

Submitted by: Susan L. Pajak, PharmD
Company/Organization: AstraZeneca/US Medical Affairs
Address: One MedImmune Way, Gaithersburg, MD 20878
Phone: 301-398-0360
E-mail: Susan.Pajak@AstraZeneca.com
Date of Request: July 2, 2019
NCCN Guidelines Panel: Ovarian Cancer

Dear Sir or Madam:

On behalf of AstraZeneca, this letter is a formal notification to the National Comprehensive Cancer Network (NCCN) Panel for Ovarian Cancer regarding an update to the LYNPARZA® (olaparib) indication for first-line maintenance treatment. On July 1, 2019, the FDA approved a companion diagnostic for *BRCAM* tumor testing for LYNPARZA.

The updated indication is as follows:

LYNPARZA is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCAM* or s*BRCAM*) advanced epithelial ovarian, fallopian tube or primary 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.¹

FoundationOne® CDx™ (F1CDx) is the companion diagnostic for *BRCAM* tumor testing for LYNPARZA and is a next-generation sequencing–based *in vitro* diagnostic device for detection of substitutions, insertion and deletion alterations (indels), and copy number alterations in 324 genes and select gene rearrangements, as well as genomic signatures including microsatellite instability and tumor mutational burden using DNA isolated from formalin-fixed, paraffin-embedded tumor tissue specimens.²

Additionally, we respectfully request NCCN to consider updating the guidelines as noted below.

Specific Changes:

- Page OV-3, under ‘PRIMARY TREATMENT’, insert ‘consider sending tumor tissue for molecular testing’ after ‘Tumor reductive surgery’
- Page MS-23, within ‘Olaparib’ section, add a summary of SOLO-1 study (Moore K et al *NEJM* 2018)
- Page MS-23, delete the following text: “Note that olaparib is transitioning from capsules (original FDA approval) to tablets for the maintenance and recurrence therapy indications. Olaparib tablets (100 mg and 150 mg) should not be substituted with olaparib capsules (50 mg) because of differences in the dosing and bioavailability of each formulation.”
 - The transition from olaparib capsules to tablets is complete; olaparib capsules were removed from the US market in September 2018.

FDA Status: The use of olaparib for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCAM* or s*BRCAM*) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy is currently FDA-approved.

Rationale:

The FDA has approved a companion diagnostic for *BRCAM* tumor testing for Lynparza in first-line maintenance treatment of certain patients with advanced ovarian cancer.

References submitted in support of this proposal:

1. LYNPARZA Prescribing Information.
2. FoundationOne CDx. Technical Information.

https://assets.ctfassets.net/vhribv12lmne/6Rt6csmCPuaguuqmg2iY8/2fe839f0e9075cf4a047bf241374e6af/F1CDx.Label.Technical_Info_Final_July_2019.pdf [Accessed July 2, 2019].

Sincerely,

A handwritten signature in black ink that reads "Patricia Judson M.D." The signature is written in a cursive style with a horizontal line extending from the end of the name.

Patricia L. Judson, MD
Gynecologic Oncologist
US Medical Head, Gynecologic Oncology
AstraZeneca Pharmaceuticals, LP
Patricia.Judson@AstraZeneca.com