Drug Therapy Guidelines

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Lynparza® (olaparib)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Applicable</strong></td>
<td><strong>Effective: 5/1/18</strong></td>
</tr>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
</tr>
<tr>
<td><strong>Next Review: 3/19</strong></td>
<td></td>
</tr>
<tr>
<td>Pharmacy- Formulary 2</td>
<td>x</td>
</tr>
<tr>
<td><strong>Date of Origin: 6/15</strong></td>
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<tr>
<td>Pharmacy- Formulary 3/Exclusive</td>
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<tr>
<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Lynparza (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor. Binding to PARP enzymes disrupts cellular homeostasis and increases formation of a PARP-DNA complex that causes cell death in tumors. This cytotoxicity is increased in cell lines that exhibit BRCA deficiencies.

II. Position Statement

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

III. Policy

Coverage of Lynparza 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 as follows:

- 50 mg capsules: 480 capsules per 30 days
- 100 mg tablets: 120 tablets per 30 days
- 150 mg tablets: 120 tablets per 30 days

V. Coverage Duration

Coverage is granted 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**

Lynparza is available as 50 mg capsules and 100 mg and 150 mg tablets.

VIII. **Summary of Policy Changes**

- 6/15/15: new policy
- 7/1/15: formulary distinctions made
- 6/15/16: no policy changes
- 4/5/17: no policy changes
- 5/1/18: coverage criteria updated to allow use as supported by current NCCN guidelines

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 applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

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.