Zejula

Description

Zejula (niraparib)

Background
Zejula is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, used in the treatment of adult patients with recurrent or advanced ovarian, fallopian tube or primary peritoneal cancer. Epithelial ovarian, fallopian tube or primary peritoneal cancer is a cancer of the tissue covering the ovary or lining the fallopian tube or abdominal wall (peritoneum). In vitro studies have shown that niraparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death (1).

Regulatory Status
FDA-approved indication: Zejula is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

1. 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
2. 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
Select patients for therapy based on an FDA-approved companion diagnostic for Zejula (1).

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) and bone marrow suppression have occurred in patients treated with Zejula. Monitor patients for hematological toxicity at baseline and monthly thereafter (i.e. monitor complete blood count). Discontinue if MDS/AML or bone marrow suppression is confirmed or until disease progression or unacceptable toxicity (1).

Zejula can cause fetal harm when administered to a pregnant woman based on its mechanism of action and findings from animal studies. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Zejula (1).

The safety and effectiveness of Zejula in pediatric patients have not been established (1).

Related policies
Lynparza, Rubraca

Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zejula may be considered medically necessary in patients 18 years of age and older for the treatment of recurrent or advanced ovarian, fallopian tube or primary peritoneal cancer, and if the conditions indicated below are met.

Zejula may be considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements
Age
18 years of age or older

Diagnosis

Patient must have ONE of the following:

1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancers
   a. Patient has had a complete or partial response to platinum-based chemotherapy
2. Advanced ovarian, fallopian tube or primary peritoneal cancers
a. Treated with three or more prior chemotherapy regimens
b. Associated with homologous recombination deficiency (HRD) positive status defined by ONE of the following:
   i. A deleterious or suspected deleterious BRCA mutation
   ii. Genomic instability and patient has progressed more than six months after response to the last platinum-based chemotherapy

AND ALL of the following for ALL diagnoses:
1. Agreement of provider to obtain a baseline complete blood count (CBC) and monthly thereafter
2. Agreement of provider to monitor for cardiovascular effects
3. Females of reproductive potential only: prescriber agrees to advise patient to use effective contraception during therapy and for 6 months after the last dose

Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnosis

Patient must have ONE of the following:

1. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancers
2. Advanced ovarian, fallopian tube or primary peritoneal cancers

AND ALL of the following:
1. Agreement of provider to obtain complete blood counts (CBCs) monthly
2. Agreement of provider to monitor for cardiovascular effects
3. NO disease progression or unacceptable toxicity
4. Females of reproductive potential only: prescriber agrees to advise patient to use effective contraception during therapy and for 6 months after the last dose

Policy Guidelines

Pre - PA Allowance
None
Prior - Approval Limits

**Quantity**  
100 mg  
270 capsules per 90 days

**Duration**  
12 months

Prior – Approval *Renewal Limits*

Same as above

**Rationale**

**Summary**

Zejula is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, which (when uninhibited) play a role in DNA repair. Zejula is indicated for the treatment of patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who have had a complete or partial response to platinum-based chemotherapy or 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. MDS/AML occurred in patients treated with Zejula, therefore monthly testing for hematological toxicity is required during treatment with Zejula. The safety and effectiveness of Zejula in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Zejula while maintaining optimal therapeutic outcomes.

**References**


**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>June 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
</tr>
<tr>
<td>---------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>March 2019</td>
<td>Annual review and reference update</td>
</tr>
<tr>
<td>November 2019</td>
<td>Addition of indication: advanced ovarian, fallopian tube, or primary peritoneal cancer, previously treated with three or more prior chemotherapy regimens</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
</tr>
</tbody>
</table>

**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.