UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1216-10
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, 12/2024, 8/2025
Effective Date	11/1/2025

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 first-line platinum-based chemotherapy and whose cancer is associated with HRD-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability. 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, in BRCA2-altered uterine leiomyosarcoma (uLMS) as a second-line or subsequent therapy for advanced, recurrent/metastatic, or inoperable disease as a single agent, and in castration-resistant distant metastatic (M1) prostate cancer.

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</u>

1. **Initial Authorization**

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

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

         (a) Epithelial ovarian cancer
         (b) Fallopian tube cancer
         (c) Primary peritoneal cancer

      -AND-

      (2) Disease is stage II-IV

      -AND-

      (3) **One** of the following:

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

            i. Maintenance therapy for those who are in complete or partial response after first-line platinum-based chemotherapy
            ii. Disease is homologous recombination deficient (HRD) defined by a deleterious or suspected deleterious BRCA mutation and/or genomic instability

         -OR-

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

            i. Maintenance therapy for those who are in complete or partial response to platinum-based chemotherapy for recurrent disease
            ii. Disease with a deleterious or suspected deleterious germline BRCA mutation

         -OR-

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

            i. Recurrent therapy for platinum-sensitive disease
            ii. 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.

C. Prostate Cancer

1. **Initial Authorization**

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

(1) Diagnosis of castration-resistant distant metastatic (M1) prostate cancer

-AND-

(2) Patient is positive for pathogenic BRCA1 or BRCA2 mutation

-AND-

(3) Patient has not had treatment since disease progression to metastatic castration-resistant prostate cancer (mCRPC)

-AND-

(4) **One** of the following:

(a) Patient has not received prior docetaxel and prior novel hormone therapy
(b) Patient had progression on prior docetaxel therapy and has not received prior novel hormone therapy
(c) Patient had progression on prior novel hormone therapy and has not received prior docetaxel therapy

-AND-

(5) Used in combination with **one** of the following:

(a) Abiraterone
(b) Yonsa (fine-particle abiraterone)

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 Sarcoma

1. **Initial Authorization**

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

(1) Diagnosis of BRCA-2 altered uterine leiomyosarcoma (LMS)

-AND-

(2) Disease is advanced, recurrent/metastatic, or inoperable

-AND-

(3) Used as second-line or subsequent 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.

E. **NCCN Recommended Regimens**

1. 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; June 2025.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed July 21, 2025.

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.
12/2024	Annual review. Updated criteria for Ovarian cancer per NCCN guidelines and consolidated sections for maintenance therapy and treatment. Added new criteria for prostate cancer per NCCN guidelines. Updated Uterine Sarcoma section per NCCN guidelines. Updated background and references.
8/2025	Annual review. Updated background due to FDA label revision. Updated criteria for Ovarian Cancer per NCCN guidelines and FDA label. Updated Prostate cancer criteria per NCCN guidelines. Updated references.