Truqap™ capivasertib 160 mg • 200 mg tablets

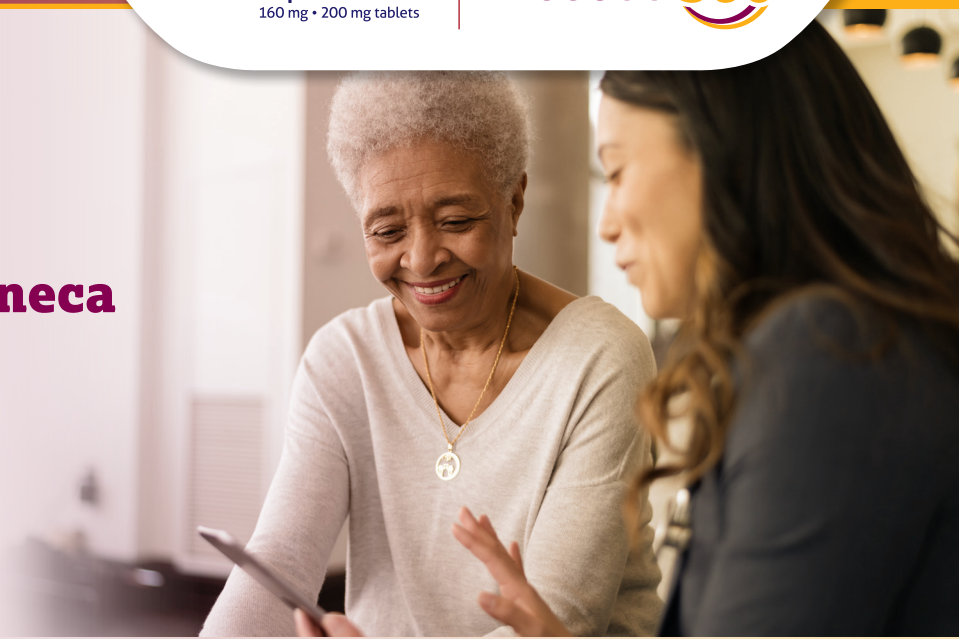
AstraZeneca Access 360™

TRUQAP™ (capivasertib) Digital Access and Reimbursement Guide

INDICATION AND USAGE

TRUQAP in combination with fulvestrant is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer with one or more *PIK3CA/AKT1/PTEN* alteration as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

Please see Important Safety Information on pages 18-19 and full Prescribing Information, including Patient Information.



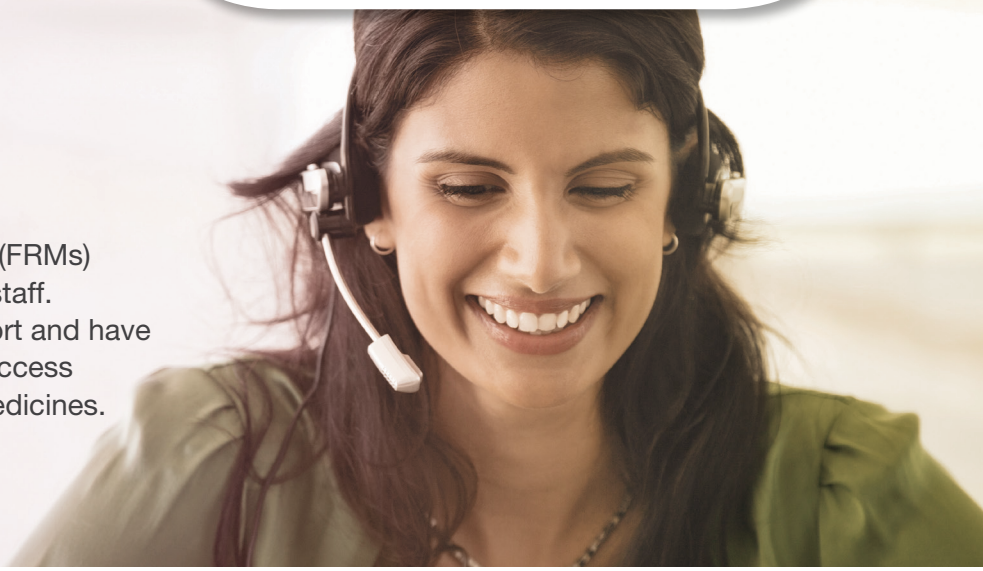
Welcome to the AstraZeneca Access 360™ Program!

