Drug Therapy Guidelines

<table>
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<th>Medical Benefit</th>
<th>Effective: 1/30/20</th>
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<td>Pharmacy- Formulary 1</td>
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<td>Pharmacy- Formulary 2</td>
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<td>Pharmacy- Formulary 3/Exclusive</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. **Medication Description**

Niraparib is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, PARP-1 and PARP-2, which play a role in DNA repair. 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. Increased niraparib-induced cytotoxicity was observed in tumor cell lines with or without deficiencies in BRCA1/2. Niraparib decreased tumor growth in mouse xenograft models of human cancer cell lines with deficiencies in BRCA1/2 and in human patient-derived xenograft tumor models with homologous recombination deficiency that had either mutated or wild type BRCA1/2.

II. **Position Statement**

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. **Policy**

Coverage of Zejula is available when the following criteria have been met:

- Member is at least 18 years of age **AND**
- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. **Quantity Limitations**

Coverage is available for up to 90 capsules per each 30 days.

V. **Coverage Duration**

Coverage is available for 6 months and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:
• Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Zejula is available as 100 mg capsules.

VIII. Summary of Policy Changes

• 7/1/17: new policy
• 1/1/18: no policy changes
• 1/15/19: no policy changes
• 1/30/20: no policy changes

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.