



# LYNPARZA Digital Access and Reimbursement Guide





The AstraZeneca Access 360<sup>™</sup> program provides personal support to help streamline access and reimbursement for LYNPARZA. Access 360 provides:

- Assistance with understanding patient insurance coverage and pharmacy options
- Prior authorization support
- Claims and appeal process support
- ✓ Eligibility requirements and enrollment assistance with AstraZeneca's Co-pay Savings Programs
- ✓ Referrals to the AZ&Me<sup>™</sup> Prescription Savings Program, AstraZeneca's patient assistance program
- ✓ Information about independent charitable patient assistance foundations

To learn more about the Access 360 program, please call **1-844-ASK-A360** (1-844-275-2360) Monday through Friday, 8 AM - 6 PM ET or visit **www.MyAccess360.com**.

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 professionals 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.

Not a real FRM.



#### 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

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

For more information, please contact AstraZeneca Access 360<sup>™</sup> at **1-844-ASK-A360**, Monday through Friday, 8 AM - 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

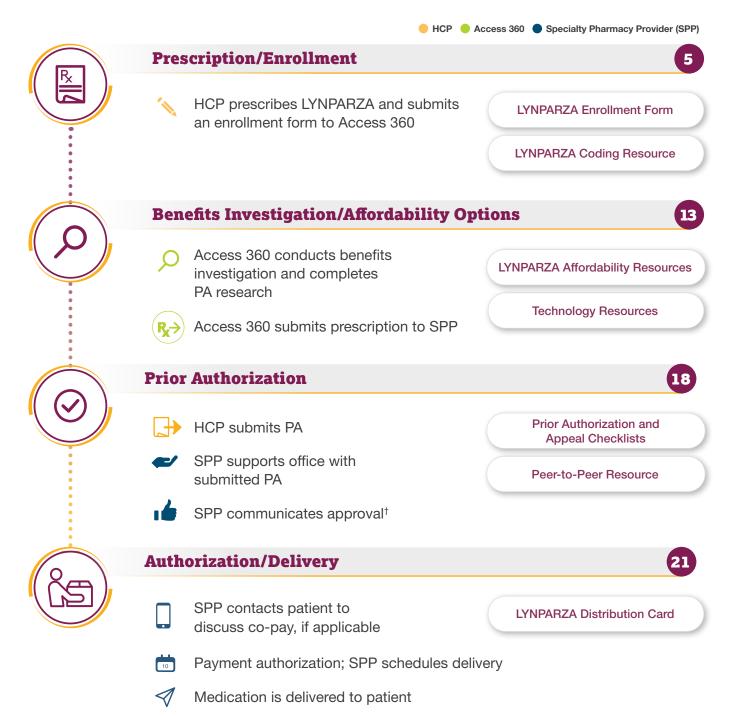
HCP=healthcare provider.







#### **Contents of This Guide and Overview of Key Steps**\*



<sup>\*</sup>Please note that patient and/or HCP attestation/consent may be required.

 $<sup>^{\</sup>dagger}\mbox{If PA}$  is denied, Access 360 can assist with appeals support.

HCP=healthcare provider; PA=prior authorization.





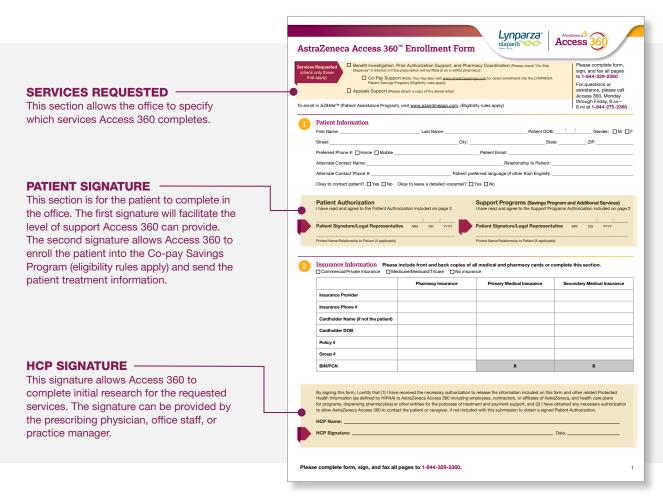
#### LYNPARZA Enrollment Form

The LYNPARZA 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.





