information](#), including [Patient Information](#).

You may report side effects related to AstraZeneca products. 



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References: 1. CALQUENCE[®] (acalabrutinib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2022.
2. American Medical Association. *ICD-10-CM 2022: The Complete Official Codebook*. Chicago, IL: American Medical Association; 2022.

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