Reference number(s)
1810-A

Specialty Guideline Management
Lynparza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Lynparza	olaparib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Ovarian Cancer

- First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer
  Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) 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.
- Maintenance Treatment of BRCA-mutated Recurrent Ovarian Cancer
  Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza

- First-Line Maintenance Treatment of HRD-positive Advanced Ovarian Cancer in Combination with Bevacizumab
  Lynparza is indicated in combination with bevacizumab for maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy 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

  Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Breast Cancer

- Lynparza is indicated for the adjuvant treatment of adult patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious *gBRCAm*, 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.

Pancreatic Adenocarcinoma

Lynparza is indicated for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.

Prostate Cancer

- Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with enzalutamide or abiraterone. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- Lynparza is indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza

Compendial Uses[2]

- Breast cancer

- Ovarian cancer, Fallopian tube cancer, Primary peritoneal cancer
- Uterine Leiomyosarcoma (uLMS)
- Prostate cancer

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Documentation of laboratory report confirming BRCA mutation status, where applicable.
- Documentation of laboratory report confirming germline or somatic HRR gene mutation, where applicable.
- Documentation of hormone receptor (HR) and human epidermal growth factor receptor 2 (HER2) status, where applicable.
- Documentation of homologous recombination deficiency (HRD) status, where applicable.

Coverage Criteria

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer[1,2]

Authorization of 12 months may be granted for the maintenance treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer that is in a complete or partial response to chemotherapy when any of the following criteria are met:

- Member has completed two or more lines of platinum-based therapy for recurrent disease, has a deleterious or suspected deleterious germline or somatic BRCA mutation and will be using the requested medication as a single agent
- Member has a deleterious or suspected deleterious germline or somatic BRCA mutation and will be using the requested medication as a single agent for advanced (stage II-IV) disease
- Member has received primary therapy that includes bevacizumab for advanced (stage II-IV) disease, will be using the requested medication in combination with bevacizumab and either of the following criteria are met:
    - Member has homologous recombination deficiency (HRD) positive disease, or
    - Member has a deleterious or suspected deleterious germline or somatic BRCA mutation

Breast Cancer[1,2]

Authorization of 12 months may be granted for the treatment of breast cancer with no response to preoperative systemic therapy, or for recurrent unresectable (local or regional) or metastatic breast cancer as a single agent in members with deleterious or suspected deleterious germline BRCA mutations.

Authorization of 12 months may be granted for use as adjuvant therapy for the treatment of HER2-negative, germline BRCA mutated breast cancer after completion of neoadjuvant/adjuvant chemotherapy in any of the following settings:

- Hormone receptor-negative breast cancer with any residual disease; OR
- Hormone receptor-negative breast cancer with either tumor size greater than or equal to 2 cm or any involved axillary nodes; OR
- Hormone receptor-positive breast cancer with greater than or equal to 4 positive lymph nodes; OR
- Hormone receptor-positive breast cancer with any residual disease and a CPS+EG (clinical stage, pathologic stage, estrogen receptor status and tumor grade) score greater than or equal to 3 following preoperative therapy

Pancreatic Adenocarcinoma[1,2]

Authorization of 12 months may be granted for the maintenance treatment of deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma as a single agent, in members whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.

Prostate Cancer[1,2]

Authorization of 12 months may be granted for treatment of metastatic castration-resistant prostate cancer (mCRPC) when either of the following criteria are met:

- The requested medication will be used as a single agent (concurrent use with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix) GnRH analog is allowed) and all of the following criteria are met:
    - Member has deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutation, which includes BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, RAD54L
    - Member has progressed on prior androgen receptor-directed therapy
    - Member is receiving therapy concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix) a gonadotropin-releasing hormone (GnRH) agonist or degarelix or has had a bilateral orchiectomy
- The requested medication will be used in combination with abiraterone or fine-particle abiraterone (Yonsa) and concurrent steroids (prednisone, prednisolone, or methylprednisolone) and all of the following criteria are met:
    - Member has deleterious or suspected deleterious BRCA mutation
    - Member has not progressed on prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, or apalutamide)

- Member is receiving therapy concurrently with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix) or has had a bilateral orchiectomy

Uterine Leiomyosarcoma[2]

Authorization of 12 months may be granted for treatment of BRCA2-altered uterine leiomyosarcoma (uLMS) as subsequent therapy when used as a single agent for advanced, recurrent, metastatic, or inoperable disease.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

- For the first-line maintenance treatment of BRCA-mutated advanced ovarian cancer in a complete response (no radiological evidence of disease), the maximum treatment duration is 2 years.
- For the first-line maintenance treatment of advanced ovarian cancer in combination with bevacizumab in a complete response (no radiological evidence of disease), the maximum treatment duration is 2 years.
- For use as adjuvant treatment of early-stage, HER2-negative, BRCA-mutated breast cancer with high-risk of recurrence, the maximum treatment duration is 1 year.

References

1. Lynparza® Tablets [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed December 16, 2024.