OLAPARIB

Generic	Brand	HICL	GCN	Exception/Other
OLAPARIB	LYNPARZA	41642		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced ovarian cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used as monotherapy
   - The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with at least three prior lines of chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, continue to #2.
   If no, continue to #3.

2. Is the request for Lynparza (olaparib) capsules?

   If yes, **approve 50mg capsules for 12 months by GPID with a quantity limit of #480 capsules per 30 days.**

   If no, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Lynparza 100mg or 150mg: #120 tablets per 30 days.**

3. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient is in complete or partial response to their most recent platinum based-chemotherapy
   - Patient has completed at least 2 or more lines of platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Lynparza 100mg or 150mg: #120 tablets per 30 days.**

   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used for maintenance treatment
   - The patient has a deleterious or suspected deleterious germline or somatic BRCA mutation (gBRCAm or sBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza (for gBRCAm only)
   - The patient is in complete or partial response to first-line platinum-based chemotherapy

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Lynparza 100mg or 150mg: #120 tablets per 30 days.**

   If no, continue to #5.

5. Does the patient have a diagnosis of HER2-negative metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting
   - The patient does not have hormone receptor (HR)-positive breast cancer

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Lynparza 100mg or 150mg: #120 tablets per 30 days.**

   If no, continue to #6.

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GUIDELINES FOR USE (CONTINUED)

6. Does the patient have a diagnosis of HER2-negative metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting
   - The patient has a hormone receptor (HR)-positive breast cancer
   - The patient has received prior treatment with endocrine therapy or be considered inappropriate for endocrine therapy

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Lynparza 100mg or 150mg: #120 tablets per 30 days.**

   If no, continue to #7.

7. Does the patient have a diagnosis of metastatic pancreatic adenocarcinoma and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The requested medication will be used for maintenance treatment
   - The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

   If yes, **approve for 12 months by GPID for the requested strength with the following quantity limits:**
   - **Lynparza 100mg or 150mg: #120 tablets per 30 days.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OLAPARIB (Lynparza)** requires the following rule(s) be met for approval:

A. You have advanced ovarian cancer, recurrent or advanced epithelial ovarian cancer, fallopian tube cancer, primary peritoneal (abdomen) cancer, HER2-negative (you do not have a certain gene mutation) metastatic breast cancer (type of breast cancer that has spread to other parts of the body), metastatic pancreatic adenocarcinoma (type of cancer).

B. If you have advanced ovarian cancer, approval also requires:

1. You are 18 years of age or older
2. The requested medication will be used as monotherapy (used alone for treatment)
3. The patient has a deleterious or suspected deleterious germline BRCA (type of gene) mutation as confirmed by an Food and Drug Administration-approved companion diagnostic for Lynparza
4. You have been treated with at least three prior lines of chemotherapy (such as, paclitaxel, docetaxel, cisplatin, carboplatin)

C. If you have advance epithelial ovarian, fallopian tube, or primary peritoneal (abdomen) cancer, approval also requires:

1. You are 18 years of age or older
2. The requested medication will be used for maintenance treatment
3. You have a deleterious or suspected deleterious germline or somatic BRCA mutation (type of gene mutation such as gBRCAm or sBRCAm) as confirmed by an Food and Drug Administration-approved companion diagnostic for Lynparza (for gBRCAm only)
4. You are in complete or partial response to first-line platinum-based chemotherapy

D. If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:

1. You are 18 years of age or older
2. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen
3. You are in complete or partial response to your most recent platinum-based chemotherapy
4. You have completed at least 2 or more lines of platinum-based chemotherapy
5. The requested medication will be used for maintenance treatment

(Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

E. If you have HER2-negative (you do not have a certain gene mutation) metastatic breast cancer, approval also requires:
1. You have a deleterious or suspected deleterious germline BRCA mutation (type of gene mutation) as confirmed by an Food and Drug Administration-approved companion diagnostic for Lynparza
2. You have been treated with chemotherapy in the neoadjuvant (given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (to treat disease that has spread to other parts of the body)
3. If you have hormone receptor (HR)-positive breast cancer, you must have additional prior treatment with endocrine (hormone) therapy or be considered inappropriate for endocrine therapy

F. If you have metastatic pancreatic adenocarcinoma (type of cancer), approval also requires:
1. You are 18 years of age or older
2. The requested medication will be used for maintenance treatment
3. You have a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (type of gene mutation) as confirmed by an FDA-approved companion diagnostic for Lynparza
4. Your disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Lynparza.

REFERENCES

- Lynparza Tablets [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceuticals. December 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 02/10/20
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P&T Approval: 01/20