

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

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 a diagnosis of advanced or recurrent ovarian cancer including epithelial ovarian, fallopian tube, or primary peritoneal cancer; **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 a diagnosis of advanced ovarian, fallopian tube, or primary peritoneal cancer; **AND**
- V. Individual has received three or more prior chemotherapy treatments; **AND**
- VI. Individual has a homologous recombination deficiency (HRD) positive status defined by either:
 - A. Confirmation of a deleterious or suspected deleterious BRCA mutation;
 - OR**
 - B. Genomic instability and the individual has progressed more than six months after response to the last platinum-based chemotherapy.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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: January 27, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 27, 2020.
 - a. Ovarian Cancer. V1.2020. Revised March 11, 2020.

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Applicable	X	X	X	X	X	X	X

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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