AstraZeneca and Merck LYNPARZA Patient Support Program

PrLYNPARZA® Enrollment and Consent Form

Patient Section
Physician Section

Form cannot be processed without physician's and patient's/legal representative's consent.
Fax the completed form to **1-877-280-6221** or email to **enrollment@azoncologypsp.ca**.
Please complete **all fields** to minimize delays. For immediate inquiries, please call **1-877-280-6208**.

The use of the word "Product" in this form is a reference to LYNPARZA (olaparib).

Breast cancer

LYNPARZA is indicated as adjuvant treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (*BRCA*m), human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Patients must have confirmation of germline *BRCA* mutation before LYNPARZA treatment is initiated.

LYNPARZA is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m), human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have progressed on or be considered inappropriate for endocrine therapy. Germline *BRCA* mutation must be confirmed before LYNPARZA treatment is initiated.

Ovarian cancer

LYNPARZA is indicated as monotherapy for the maintenance treatment of adult patients with advanced *BRCA*-mutated high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) to first-line platinum-based chemotherapy. Patients must have confirmation of *BRCA* mutation (identified by either germline or tumour testing) before LYNPARZA treatment is initiated.

LYNPARZA is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed (PSR) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete response or partial response) to platinum-based chemotherapy. Platinum-sensitive relapse is defined as disease progression occurring at least 6 months following completion of platinum chemotherapy.

LYNPARZA is indicated as an add-on maintenance treatment to bevacizumab of adult patients with advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer:

- who are in response (complete or partial) to prior treatment with first-line platinum-based chemotherapy in combination with bevacizumab 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. *BRCA* mutation status (germline or somatic) and/or genomic instability must be confirmed before LYNPARZA treatment is initiated.

Pancreatic cancer

LYNPARZA is indicated as monotherapy for the maintenance treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m) metastatic adenocarcinoma of the pancreas whose disease has not progressed on a minimum of 16 weeks of first-line platinum-based chemotherapy. Germline *BRCA* mutation must be confirmed before LYNPARZA treatment is initiated.

Prostate cancer

LYNPARZA is indicated as monotherapy for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic *BRCA* or *ATM* mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with a new hormonal agent. *BRCA* or *ATM* mutations must be confirmed before LYNPARZA treatment is initiated.

LYNPARZA is indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious germline and/or somatic *BRCA* mutated metastatic castration resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated. *BRCA* mutation must be confirmed before LYNPARZA treatment is initiated.

SECTION 1: PATIENT INFORMATION (Patient Section)

Patient First Name: Patient Last Name:

Date of Birth (DD/MM/YYYY): Sex: M F Other Language: En Fr

Legal Representative Name (if applicable):

Patient Home Address: City:

Province: Postal Code:

Email Address:

Home Phone: Alternative Phone:

Best time to be reached: Morning Afternoon Evening

Best method of contact: Phone Email

May we leave a voicemail or a message with someone who answers? Yes No

Insurance Type: Private Public Unsure

SECTION 2: PATIENT CONSENT (Patient Section)

SEE FULL PATIENT CONSENT AND PRIVACY INFORMATION SECTION ON PAGE 4. PLEASE ENSURE YOU HAVE READ AND FULLY UNDERSTAND THIS INFORMATION.

I have read and understand the Patient Consent and Privacy Information and agree to the collection, use and disclosure of my personal information and health information in accordance with those terms.

Patient Signature

Date (DD/MM/YYYY):

OR

Patient has given verbal consent to proceed with enrollment at this time and the Program Administrator will provide the Patient Consent and Privacy Information at a later date.

Name of Person Collecting Verbal Consent

Signature

Date verbal consent collected (DD/MM/YYYY):

OPTIONAL INFORMATION (Patient Section)

Your decision on the following checkboxes will have no impact on your ability to access the products and services through this program. Do you consent to:

Be connected with patient advocacy organization(s) for patient advocacy opportunities.

Yes

No

Be contacted by AstraZeneca's Program Administrator or a third-party working on its behalf for purposes of market research to help improve our support programs, patient and clinician information and diagnostic testing initiatives.

Yes

No

Be contacted by an AstraZeneca Medical Evidence Lead or a third-party working on its behalf, to understand your interest in participating in a Real-World study.