Download the LYNPARZA Enrollment Form from MyAccess360.com.



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.







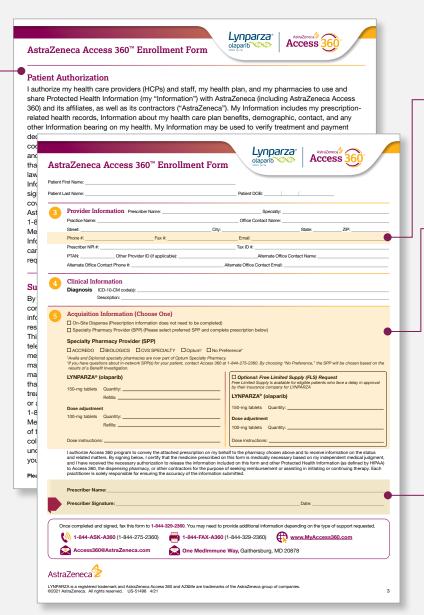
#### LYNPARZA Enrollment Form (cont'd)



Download the LYNPARZA Enrollment Form from MyAccess360.com.

#### PATIENT **AUTHORIZATION** AND SUPPORT **PROGRAMS** (PAGE 2) This page details 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.



#### **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.







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.





Download the LYNPARZA Coding Resource from MyAccess360.com.

#### National Drug Code (NDC)1

#### 10-digit NDC

Dosage	Code
150 mg Tablets — 120 ct Bottle	0310-0679-12
150 mg Tablets — 60 ct Bottle	0310-0679-60
100 mg Tablets — 120 ct Bottle	0310-0668-12
100 mg Tablets — 60 ct Bottle	0310-0668-60

#### 11-digit NDC

Dosage	Code
150 mg Tablets — 120 ct Bottle	00310-0679-12
150 mg Tablets — 60 ct Bottle	00310-0679-60
100 mg Tablets — 120 ct Bottle	00310-0668-12
100 mg Tablets — 60 ct Bottle	00310-0668-60

#### Diagnosis Codes<sup>2</sup>

ICD-10-CM	Description				
EPITHELIAL (	EPITHELIAL OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER				
C48.1	Malignant neoplasm of specified parts of peritoneum				
C48.2	Malignant neoplasm of peritoneum, unspecified				
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum				
C56.1	Malignant neoplasm of right ovary				
C56.2	Malignant neoplasm of left ovary				
C56.3	Malignant neoplasm of bilateral ovaries				
C56.9	Malignant neoplasm of unspecified ovary				
C57.00	Malignant neoplasm of unspecified fallopian tube				
C57.01	Malignant neoplasm of right fallopian tube				
C57.02	Malignant neoplasm of left fallopian tube				
C57.10	Malignant neoplasm of unspecified broad ligament				
C57.11	Malignant neoplasm of right broad ligament				

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



Diagnosis Codes<sup>2</sup> (cont'd)

Diagnosis Codes <sup>2</sup> (contd)					
ICD-10-CM	Description				
EPITHELIAL (	OVARIAN, FALLOPIAN TUBE, OR PRIMARY PERITONEAL CANCER (cont'd)				
C57.12	Malignant neoplasm of left broad ligament				
C57.20	Malignant neoplasm of unspecified round ligament				
C57.21	Malignant neoplasm of right round ligament				
C57.22	Malignant neoplasm of left round ligament				
C57.3	Malignant neoplasm of parametrium				
C57.4	Malignant neoplasm of uterine adnexa, unspecified				
C57.7	Malignant neoplasm of other specified female genital organs				
C57.8	Malignant neoplasm of overlapping sites of female genital organs				
C57.9	Malignant neoplasm of female genital organ, unspecified				
PERSONAL H	PERSONAL HISTORY OF MALIGNANT NEOPLASM OF OVARY				
Z85.43	Personal history of malignant neoplasm of ovary				
PERSONAL H	IISTORY OF DRUG THERAPY				
Z92.21	Personal history of antineoplastic chemotherapy				
Z92.22	Personal history of monoclonal drug therapy				
MALIGNANT	NEOPLASMS OF BREAST				
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				

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.