Access 360 provides personal support to help streamline access and reimbursement for TRUQAP. 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*

HCP · Access 360 · Specialty Pharmacy Provider (SPP)

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- HCP prescribes TRUQAP and submits an enrollment form to Access 360

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- Access 360 conducts benefits investigation and completes PA research
- Access 360 submits prescription to SPP

TRUQAP Affordability Resources

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- HCP submits PA
- SPP supports office with submitted PA
- SPP communicates approval†

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- SPP contacts patient to discuss co-pay, if applicable
- Payment authorization; SPP schedules delivery
- Medication is delivered to patient

TRUQAP Distribution Card

*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.

Truqap™ capivasertib 160 mg • 200 mg tablets | AstraZeneca Access 360™

TRUQAP™ (capivasertib) Enrollment Form

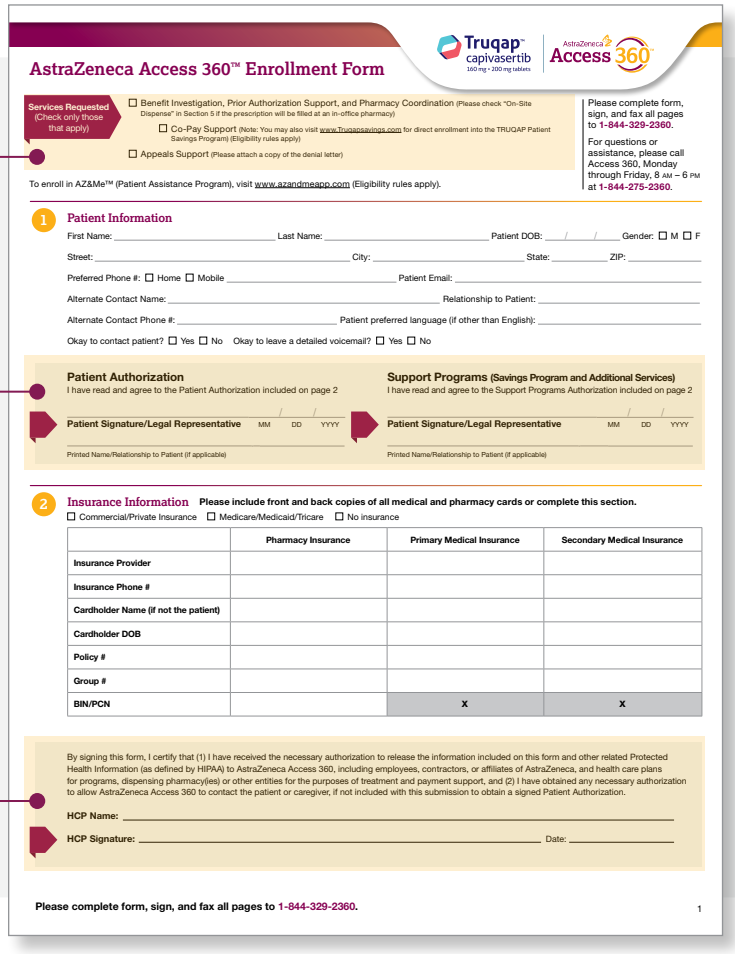
The TRUQAP Enrollment Form is used to capture necessary patient, provider, and prescription information to start a new request for support from Access 360. We recommend that you and your patient fill out this form so your patient can enroll in Access 360. The patient and the provider are each responsible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

To download the Enrollment Form from MyAccess360.com, 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 Dispense" in Section 5 if the prescription will be filled at an in-office pharmacy)
- ☐ Co-Pay Support (Note: You may also visit www.Truqapsavings.com for direct enrollment into the TRUQAP Patient Savings Program) (Eligibility rules apply)
- ☐ Appeals Support (Please attach a copy of the denial letter)

To enroll in AZ&Me™ (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 AM – 6 PM 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

Patient Signature/Legal Representative MM DD YYYY

Printed Name/Relationship to Patient (if applicable)

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)

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 #			
BIN/PCN		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.

1

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.

