Utilization Management Policy Name: Talzenna - NC Standard

Restricted Product(s):
- Talzenna® (talazoparib)

FDA Approved Use:
- As a single agent, for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), HER2-negative, locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.
- In combination with enzalutamide for the treatment of adult patients with HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Criteria for Approval of Restricted Product(s):
1. The patient is currently taking the requested medication for a cancer diagnosis; AND
   a. The patient will utilize the generic formulation of this product (if available); OR
2. The patient is 18 years of age or older; AND
3. The patient is being managed by or in consultation with an oncologist; AND
4. The patient has been diagnosed with locally advanced or metastatic breast cancer; AND
   a. The patient has a deleterious or suspected deleterious germline BRCA mutation (gBRCAm) (medical record documentation required); AND
   b. The patient is human epidermal growth factor receptor 2 (HER2)-negative (medical record documentation required); OR
5. The patient has been diagnosed with metastatic castration-resistant prostate cancer; AND
   a. The patient has HRR gene-mutation (medical record documentation required); AND
   b. The patient will be treated concomitantly with enzalutamide; AND
6. Indications outside of FDA labeling will be subject to medical necessity review in accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached. Medical records and references / evidence must be provided; AND

7. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies.

**Duration of Approval:** 365 days (1 year)

**Quantity Limitations:** quantity limitations apply to brand and associated generic products.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Quantity per Day (unless specified)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Talzenna (talazoparib) 0.1 mg capsule</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Talzenna (talazoparib) 0.25 mg capsule</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Talzenna (talazoparib) 0.35 mg capsule</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Talzenna (talazoparib) 0.5 mg capsule</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Talzenna (talazoparib) 0.75 mg capsule</td>
<td>1 capsule</td>
</tr>
<tr>
<td>Talzenna (talazoparib) 1 mg capsule</td>
<td>1 capsule</td>
</tr>
</tbody>
</table>

**Quantity Limit Exception Criteria:**

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer's product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

**Duration of Approval:** 365 days (1 year)
References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information:

July 2023: Criteria change: Added new indication for metastatic castration-resistant prostate cancer. Added new to market Talzenna capsules 0.1 mg and 0.35 mg with associated quantity limits.
December 2022: Criteria update: Criteria review and formatting changes.
February 2022: Criteria change: Added new to market Talzenna 0.5 mg and 0.75 mg capsule; updated quantity limits
September 2020: Criteria update: Allow for approval if currently taking for a cancer diagnosis and utilizing the generic (if available).
August 2019: Criteria change: Removed criteria point regarding previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting
November 2018: Original utilization management criteria issued.