Diagnosis Codes<sup>2</sup> (cont'd)

ICD-10-CM	Description				
MALIGNANT NEOPLASMS OF BREAST (cont'd)					
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				
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				

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

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Diagnosis Codes<sup>2</sup> (cont'd)

ICD-10-CM	Description					
MALIGNANT	MALIGNANT NEOPLASMS OF BREAST (cont'd)					
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					
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast					

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

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Diagnosis Codes<sup>2</sup> (cont'd)

Diagnosis Codes <sup>2</sup> (contd)				
ICD-10-CM	Description			
MALIGNANT	NEOPLASMS OF BREAST (cont'd)			
C50.911	Malignant neoplasm of unspecified site of right female breast			
C50.912	Malignant neoplasm of unspecified site of left female breast			
C50.919	Malignant neoplasm of unspecified site of unspecified female breast			
C50.921	Malignant neoplasm of unspecified site of right male breast			
C50.922	Malignant neoplasm of unspecified site of left male breast			
C50.929	Malignant neoplasm of unspecified site of unspecified male breast			
PERSONAL H	HISTORY OF MALIGNANT NEOPLASM OF BREAST			
Z85.3	Personal history of malignant neoplasm of breast			
MALIGNANT	NEOPLASMS OF THE PANCREAS			
C25.0	Malignant neoplasm of head of pancreas			
C25.1	Malignant neoplasm of body of pancreas			
C25.2	Malignant neoplasm of tail of pancreas			
C25.3	Malignant neoplasm of pancreatic duct			
C25.7	Malignant neoplasm of other parts of pancreas			
C25.8	Malignant neoplasm of overlapping sites of pancreas			
C25.9	Malignant neoplasm of pancreas, unspecified			
MALIGNANT	NEOPLASM OF PROSTATE			
C61	Malignant neoplasm of prostate			
SECONDARY	AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES AND OTHER SITES			
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck			
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes			

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.





Diagnosis Codes<sup>2</sup> (cont'd)

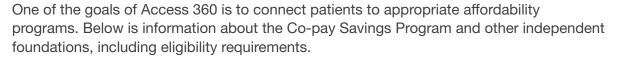
22 to 22 Post iii					
ICD-10-CM	Description				
SECONDARY	SECONDARY AND UNSPECIFIED MALIGNANT NEOPLASM OF LYMPH NODES AND OTHER SITES (cont'd)				
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes				
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes				
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes				
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes				
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions				
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified				
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct				
C79.51	Secondary malignant neoplasm of bone				
PERSONAL H	IISTORY				
Z15.01	Genetic susceptibility to malignant neoplasm of breast				
Z15.02	Genetic susceptibility to malignant neoplasm of ovary				
Z15.03	Genetic susceptibility to malignant neoplasm of prostate				
Z19.2	Hormone resistant malignancy status				
Z85.46	Personal history of malignant neoplasm of prostate				
Z92.21	Personal history of antineoplastic chemotherapy				
Z92.29	Personal history of other drug therapy				

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.



## LYNPARZA Affordability Resources







Learn more about affordability resources for LYNPARZA.

#### **Co-pay Savings Program**

For eligible, commercially insured patients

#### LYNPARZA Co-pay Savings Program

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

Most eligible patients will pay \$0 per month and may have access to up to \$26,000 per year to assist with LYNPARZA out-of-pocket costs. There are no income requirements to participate in the program.

For additional information, please visit <u>www.AstraZenecaSpecialtySavings.com</u> 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 LYNPARZA, 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 LYNPARZA Co-pay Savings Program covers the cost of the drug only and 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.



#### LYNPARZA Affordability Resources (cont'd)

#### **AZ&Me**<sup>TM</sup>

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



#### Who can apply?

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





Learn more about the AZ&Me Prescription Savings Program.

#### **Other Resources for Patients Requiring Additional Assistance**

AstraZeneca Access 360<sup>™</sup> 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





Learn more about affordability resources for LYNPARZA.

## Technology Resources

These technology resources are designed to help you manage your patients' care and may help streamline access to LYNPARZA. 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 Patient Access Navigators. 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 Patient Access Navigator every time you call by dialing 1-844-275-2360 and selecting your navigator'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 patients 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





Visit the Access 360 Provider Portal.

