For patients with HER2-negative mBC

*g*BRCA *testing may help inform clinical decisions and eligibility for* LYNPARZA[1]

Lynparza® olaparib tablets 150 mg

WHY *g*BRCA test at diagnosis

Identifying g*BRCA* mutations in your patients with HER2-negative mBC can help determine the **earliest eligibility for LYNPARZA.**[1]

RECOMMENDED

NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer recommendations for g*BRCA1/2* testing:
Assess for germline *BRCA1/2* mutations in all HER2-negative mBC patients with recurrent or metastatic disease to identify candidates for PARP inhibitor therapy.[2]

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Identifying g*BRCA* mutations helps assess hereditary risk for breast cancer.[3]

RECOMMENDED

The American Society of Breast Surgeons Consensus Guideline on Genetic Testing for Hereditary Breast Cancer supports g*BRCA1/2* testing:
Genetic testing, including *BRCA1/2*, should be made available to all patients with a personal history of breast cancer.[3]

WHEN to g*BRCA* test

Test **all patients** with HER2-negative mBC at **initial metastatic workup** for early detection of g*BRCA* mutations.[1]

Early identification of g*BRCA* mutations is critical because g*BRCA* test results can inform future treatment decisions and help assess hereditary risk.

By ordering testing at initial metastatic workup, you can avoid the waiting period for results and efficiently make clinical decisions based on those results.

HOW to test

Test your patients with the **FDA-approved** BRACAnalysis CDx® from Myriad Genetics.

Results usually take less than 2 weeks and are sent either to the ordering healthcare provider or a designated "mail to" provider identified on the test request form.[4]

Call Myriad at **1-800-4-MYRIAD** or visit **BRACAnalysisCDx.com/order-test** to order test kits.

INDICATION

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

g*BRCA*m, HER2-Negative Metastatic Breast Cancer

For the treatment of adult patients with deleterious or suspected deleterious g*BRCA*m, 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.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

There are no contraindications for LYNPARZA.

WARNINGS AND PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): Occurred in approximately 1.5% of patients exposed to LYNPARZA monotherapy, and the majority of events had a fatal outcome. The median duration of therapy in patients who developed MDS/AML was 2 years (range: <6 months to >10 years). All of these patients had previous chemotherapy with platinum agents and/or other DNA-damaging agents, including radiotherapy.

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.

Please see additional Important Safety Information on the reverse side and accompanying complete Prescribing Information, including Patient Information (Medication Guide).

g*BRCA*=germline *BRCA*; HER2=human epidermal growth factor receptor 2; mBC=metastatic breast cancer; NCCN=National Comprehensive Cancer Network; PARP=poly (ADP-ribose) polymerase.

RECOMMENDED

NCCN Guidelines®: Category 1[2]

Olaparib (LYNPARZA) is a category 1* preferred option in the NCCN Guidelines for g*BRCA*m HER2-negative mBC patients with recurrent or stage IV disease.

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*Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[2]

IMPORTANT SAFETY INFORMATION (Cont'd)

WARNINGS AND PRECAUTIONS (Cont'd)

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.

Embryo-Fetal Toxicity: Based on its mechanism of action and findings in animals, LYNPARZA can cause fetal harm. A pregnancy test is recommended for 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—g*BRCA*m, HER2-Negative Metastatic Breast Cancer

Most common adverse reactions (Grades 1-4) in ≥20% of patients in **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 in **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%).

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).]

Please see additional Important Safety Information on the reverse side and accompanying complete Prescribing Information, including Patient Information (Medication Guide).

You may report side effects related to AstraZeneca products by clicking here.

For more information, visit LYNPARZAhcp.com

g*BRCA*m=germline *BRCA*-mutated

References: 1. LYNPARZA® (olaparib) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2021. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.4.2021. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed April 28, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Manahan ER, Kuerer HM, Sebastian M, et al. Consensus guidelines on genetic testing for hereditary breast cancer from the American Society of Breast Surgeons. *Ann Surg Oncol*. 2019;26(10):3025-3031. **4.** BRACAnalysis CDx®. Myriad Oncology website. Accessed May 3, 2021. https://myriad-oncology.com/bracanalysiscdx/

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