

Reference number(s)
1687-A

# Specialty Guideline Management

## Zejula

### 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
Zejula	niraparib

### 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<sup>1</sup>

- 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 homologous recombination deficiency (HRD)-positive status defined by either:
  - a deleterious or suspected deleterious BRCA mutation, and/or
  - genomic instability.
- Maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

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## Compendial Uses<sup>2</sup>

- Ovarian, fallopian tube, or primary peritoneal cancer – maintenance therapy for stage II-IV disease with germline or somatic BRCA mutation
- 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.

## Coverage Criteria

### Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer<sup>1,2</sup>

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

- Member has advanced (stage II-IV) disease and requested medication will be used as a single agent or in combination with bevacizumab.
- Member has recurrent disease with a deleterious or suspected deleterious germline BRCA mutation and requested medication will be used as a single agent.

### Uterine Leiomyosarcoma<sup>2</sup>

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

### Prostate Cancer<sup>2</sup>

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

- Member has deleterious or suspected deleterious BRCA mutation.

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- 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.
- The requested medication will be used in combination with abiraterone and concurrent steroids (prednisone, prednisolone, or methylprednisolone).
- Member has not progressed on prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, or apalutamide).

## 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.

## References

1. Zejula [package insert]. Durham, NC: GlaxoSmithKline; June 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed September 10, 2025.