HCP=healthcare provider; PA=prior authorization.

<sup>\*</sup>Protected health information should not be included in any email communications.







#### **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<sup>®</sup>

This program is not associated with AstraZeneca. Specific details about this independent service can be found directly on the provided website. Access 360 is associated with AstraZeneca.



#### **Technology Resources** (cont'd)

#### **AstraZeneca Specialty Savings Portal**

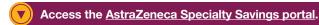
The goal of affordability programs is to make every attempt to remove cost as a barrier for patients gaining access to necessary AstraZeneca medications.

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 <a href="https://www.AstraZenecaSpecialtySavings.com">www.AstraZenecaSpecialtySavings.com</a> 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

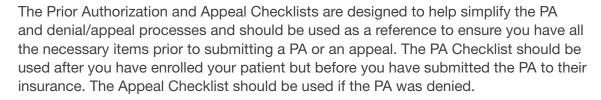




**AstraZeneca Specialty Savings Portal** 



#### **Prior Authorization and Appeal Checklists**







Download the Prior Authorization and Appeal Checklists from MyAccess360.com.

#### 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:
  - O Patient name, insurance policy number, and date of birth
  - O Physician name and tax ID number
  - Facility name and tax ID number
  - O Date of service

- O 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





Download the Sample Letter of Medical Necessity from MyAccess360.com.

- Documentation that supports the treatment decision, such as:
  - Previous treatments/therapies
  - O Patient-specific clinical notes detailing the relevant diagnosis
  - Relevant laboratory results
  - O 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.

<sup>\*</sup>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)



Download the Prior Authorization and Appeal Checklists from MyAccess360.com.

#### **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





Download the Sample Letter of Appeal from MyAccess360.com.

*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

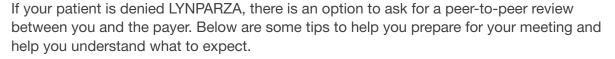
*If the denial is upheld again:* 

- ☐ Ask for a onetime 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





## Peer-to-Peer Resource







Download the Peer-to-Peer Resource from MyAccess360.com.

#### **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:

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

#### **What to Expect During Your Meeting:**

Prepare to provide/discuss the following resources:

#### □ Drug information

- O Brand and established name
- O Relevant NDC number(s)
- Prescribing Information
- O Dosing and administration
- O 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
- O 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.



## tablets 150 mg





Download the LYNPARZA Distribution Card from MyAccess360.com.



#### **Specialty Pharmacy Providers (SPPs)**

LYNPARZA is available for order from these authorized SPPs, which also provide support to help patients with their prescribed treatments:

Specialty Pharmacy	Phone	Fax	Website
ACCREDO	1-877-732-3431	1-877-251-9299	www.accredo.com
BIOLOGICS	1-800-850-4306	1-800-823-4506	https://biologics.mckesson.com
CVS SPECIALTY*	1-888-280-1193	1-800-323-2445	https://www.cvsspecialty.com/
OPTUM†	1-855-427-4682	1-877-342-4596	https://specialty.optumrx.com

<sup>\*</sup>US Bioservices is now part of CVS Specialty.

#### **Specialty Distributors**

LYNPARZA 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
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.

<sup>&</sup>lt;sup>†</sup>Avella and Diplomat specialty pharmacies are now part of Optum Specialty Pharmacy.





#### **IMPORTANT SAFETY INFORMATION**

#### **CONTRAINDICATIONS**

There are no contraindications for LYNPARZA.

#### WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid **Leukemia (MDS/AML):** Occurred in approximately 1.2% of patients with various BRCAm, gBRCAm, HRR gene-mutated or HRD-positive cancers who received LYNPARZA as a single agent or as part of a combination regimen, consistent with the approved indications, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was approximately 2 years (range: <6 months to >4 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

In SOLO-1, patients with newly diagnosed advanced BRCAm ovarian cancer, the incidence of MDS/AML was 1.9% (5/260) in patients who received LYNPARZA and 0.8% (1/130) in patients who received placebo based on an updated analysis. In PAOLA-1, of patients with newly diagnosed advanced ovarian cancer with HRD-positive status, the incidence of MDS/AML was 1.6% (4/255) in patients who received LYNPARZA and 2.3% (3/131) in the control arm.

