**Generic Name:** niraparib

**Therapeutic Class or Brand Name:** Zejula

**Applicable Drugs:** N/A

**Preferred:** N/A

**Non-preferred:** N/A

**Date of Origin:** N/A

**Date Last Reviewed / Revised:** 2/9/2026

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to IV are met.)

I. Documentation of one of the following diagnoses (A) AND must meet all criteria listed under the applicable diagnosis:

FDA-Approved Indication(s)

A. Ovarian Cancer

i. Documentation of ONE of the following:

1. Epithelial ovarian cancer
2. Fallopian tube cancer
3. Primary peritoneal cancer

ii. Patient meets ONE of the following criteria (1 or 2):

1. Disease is advanced or metastatic

a. Homologous recombination deficiency (HRD)-positive status defined by either documentation of a deleterious or suspected deleterious BRCA mutation and/or genomic instability

b. Documentation of complete or partial response to first-line treatment with a platinum-based chemotherapy regimen (ex: carboplatin or cisplatin, etc.)

2. Disease is recurrent

a. Documentation of a deleterious or suspected deleterious germline BRCA mutation

b. Documentation of complete or partial response to platinum-based chemotherapy (ex: carboplatin or cisplatin-based chemotherapy regimen)

iii. Zejula will be used for maintenance treatment

iv. Minimum age requirement: 18 years old

Other Uses With Supportive Evidence

B. Prostate cancer

C. Uterine sarcoma

II. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

## EXCLUSION CRITERIA

- Patient has completed three or more lines of chemotherapy for ovarian cancer.

## OTHER CRITERIA

- N/A

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Maximum quantity: 30 (thirty) tablets per 30-day supply

## APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

## APPENDIX

N/A

## REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Prostate Cancer. Version 4.2026. Updated December 4, 2025. Accessed December 14, 2025. www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Ovarian Cancer. Version 3.2025. updated July 16, 2025. Accessed December 14, 2025. www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf
3. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 2.2026. Updated November 14, 2025. Accessed December 14, 2025. www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

2. Zejula. Prescribing Information. GlaxoSmithKline. 2025. Accessed December 14, 2025. . gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Zejula_Tablets/pdf/ZEJULA-TABLETS-PI-PIL.PDF