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

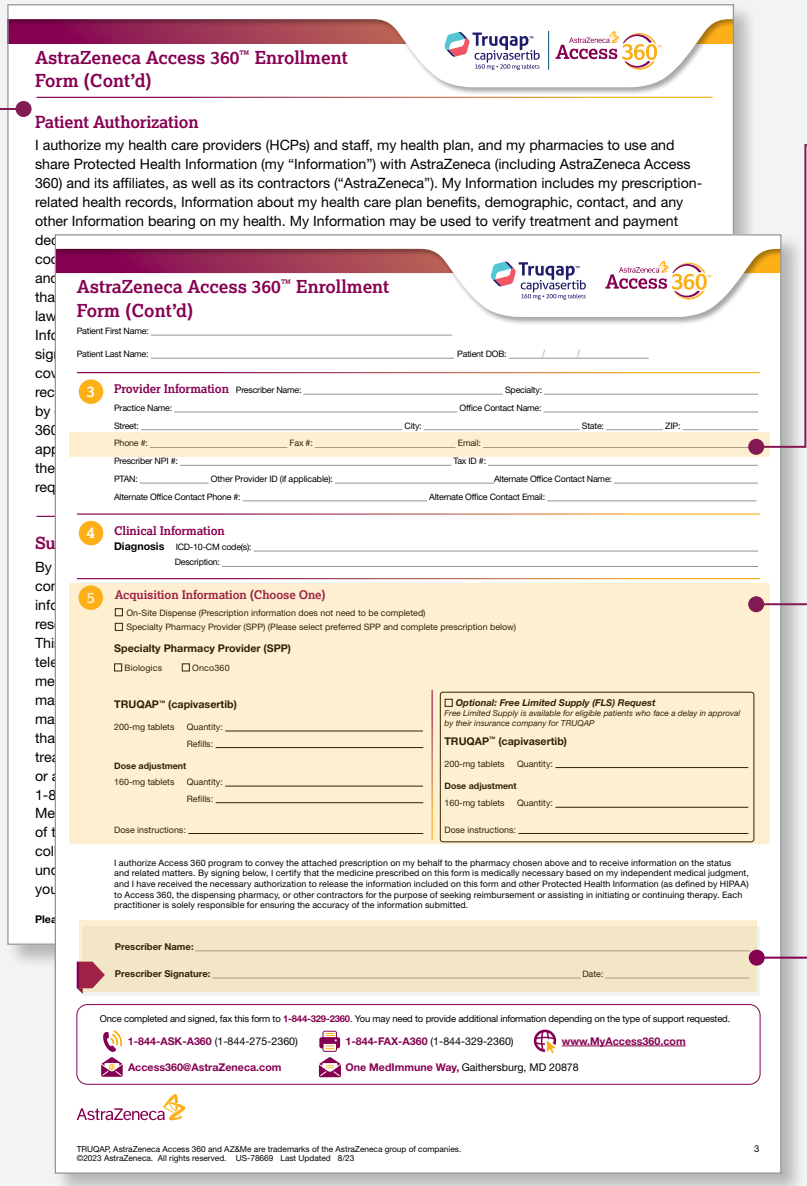
- Submit signature electronically at www.MyAccess360.com.
- Download and print the patient authorization form here. Once signed, fax the document to Access 360.
- Call Access 360 to provide verbal authorization (1-844-275-2360).

HCP=healthcare provider.

TRUQAP™ (capivasertib) 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 (Cont'd)

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 (Cont'd)

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

TRUQAP™ (capivasertib)

200-mg tablets Quantity: _____

Refills: _____

Dose adjustment

160-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 TRUQAP

TRUQAP™ (capivasertib)

200-mg tablets Quantity: _____

Dose adjustment

160-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

3

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.

TRUQAP™ (capivasertib) 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
160 mg Bottle	0310-9500-01
200 mg Bottle	0310-9501-01

11-digit NDC

Dosage	Code
160 mg Bottle	00310-9500-01
200mg Bottle	00310-9501-01

Diagnosis Codes[2]

ICD-10-CM	Description
PRIMARY BREAST CANCER SITE	
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast

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

TRUQAP™ (capivasertib) Coding Resource (cont'd)

To download the Coding Resource from MyAccess360.com, click here.

ICD-10-CM	Description
PRIMARY BREAST CANCER SITE (cont'd)	
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast

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.

TRUQAP™ (capivasertib) 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 TRUQAP, click here.

Co-pay Savings Program

For eligible commercially insured patients

TRUQAP Co-pay Savings Program

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

Most eligible patients will pay $0 per month and may have access to up to $26,000 per year to assist with TRUQAP 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 TRUQAP, 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 TRUQAP 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 120 days from the date of service.

VA=Veterans Affairs.