In SOLO-2, patients with BRCAm platinum-sensitive relapsed ovarian cancer, the incidence of MDS/AML was 8% (15/195) in patients who received LYNPARZA and 4% (4/99) in patients who received placebo. The duration of LYNPARZA treatment prior to the diagnosis of MDS/AML ranged from 0.6 years to 4.5 years.

Do not start LYNPARZA until patients have recovered from hematological toxicity caused by previous chemotherapy (≤Grade 1). Monitor complete blood count for cytopenia at baseline and monthly thereafter for clinically significant changes during treatment. For prolonged hematological toxicities, interrupt LYNPARZA and monitor blood count weekly until recovery.

If the levels have not recovered to Grade 1 or less after 4 weeks, refer the patient to a hematologist for further investigations, including bone marrow analysis and blood sample for cytogenetics. Discontinue LYNPARZA if MDS/AML is confirmed.

Pneumonitis: Occurred in 0.8% of patients exposed to LYNPARZA monotherapy, and some cases were fatal. If patients present with new or worsening respiratory symptoms such as dyspnea, cough, and fever, or a

radiological abnormality occurs, interrupt LYNPARZA treatment and initiate prompt investigation. Discontinue LYNPARZA if pneumonitis is confirmed and treat patient appropriately.

Venous Thromboembolism (VTE): Including severe or fatal pulmonary embolism (PE) occurred in patients treated with LYNPARZA. In the combined data of two randomized, placebo-controlled clinical studies (PROfound and PROpel) in patients with metastatic castration-resistant prostate cancer (N=1180), VTE occurred in 8% of patients who received LYNPARZA, including pulmonary embolism in 6%. In the control arms, VTE occurred in 2.5%, including pulmonary embolism in 1.5%. Monitor patients for signs and symptoms of venous thrombosis and pulmonary embolism, and treat as medically appropriate, which may include long-term anticoagulation as clinically indicated.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating treatment.

#### Females

Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment and for 6 months following the last dose. Males

Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment and for 3 months following the last dose of LYNPARZA and to not donate sperm during this time.

#### **ADVERSE REACTIONS—First-Line Maintenance BRCAm Advanced Ovarian Cancer**

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the first-line maintenance setting for SOLO-1 were: nausea (77%), fatigue (67%), abdominal pain (45%), vomiting (40%), anemia (38%), diarrhea (37%), constipation (28%), upper respiratory tract infection/ influenza/nasopharyngitis/bronchitis (28%), dysgeusia (26%), decreased appetite (20%), dizziness (20%), neutropenia (17%), dyspepsia (17%), dyspnea (15%), leukopenia (13%), urinary tract infection (13%), thrombocytopenia (11%), and stomatitis (11%). Most common laboratory abnormalities (Grades 1-4)

in ≥25% of patients who received LYNPARZA in the



#### **IMPORTANT SAFETY INFORMATION** (cont'd)

#### ADVERSE REACTIONS—First-Line Maintenance BRCAm Advanced Ovarian Cancer (cont'd)

first-line maintenance setting for SOLO-1 were: decrease in hemoglobin (87%), increase in mean corpuscular volume (87%), decrease in leukocytes (70%), decrease in lymphocytes (67%), decrease in absolute neutrophil count (51%), decrease in platelets (35%), and increase in serum creatinine (34%).

#### ADVERSE REACTIONS—First-Line Maintenance Advanced Ovarian Cancer in Combination with Bevacizumab

Most common adverse reactions (Grades 1-4) in  $\geq$ 10% of patients treated with LYNPARZA/bevacizumab and at a  $\geq$ 5% frequency compared to placebo/bevacizumab in the **first-line maintenance setting** for **PAOLA-1** were: nausea (53%), fatigue (including asthenia) (53%), anemia (41%), lymphopenia (24%), vomiting (22%), and leukopenia (18%). In addition, the most common adverse reactions ( $\geq$ 10%) for patients receiving LYNPARZA/bevacizumab irrespective of the frequency compared with the placebo/bevacizumab arm were: diarrhea (18%), neutropenia (18%), urinary tract infection (15%), and headache (14%).