Yes

No

SECTION 3: PRESCRIBING PHYSICIAN INFORMATION (Physician Section)

First Name: Last Name:

Clinic Name and Address:

Administrator/Office Contact Name:

City: Province:

Postal Code: Office Contact Email Address:

Office Phone: Office Fax:

Preferred Method of Communication: Email Fax Both

Secondary Point of Contact: Name: Email:

SECTION 4: PATIENT ELIGIBILITY (Physician Section)

Reset Section 4

I hereby confirm the patient is ≥18 years of age and is being prescribed LYNPARZA for the treatment in **A) Ovarian cancer** or **B) Metastatic breast cancer** or **C) Early breast cancer** or **D) Pancreatic cancer** or **E) Prostate cancer: Monotherapy** or **F) Prostate cancer: Combination Therapy** in one of the following categories:

For the treatment of:		**Required:**
A. Ovarian cancer B. Metastatic breast cancer C. Early breast cancer D. Pancreatic cancer E. Prostate cancer: Monotherapy F. Prostate cancer: Combination Therapy	***BRCA*-mutated First-line Maintenance** *BRCA*-mutated (germline or somatic), advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in response (complete or partial) to first-line platinum-based chemotherapy. **Relapsed Maintenance** Platinum-sensitive relapsed (PSR) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in response (complete or partial) to platinum-based chemotherapy. **HRD-positive Add-on Maintenance** Advanced high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer in response (complete or partial) to first-line platinum-based chemotherapy in combination with bevacizumab.	Check the appropriate box(es) below. HRD-positive status defined by: Tumour *BRCA* mutation test performed Germline *BRCA* mutation test performed Genomic instability Date of last round of platinum-based chemotherapy completed: DD/MM/YYYY Clinical response after chemotherapy: Complete response Partial response Has your patient been on Bevacizumab? Yes No I understand that funding of Bevacizumab must be secured for use in combination with LYNPARZA, outside of the AstraZeneca and Merck LYNPARZA Patient Support Program: Yes

SECTION 5: PRESCRIBING PHYSICIAN AUTHORIZATION (Physician Section)

I certify that I am the patient's prescribing physician and confirm that the patient has been prescribed the Product as per the Canadian Product Monograph. This Product has been prescribed for this patient based on my independent medical judgment and the patient's informed consent.

I agree to be contacted by NavieGo Patient Programs Ltd & Affiliates, or the current administrator of the Program, if different (the "Program Administrator"), about the patient, the Product, the LYNPARZA Patient Support Program (the "Program") and any adverse events or Product complaints. I consent to the use of my prescribing information for the purpose of administering, monitoring, and assessing the Program. My personal information will be collected, stored and processed for use as described in this informed consent form. Questions regarding privacy and compliance may be addressed to the Program Administrator's Privacy Officer via email (privacyofficer@bioscript.ca) or telephone (1-888-734-3814).

I authorize the PSP accredited pharmacy to be my designated agent to forward this prescription by fax or other mode of delivery to the pharmacy chosen by the above named patient. This prescription represents the original prescription drug order. The patient's chosen pharmacy is the only intended recipient and there are no others.

I agree to keep all confidential information provided to me about the Program in strict confidence and shall not, without AstraZeneca and Merck's prior written consent, disclose any confidential information to any third party.

Physician Signature Date (DD/MM/YYYY):

SECTION 6: PRESCRIPTION INFORMATION (Physician Section)

Allergies: None or specify:

Recommended Dosage:*

LYNPARZA (olaparib): 300 mg PO twice daily (BID) (2 x 150 mg **tablets** BID)

Reduced Dosage:

LYNPARZA (olaparib): reduced dose of mg PO BID (x 100 mg **tablets** BID / x 150 mg **tablets** BID)

I approve the patient to start LYNPARZA immediately upon approval in the Patient Support Program.

Yes No, pending test results

No (other, please specify below)

Quantity: Month(s) Repeat:

Licence #: Physician Signature:

Date (DD/MM/YYYY):

* Please see the Product Monograph for complete dosing and administration.
Please complete all sections in their entirety to ensure accuracy of the submission.
Fax the completed form to **1-877-280-6221** or email to **enrollment@azoncologypsp.ca**

Patient Consent and Privacy Information

About the Program

LYNPARZA is part of a global strategic oncology collaboration between Merck and AstraZeneca. The purpose of the LYNPARZA Patient Support Program ("Program") is to provide patients with support including reimbursement navigation and services related to LYNPARZA.

The Program is managed by AstraZeneca Canada Inc. ("AstraZeneca") and is administered by its third-party service provider, NavieGo Patient Programs Ltd & Affiliates (the "Program Administrator"). AstraZeneca may, at its sole discretion, appoint a new program administrator at any time.

