UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1216-8
Program	Prior Authorization/Notification
Medication	Zejula™ (niraparib)
P&T Approval Date	5/2017, 5/2018, 5/2019, 3/2020, 6/2020, 6/2021, 6/2022, 6/2023
Effective Date	9/1/2023; Oxford only: 9/1/2023

1. Background:

Zejula (niraparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy. Zejula is also indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer with deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) who are in a complete or partial response to platinum-based chemotherapy.

The National Comprehensive Cancer Network (NCCN) recommends Zejula therapy as recurrence therapy in epithelial ovarian/fallopian tube/primary peritoneal cancer for persistent disease or recurrence in combination with bevacizumab for platinum-sensitive disease. NCCN also recommends Zejula in BRCA2-altered uterine leiomyosarcoma (uLMS) as a second-line or subsequent therapy for advanced, recurrent/metastatic, or inoperable disease as a single agent.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Zejula** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Ovarian Cancer (Maintenance Therapy)</u>

1. **<u>Initial Authorization</u>**

   a. **Zejula** will be approved based on the following criteria:

      (1) **<u>All</u>** of the following:

(a) Diagnosis of **one** of the following:

i. Epithelial ovarian cancer
ii. Fallopian tube cancer
iii. Primary peritoneal cancer

-AND-

(b) Disease is **one** of the following:

i. Recurrent, with deleterious or suspected deleterious germline BRCA mutation
ii. Advanced

-AND-

(c)Patient is in a complete or partial response to a platinum-based chemotherapy

-AND-

(d) Request is for maintenance therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zejula** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zejula therapy

Authorization will be issued for 12 months.

C. Ovarian Cancer (Treatment)

1. **Initial Authorization**

a. **Zejula** will be approved based on the following criteria:

(1) **All** of the following:

(a) Diagnosis of advanced, persistent, or recurrent ovarian, fallopian tube, or primary peritoneal cancer

-AND-

(b) Disease is platinum-sensitive

-AND-

(c) Used in combination with bevacizumab

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zejula** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zejula therapy

Authorization will be issued for 12 months.

D. Uterine Cancer

1. **Initial Authorization**

a. **Zejula** will be approved based on the following criteria:

(1) **Both** of the following:

(a) Diagnosis of BRCA altered uterine leiomyosarcoma (uLMS)

-AND-

(b) Disease has progressed following prior treatment with **one** of the following:

i. gemcitabine plus docetaxel
ii. doxorubicin

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Zejula** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Zejula therapy

Authorization will be issued for 12 months.

E. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

3. **Additional Clinical Rules:**
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

4. **References:**

   1. Zejula™ [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2022.
   2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed April 25, 2023.

Program	Prior Authorization/Notification – Zejula (niraparib)
Change Control	
5/2017	New program for Zejula approved by FDA on 3/27/2017.
5/2018	Annual review. No changes to criteria.
5/2019	Annual review. No changes to criteria. Updated references.
3/2020	Updated criteria for expanded indication. Updated background and references.
6/2020	Updated background and criteria to reflect expanded indication for maintenance therapy. Updated references.
6/2021	Annual review. No changes to criteria. Updated background and references.
6/2022	Annual review. Updated background and criteria to include indication for uterine cancer per NCCN guidelines. Updated references.
6/2023	Annual review. Updated background to reflect the changes in FDA indications. Updated clinical guidelines for Ovarian cancer (treatment and maintenance). Added state mandate footnote. Updated references.