STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OLAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OLAPARIB	LYNPARZA	41642		GPI-10 (2153556000)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube or primary peritoneal cancer, and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used for maintenance treatment
   - The patient is in complete or partial response to first-line platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient's diagnosis is confirmed by an FDA-approved companion diagnostic for Lynparza

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

2. Does the patient meet **ONE** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation
   - The patient's cancer is associated with a homologous recombination deficiency (HRD)-positive status as defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability, AND Lynparza will be used in combination with bevacizumab

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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 patient is in complete or partial response to their most recent platinum based-chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - The patient has completed at least 2 or more lines of platinum-based chemotherapy (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)
   - Lynparza will be used as monotherapy for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #4.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient have a diagnosis of HER2-negative high risk early breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Lynparza will be used as adjuvant treatment
   - The patient's cancer 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 neoadjuvant or adjuvant chemotherapy (e.g., doxorubicin, paclitaxel)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   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 is 18 years of age or older
   - The patient's cancer 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 (e.g., doxorubicin, docetaxel) in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #6.
   If no, continue to #7.

6. Does the patient meet **ONE** of the following criteria?
   - The patient does not have hormone receptor (HR)-positive breast cancer
   - The patient has a hormone receptor (HR)-positive breast cancer and has been treated with a prior endocrine therapy or is considered inappropriate for endocrine therapy (e.g., tamoxifen, Arimidex [anastrozole])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   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)

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
   - Lynparza will be used for maintenance treatment
   - The patient's cancer 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 (e.g., paclitaxel, docetaxel, cisplatin, carboplatin)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
   If no, continue to #8.

8. Does the patient have a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, continue to #9.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

9. Does the patient meet **BOTH** of the following criteria?
   - The patient's cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation as confirmed by an FDA-approved companion diagnostic for Lynparza
   - The patient's disease has progressed following prior treatment with enzalutamide (Xtandi) or abiraterone (Yonsa, Zytiga)

   If yes, continue to #11.
   If no, continue to #10.

10. Does the patient meet **BOTH** of the following criteria?
    - Lynparza will be used in in combination with abiraterone (Yonsa, Zytiga) AND prednisone or prednisolone
    - The patient's cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm) as confirmed by an FDA-approved companion diagnostic for Lynparza

    If yes, continue to #11.
    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)

11. Does the patient meet **ONE** of the following criteria?
    - The patient previously had a bilateral orchiectomy
    - The patient has a castrate testosterone level (i.e., less than 50 ng/dL)
    - Lynparza will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

    If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
    If no, do not approve.

    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 ONE of the following diagnoses:
        1. Recurrent (returning) or advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (types of reproductive system cancers)
        2. HER2 (a type of protein)-negative high risk early breast cancer (a type of breast cancer)
        3. HER2-negative metastatic breast cancer (a type of breast cancer that has spread to other parts of the body)
        4. Metastatic pancreatic adenocarcinoma (a type of pancreas cancer that has spread to other parts of the body)
        5. Homologous recombination repair (HRR) gene-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)
        6. BRCA-mutated (type of mutation) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and does not respond to hormone therapy)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. You are in complete or partial response to first-line platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   4. Your diagnosis is confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   5. You meet ONE of the following:
      a. Your cancer has a deleterious or suspected deleterious germline or somatic BRCA mutation (a type of gene mutation)
      b. Your cancer is associated with a homologous recombination deficiency (HRD: type of gene mutation) positive status as defined by either a deleterious or suspected deleterious BRCA mutation (type of gene mutation), and/or genomic instability (high rate of gene mutation), AND Lynparza will be used in combination with bevacizumab

C. **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. You are in complete or partial response to your most recent platinum-based chemotherapy (such as paclitaxel, docetaxel, cisplatin, carboplatin)
   3. You have completed at least two or more lines of platinum-based chemotherapy such as paclitaxel, docetaxel, cisplatin, carboplatin
   4. Lynparza will be used as monotherapy (used alone) for maintenance treatment

D. **If you have HER2-negative high risk early breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used as adjuvant (add-on) treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You have been treated with neoadjuvant or adjuvant chemotherapy (cancer treatment given before main treatment or as add-on therapy such as doxorubicin, paclitaxel)

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

E. **If you have HER2-negative metastatic breast cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. You have been treated with chemotherapy (such as doxorubicin, docetaxel) 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)
   4. You meet ONE of the following:
      a. You do not have hormone receptor (HR)-positive breast cancer
      b. You have hormone receptor (HR)-positive breast cancer and you have been treated with a prior endocrine (hormone) therapy (such as tamoxifen, Arimidex [anastrozole]) or endocrine therapy is considered inappropriate for you

F. **If you have metastatic pancreatic adenocarcinoma, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used for maintenance treatment
   3. Your cancer has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (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 (such as paclitaxel, docetaxel, cisplatin, carboplatin)

G. **If you have homologous recombination repair gene-mutated metastatic castration-resistant prostate cancer, approval also requires:**
   1. You are 18 years of age or older
   2. Your cancer has a deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation (type of mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   3. Your disease has worsened following prior treatment with enzalutamide or abiraterone
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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OLAPARIB

GUIDELINES FOR USE (CONTINUED)

H. **If you have BRCA-mutated metastatic castration-resistant prostate cancer, approval also requires, approval also requires:**
   1. You are 18 years of age or older
   2. Lynparza will be used in in combination with abiraterone (Yonsa or Zytiga) AND prednisone or prednisolone
   3. Your cancer has a deleterious or suspected deleterious BRCA mutation (BRCAm: a type of gene mutation) as confirmed by a Food and Drug Administration (FDA)-approved companion diagnostic for Lynparza
   4. You meet ONE of the following:
      a. You previously had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Lynparza will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron Depot [leuprolide], Zoladex [goserelin], Firmagon [degarelix])

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. May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
Created: 12/14
Client Approval: 08/23
P&T Approval: 07/23