TRUQAP™ (capivasertib) Affordability Resources (cont'd)

AZ&Me™

AZ&ME™ AstraZeneca Prescription Savings Program

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.

Technology Resources

These technology resources are designed to help you manage your patients' care and may help streamline access to TRUQAP. 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.myaccess360providerportal.com/

*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

*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

www.azpatientsupport.com

AstraZeneca | AstraZeneca Specialty Savings Portal

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
- ○ Physician name and tax ID number
- ○ Facility name and tax ID number
- ○ Date of service
- ○ Patient diagnosis (ICD-10 code[s])
- ○ Relevant procedure and HCPCS codes for services/products to be performed/provided
- ○ Product NDC
- ○ 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

FRM=field reimbursement manager; PA=prior authorization.

Peer-to-Peer Resource

If your patient is denied TRUQAP, 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

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

TRUQAP™ (capivasertib) Distribution Card

To download the Distribution Card from MyAccess360.com, click here.

Specialty Pharmacy Providers (SPPs)

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

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

Specialty Distributors

TRUQAP is available for purchase from these authorized Specialty Distributors:

Specialty Distributors	Phone	Fax	Website
AMERISOURCEBERGEN			
ASD Healthcare	1-800-746-6273	1-800-547-9413	www.asdhealthcare.com
Oncology Supply	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
DAKOTA DRUG INC.	866-210-5887	763-421-0661	www.dakdrug.com
DMS PHARMACEUTICAL GROUP, INC.	877-788-1100	847-518-1105	www.dmspharma.com
McKESSON SPECIALTY			
McKesson Specialty Health (MD Offices)	1-800-482-6700	1-800-289-9285	https://mscs.mckesson.com
McKesson Plasma and Biologics (Hospitals, IDNs, VA)	1-877-625-2566	1-888-752-7626	www.mckesson.com/plasmabiologics

IDN=integrated delivery network; VA=Veterans Affairs.

Important Safety Information

INDICATIONS AND USAGE

TRUQAP in combination with fulvestrant is indicated for the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer with one or more *PIK3CA/AKT1/PTEN* alteration as detected by an FDA-approved test following progression on at least one endocrine-based regimen in the metastatic setting or recurrence on or within 12 months of completing adjuvant therapy.

IMPORTANT SAFETY INFORMATION ABOUT TRUQAP™ (capivasertib) tablets

TRUQAP is contraindicated in patients with severe hypersensitivity to TRUQAP or any of its components.

Hyperglycemia

Severe hyperglycemia, associated with ketoacidosis, has occurred in patients treated with TRUQAP. The safety of TRUQAP has not been established in patients with Type I diabetes or diabetes requiring insulin. Patients with insulin-dependent diabetes were excluded from CAPItello-291.

Hyperglycemia occurred in 18% of patients treated with TRUQAP (n=355). Grade 3 (insulin therapy initiated; hospitalization indicated) or Grade 4 (life-threatening consequences; urgent intervention indicated) hyperglycemia occurred in 2.8% of patients. Diabetic ketoacidosis occurred in 0.3% of patients and diabetic metabolic decompensation in 0.6% of patients. Dose reduction for hyperglycemia was required in 0.6% and permanent discontinuation was required in 0.6% of patients. The median time to first occurrence of hyperglycemia was 15 days (range: 1 to 367).

In the 65 patients with hyperglycemia, 45% required treatment with anti-hyperglycemic medication (insulin in 15% and metformin in 29%). Of the 29 patients who required anti-hyperglycemic medication during treatment with TRUQAP, 66% (19/29) remained on these medications at treatment discontinuation or last follow-up.

Evaluate fasting blood glucose (FG) and hemoglobin A1C (HbA1C) and optimize blood glucose prior to treatment. Before initiating TRUQAP, inform patients about TRUQAP's potential to cause hyperglycemia and to immediately contact their healthcare professional if hyperglycemia symptoms occur (eg, excessive thirst, urinating more often than usual or greater amount of urine than usual, or increased appetite with weight loss). Evaluate FG at least every two weeks during the first month and at least once a month starting from the second month, prior to the scheduled dose of TRUQAP. Monitor HbA1C every three months. Monitor FG more frequently during treatment with TRUQAP in patients with a medical history of diabetes mellitus and in patients with risk factors for hyperglycemia such as obesity (BMI ≥ 30), elevated FG of > 160 mg/dL (> 8.9 mmol/L), HbA1C at or above the upper limit of normal, use of concomitant systemic corticosteroids, or intercurrent infections.

