UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zejula

Program	Prior Authorization
Medication	Zejula (niraparib)
Markets in Scope	Arizona, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, California, South Carolina
Issue Date	5/2017
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Zejula (niraparib) is a poly(ADP-ribose) polymerase (PARP) inhibitor indicated for the maintenance treatment of adult patients with recurrent 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 treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either a deleterious or suspected deleterious *BRCA* mutation or genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy. Zejula is also 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. The National Comprehensive Cancer Network (NCCN) also recommends Zejula therapy for persistent disease or recurrence in combination with bevacizumab for platinum-sensitive disease.

2. Coverage Criteria:

A. <u>Ovarian Cancer</u>

1. **<u>Initial Authorization (Maintenance Therapy)</u>**

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

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

         (a) Diagnosis of **<u>one</u>** of the following:

            i. Recurrent or advanced epithelial ovarian cancer

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ii. Recurrent or advanced fallopian tube cancer
iii. Recurrent or advanced primary peritoneal cancer

-AND-

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

-AND-

(c) 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

B. Ovarian Cancer (Treatment)

1. **Initial Authorization**

a. **Zejula** will be approved based on the following criteria:
(1) **Both** of the following:

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

-AND-

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

i. **Both** of the following:

a. Patient has been treated with three or more prior chemotherapy regimens

-AND-

b. Patient's cancer is associated with homologous

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recombination deficiency (HRD) positive status defined by **one** of the following:

1. Presence of deleterious or suspected deleterious *BRCA* mutation

-OR-

2. **Both** of the following:

- Genomic instability
- Cancer has progressed more than 6 months after response to the last platinum-based chemotherapy (e.g., cisplatin, carboplatin)

-OR-

ii. **Both** of the following:

a. Disease is platinum-sensitive

-AND-

b. 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. NCCN Recommended Regimens

1. Initial Authorization

a. **Zejula** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

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2. Reauthorization

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

(1) Documentation of positive clinical response to Zejula therapy

Authorization will be issued for 12 months.

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; April 2020
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed May 12, 2020.

Program	Prior Authorization –Zejula (niraparib)
Change Control	
Date	Change
5/2017	New program. FDA-approved on 3/27/2017.
5/2018	Minor changes to the diagnosis language. Added NCCN Recommended Regimens. Updated references.
5/2019	Annual review. No changes to clinical criteria.
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.

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