

# Zejula (niraparib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Zejula (niraparib)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Zejula (niraparib) may be approved if the following criteria are met:

- I. Individual has deleterious or suspected deleterious germline BRCA-mutated recurrent, ovarian cancer, including epithelial, fallopian tube, or primary peritoneal (Label, NCCN 1); **AND**
- II. Individual is using for maintenance treatment; **AND**
- III. Individual had a complete or partial response to a platinum-based chemotherapy;

### **OR**

- IV. Individual has advanced epithelial ovarian, fallopian, or primary peritoneal cancer (Label); **AND**
  - A. Individual is using for maintenance treatment; **AND**
  - B. Individual has a complete or partial response to first-line platinum-based chemotherapy;

### **OR**

- V. Individual has a diagnosis of advanced, recurrent, or metastatic uterine neoplasms (NCCN 2A);
  - A. Individual is using as a single agent; **AND**
  - B. Individual has germline or somatic BRCA mutation; **AND**
  - C. Individual is using as second-line or subsequent therapy.

## **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 28, 2023
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 28, 2023.
  - a. Ovarian Cancer. V2.2023. Revised June 2, 2023
  - b. Uterine Neoplasms. V2.2023. Revised April 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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