If a patient experiences hyperglycemia after initiating treatment with TRUQAP, monitor FG as clinically indicated, and at least twice weekly until FG decreases to normal levels. During treatment with anti-hyperglycemic medication, continue monitoring FG at least once a week for 8 weeks, followed by once every 2 weeks and as clinically indicated. Consider consultation with a healthcare practitioner with expertise in the treatment of hyperglycemia and counsel patients on lifestyle changes. Withhold, dose reduce, or permanently discontinue TRUQAP based on severity.

Diarrhea

Severe diarrhea associated with dehydration occurred in patients who received TRUQAP (n=355).

Diarrhea occurred in 72% of patients. Grade 3 or 4 diarrhea occurred in 9% of patients. The median time to first occurrence was 8 days (range: 1 to 519). In the 257 patients with diarrhea, 59% required antidiarrheal medications to manage symptoms. Dose reductions were required in 8% of patients and 2% of patients permanently discontinued TRUQAP due to diarrhea. In patients with Grade ≥ 2 diarrhea (n=93) with at least 1 grade improvement (n=89), median time to improvement from the first event was 4 days (range: 1 to 154).

Monitor patients for signs and symptoms of diarrhea. Advise patients to increase oral fluids and start antidiarrheal treatment at the first sign of diarrhea while taking TRUQAP. Withhold, reduce dose, or permanently discontinue TRUQAP based on severity.

Important Safety Information (cont'd)

IMPORTANT SAFETY INFORMATION ABOUT TRUQAP™ (capivasertib) tablets (cont'd)

Cutaneous Adverse Reactions

Cutaneous adverse reactions, which can be severe, including erythema multiforme (EM), palmar-plantar erythrodysesthesia, and drug reaction with eosinophilia and systemic symptoms (DRESS), occurred in patients who received TRUQAP (n=355).

Cutaneous adverse reactions occurred in 58% of patients. Grade 3 or 4 cutaneous adverse reactions occurred in 17% of patients receiving TRUQAP. EM occurred in 1.7% of patients and DRESS occurred in 0.3% of patients. Dose reduction was required in 7% of patients and 7% of patients permanently discontinued TRUQAP due to cutaneous adverse reactions.

Monitor patients for signs and symptoms of cutaneous adverse reactions. Early consultation with a dermatologist is recommended. Withhold, dose reduce, or permanently discontinue TRUQAP based on severity.

Embryo-Fetal Toxicity

Based on findings from animals and mechanism of action, TRUQAP can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with TRUQAP and for 1 month after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with TRUQAP and for 4 months after the last dose.

TRUQAP is used in combination with fulvestrant. Refer to the full Prescribing Information of fulvestrant for pregnancy and contraception information.

ADVERSE REACTIONS

Among the 355 patients who received TRUQAP in CAPItello-291, the most common (≥ 20%) adverse reactions, including laboratory abnormalities, were diarrhea (72%), cutaneous adverse reactions (58%), increased random glucose (57%), decreased lymphocytes (47%), decreased hemoglobin (45%), increased fasting glucose (37%), nausea and fatigue (35% each), decreased leukocytes (32%), increased triglycerides (27%), decreased neutrophils (23%), increased creatinine (22%), vomiting (21%), and stomatitis (20%).

In the 155 patients with *PIK3CA/AKT1/PTEN* alterations treated with TRUQAP + fulvestrant, dose reductions due to adverse reactions were reported in 21% of patients. Permanent TRUQAP discontinuation due to an adverse reaction occurred in 10% of patients. Dose interruptions of TRUQAP occurred in 39% of patients.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid concomitant use with a strong CYP3A inhibitor. If concomitant use cannot be avoided, reduce the dose of TRUQAP and monitor patients for adverse reactions.

Moderate CYP3A Inhibitors: When concomitantly used with a moderate CYP3A inhibitor, reduce the dose of TRUQAP and monitor patients for adverse reactions.

Strong or Moderate CYP3A Inducers: Avoid concomitant use of TRUQAP with strong or moderate CYP3A inducers.

Please see full Prescribing Information, including Patient Information for TRUQAP.

You may report side effects related to AstraZeneca products.

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

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*This card should be populated by an FRM only.

FRM=field reimbursement manager.

References: 1. TRUQAP™ (capivasertib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023.
2. Centers for Medicare & Medicaid Services. 2023 ICD-10-CM. Accessed October 1, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm

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