The Program is not intended to provide medical advice or medical diagnoses. You should always seek the advice of your physician if you have any health concerns. AstraZeneca reserves the right to modify, discontinue or terminate the Program at any time, without prior notice. You do not have to sign this consent form. If you do not sign this consent form, you will not be able to participate in the Program, but you do not need to participate in the Program to obtain the Product. However, AstraZeneca and the Program Administrator do not provide support for Product not obtained via the Program. If you choose to participate in the Program, you can withdraw at any time. You may also be withdrawn from the Program (for example, if your doctor has decided that you should no longer be prescribed the product).

Privacy Information

In order to provide the Program services, the Program Administrator will collect your name and contact information, information about your insurance, and health information including information about your prescriptions, medical condition, and diagnostic test results ("Personal Information"). The Program Administrator may collect this information directly from you, or from your insurer or health care providers.

The Program Administrator will use your Personal Information to:

- provide the Program services, such as reimbursement navigation, the delivery of Product to your home, and Program monitoring.
- communicate with you in connection with the Program; if you have provided a mobile telephone number, this may include sending you Program-related communications via text message, which may be subject to charges from your phone plan provider. You can unsubscribe from text messages at any time by replying "STOP".

The Program Administrator may share your Personal Information with:

- AstraZeneca for Program auditing and troubleshooting purposes and to fulfill its legal adverse drug event reporting and complaints handling obligations to Health Canada (see Drug Safety section below for more detailed information);
- public and private insurers for the purpose of investigating your drug reimbursement options;
- healthcare provider(s), who may share your personal information with your insurers for the purpose of investigating drug reimbursement options; and
- any successor program administrator appointed by AstraZeneca to administer the Program; your prescription will also be shared with the successor administrator.

Coded Data: Coded data is information that has been modified by replacing direct identifiers with a code. Only the Program Administrator has the key to that code. AstraZeneca will have access to your coded Personal Information for auditing purposes and internal evaluation purposes (such as to determine whether certain aspects of this Program require improvement), for real-world evidence research (with research ethics board approval), and to create aggregated data, as further described below.

Aggregated Data: AstraZeneca may use your coded data to generate fully anonymous aggregated data that does not contain Personal Information (the "Aggregated Data"). AstraZeneca may use the Aggregated Data for any lawful purpose, including but not limited to, other research projects, market research, clinical publications and generating insights to be used in activities geared at improving patient care. It may also share Aggregated Data with third parties for research or to improve future programs. Any third parties that receive Aggregated Data must agree that they will not attempt to make the information personally identifiable, such as by combining it with other databases.

Safeguards

The Program Administrator and AstraZeneca have reasonable physical, administrative, and technical safeguards in place to protect Personal Information in our control against loss, theft and unauthorized access, use or disclosure. Please note that no security measures can guarantee absolute security. If you choose to communicate Personal Information by email, we encourage you to use appropriate security measures, such as encryption.

The Program Administrator is required to maintain Personal Information in Canada. However, coded Personal Information may be processed or stored outside your province of residence or outside of Canada including in Ireland, Mexico or India.

Drug Safety

AstraZeneca is legally required to report adverse drug events to various local and international health authorities and to monitor Product complaints. Identifiable Personal Information provided to the Program Administrator may be (i) monitored by AstraZeneca for safety related data to ensure compliance with these legal reporting requirements and (ii) reported to local or international health authorities. The Program Administrator or AstraZeneca may contact you or your physician for additional information to fulfill these obligations.

Your Privacy Rights

You may have the right under applicable law to request access to or correction of your Personal Information, to request that your Personal Information be transferred to another person, or to withdraw your consent. These rights are subject to applicable legal restrictions. If you withdraw your consent, you may no longer be able to participate in the Program. The withdrawal of your consent will not be retroactive and any activities relating to your Personal Information prior to your withdrawal will not be affected. To exercise any of your privacy rights or to ask any questions about privacy and compliance please contact the Program Administrator's Privacy Officer by email (privacyofficer@bioscript.ca) or telephone (1-888-734-3814).

Your Consent

By signing this informed consent form:

- You confirm that you have discussed the benefits and risks of LYNPARZA with your physician, that you have read and understood this informed consent form, and that you consent to be enrolled in the Program.
- You consent to the collection, use, and disclosure of your Personal Information as described in the Privacy Information section above.
- You acknowledge that your consents are valid for as long as you participate in the Program.

For more information on the Product, please consult the patient medication information section of the product monograph at lynparza-en.azpm.ca.

Consult the product monograph at lynparza-en.azpm.ca for contraindications, warnings, precautions, adverse reactions, interactions, dosing, and conditions of clinical use. The product monograph is also available through our medical department. Call us at **1-800-668-6000**.

MEMBER OF INNOVATIVE MEDICINES CANADA

CA-10684E