In addition, venous thromboembolism occurred more commonly in patients receiving LYNPARZA/ bevacizumab (5%) than in those receiving placebo/ bevacizumab (1.9%).

Most common laboratory abnormalities (Grades 1-4) in  $\geq$ 25% of patients for LYNPARZA in combination with bevacizumab in the **first-line maintenance setting** for **PAOLA-1** were: decrease in hemoglobin (79%), decrease in lymphocytes (63%), increase in serum creatinine (61%), decrease in leukocytes (59%), decrease in absolute neutrophil count (35%), and decrease in platelets (35%).

## ADVERSE REACTIONS—Maintenance gBRCAm Recurrent Ovarian Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients who received LYNPARZA in the **maintenance setting** for **SOLO-2** were: nausea (76%), fatigue (including asthenia) (66%), anemia (44%), vomiting (37%), nasopharyngitis/upper respiratory tract infection (URI)/influenza (36%), diarrhea (33%), arthralgia/myalgia (30%), dysgeusia (27%), headache (26%), decreased appetite (22%), and stomatitis (20%). Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the

maintenance setting for SOLO-2 were: increase in mean corpuscular volume (89%), decrease in hemoglobin (83%), decrease in leukocytes (69%), decrease in lymphocytes (67%), decrease in absolute neutrophil count (51%), increase in serum creatinine (44%), and decrease in platelets (42%).

## ADVERSE REACTIONS—Adjuvant Treatment of gBRCAm, HER2-Negative, High-Risk Early Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: nausea (57%), fatigue (including asthenia) (42%), anemia (24%), vomiting (23%), headache (20%), diarrhea (18%), leukopenia (17%), neutropenia (16%), decreased appetite (13%), dysgeusia (12%), dizziness (11%), and stomatitis (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **adjuvant setting** for **OlympiA** were: decrease in lymphocytes (77%), increase in mean corpuscular volume (67%), decrease in hemoglobin (65%), decrease in leukocytes (64%), and decrease in absolute neutrophil count (39%).

## ADVERSE REACTIONS—gBRCAm, HER2-Negative Metastatic Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: nausea (58%), anemia (40%), fatigue (including asthenia) (37%), vomiting (30%), neutropenia (27%), respiratory tract infection (27%), leukopenia (25%), diarrhea (21%), and headache (20%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **metastatic setting** for **OlympiAD** were: decrease in hemoglobin (82%), decrease in lymphocytes (73%), decrease in leukocytes (71%), increase in mean corpuscular volume (71%), decrease in absolute neutrophil count (46%), and decrease in platelets (33%).

## ADVERSE REACTIONS—First-Line Maintenance gBRCAm Metastatic Pancreatic Adenocarcinoma

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA in the **first-line maintenance setting** for **POLO** were: fatigue (60%), nausea (45%), abdominal pain (34%), diarrhea (29%),





#### **IMPORTANT SAFETY INFORMATION** (cont'd)

#### **ADVERSE REACTIONS—First-Line Maintenance** gBRCAm Metastatic Pancreatic Adenocarcinoma (cont'd)

anemia (27%), decreased appetite (25%), constipation (23%), vomiting (20%), back pain (19%), arthralgia (15%), rash (15%), thrombocytopenia (14%), dyspnea (13%), neutropenia (12%), nasopharyngitis (12%), dysgeusia (11%), and stomatitis (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA in the **first-line maintenance setting** for **POLO** were: increase in serum creatinine (99%), decrease in hemoglobin (86%), increase in mean corpuscular volume (71%), decrease in lymphocytes (61%), decrease in platelets (56%), decrease in leukocytes (50%), and decrease in absolute neutrophil count (25%).

#### ADVERSE REACTIONS—HRR Gene-mutated **Metastatic Castration-Resistant Prostate Cancer**

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA for PROfound were: anemia (46%), fatigue (including asthenia) (41%), nausea (41%), decreased appetite (30%), diarrhea (21%), vomiting (18%), thrombocytopenia (12%), cough (11%), and dyspnea (10%).

Most common laboratory abnormalities (Grades 1-4) in ≥25% of patients who received LYNPARZA for PROfound were: decrease in hemoglobin (98%), decrease in lymphocytes (62%), decrease in leukocytes (53%), and decrease in absolute neutrophil count (34%).

#### **ADVERSE REACTIONS—Metastatic Castration-Resistant Prostate Cancer in Combination with** Abiraterone and Prednisone or Prednisolone

Most common adverse reactions (Grades 1-4) in ≥10% of patients who received LYNPARZA/abiraterone with a difference of ≥5% compared to placebo for **PROpel** were: anemia (48%), fatigue (including asthenia) (38%), nausea (30%), diarrhea (19%), decreased appetite (16%), lymphopenia (14%), dizziness (14%), and abdominal pain (13%).

Most common laboratory abnormalities (Grades 1-4) in ≥20% of patients who received LYNPARZA/ abiraterone for PROpel were: decrease in hemoglobin (97%), decrease in lymphocytes (70%), decrease in platelets (23%), and decrease in absolute neutrophil count (23%).

#### **DRUG INTERACTIONS**

Anticancer Agents: Clinical studies of LYNPARZA with other myelosuppressive anticancer agents, including DNA-damaging agents, indicate a potentiation and prolongation of myelosuppressive toxicity.

CYP3A Inhibitors: Avoid coadministration of strong or moderate CYP3A inhibitors when using LYNPARZA. If a strong or moderate CYP3A inhibitor must be coadministered, reduce the dose of LYNPARZA, Advise patients to avoid grapefruit, grapefruit juice, Seville oranges, and Seville orange juice during LYNPARZA treatment.

CYP3A Inducers: Avoid coadministration of strong or moderate CYP3A inducers when using LYNPARZA.

#### **USE IN SPECIFIC POPULATIONS**

Lactation: No data are available regarding the presence of olaparib in human milk, its effects on the breastfed infant or on milk production. Because of the potential for serious adverse reactions in the breastfed infant, advise a lactating woman not to breastfeed during treatment with LYNPARZA and for 1 month after receiving the final dose.

Pediatric Use: The safety and efficacy of LYNPARZA have not been established in pediatric patients.

**Hepatic Impairment:** No adjustment to the starting dose is required in patients with mild or moderate hepatic impairment (Child-Pugh classification A and B). There are no data in patients with severe hepatic impairment (Child-Pugh classification C).

Renal Impairment: No dosage modification is recommended in patients with mild renal impairment (CLcr 51-80 mL/min estimated by Cockcroft-Gault). In patients with moderate renal impairment (CLcr 31-50 mL/min), reduce the dose of LYNPARZA to 200 mg twice daily. There are no data in patients with severe renal impairment or end-stage renal disease (CLcr ≤30 mL/min).

#### **INDICATIONS**

LYNPARZA is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

#### First-Line Maintenance BRCAm Advanced Ovarian Cancer

For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary







#### **INDICATIONS** (cont'd)

#### First-Line Maintenance BRCAm Advanced Ovarian Cancer (cont'd)

peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### First-Line Maintenance HRD-Positive Advanced **Ovarian Cancer in Combination with Bevacizumab**

In combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either:

- a deleterious or suspected deleterious BRCA mutation, and/or
- genomic instability

Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### Maintenance BRCA-mutated Recurrent Ovarian Cancer

For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### Adjuvant Treatment of gBRCAm, HER2-Negative, **High-Risk Early Breast Cancer**

For the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative, high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### gBRCAm, HER2-Negative Metastatic Breast Cancer

For the treatment of adult patients with deleterious or suspected deleterious gBRCAm, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### First-Line Maintenance gBRCAm Metastatic **Pancreatic Cancer**

For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### HRR Gene-mutated Metastatic Castration-Resistant **Prostate Cancer**

For the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

#### **BRCAm Metastatic Castration-Resistant Prostate Cancer in Combination with Abiraterone and Prednisone or Prednisolone**

In combination with abiraterone and prednisone or prednisolone (abi/pred) for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castrationresistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for LYNPARZA.

Please see additional Important Safety Information on pages 22-24 and complete Prescribing Information, including Medication Guide.

You may report side effects related to AstraZeneca products.





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**References: 1.** LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2023. **2.** Centers for Medicare & Medicaid Services. 2024 ICD-10-CM. Accessed November 27, 2023. https://www.cms.gov/medicare/coding-billing/icd-10-codes/2024-icd-10-cm

