Talzenna

Description

Talzenna (talazoparib)

Background
Talzenna (talazoparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1 and PARP2 which play a role in DNA repair. Talazoparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, decreased cell proliferation, and apoptosis. Talazoparib anti-tumor activity was observed in human patient-derived xenograft breast cancer tumor models that expressed mutated or wild-type BRCA 1 and 2 (1).

Regulatory Status
FDA-approved indication: Talzenna is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated 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 based on an FDA-approved companion diagnostic for Talzenna (1).

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) can occur in patients treated with Talzenna. Talzenna should not be started until patients have adequately recovered from hematological toxicity caused by previous chemotherapy. Complete blood counts should be monitored for cytopenia at baseline and monthly thereafter. If MDS/AML is confirmed, Talzenna should be discontinued (1).
Talzenna can also cause myelosuppression, consisting of anemia, leukopenia/neutropenia, and/or thrombocytopenia. Talzenna should not be started until patients have adequately recovered from hematological toxicity caused by previous chemotherapy (1).

Talzenna can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment and for at least 7 months following the last dose of Talzenna. Male patients with female partners of reproductive potential or who are pregnant should be advised to use effective contraception during treatment and for at least 4 months following the last dose of Talzenna (1).

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

Related policies

Lynparza

Policy

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

Talzenna may be considered medically necessary in patients 18 years of age and older with locally advanced or metastatic breast cancer and if the conditions indicated below are met.

Talzenna is considered investigational in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age

18 years of age and older

Diagnosis

The patient must have the following:

Locally advanced or metastatic breast cancer

AND ALL of the following:

1. BRCA-positive mutation as detected by an FDA-approved test
2. HER2-negative
3. Prescriber agrees to monitor complete blood counts at baseline and monthly thereafter
4. Women of reproductive potential must use effective contraception during therapy and for 7 months after the last dose
5. Men with a partner of reproductive potential must use effective contraception during therapy and for 4 months after the last dose

**Prior – Approval Renewal Requirements**

**Age**
18 years of age and older

**Diagnosis**

The patient must have the following:

Locally advanced or metastatic breast cancer

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor complete blood counts monthly
3. Women of reproductive potential must use effective contraception during therapy and for 7 months after the last dose
4. Men with a partner of reproductive potential must use effective contraception during therapy and for 4 months after the last dose

**Policy Guidelines**

**Pre - PA Allowance**

None

**Prior - Approval Limits**

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity limit per 90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.25 mg capsule</td>
<td>270 capsules per 90 days OR</td>
</tr>
<tr>
<td>1 mg capsule</td>
<td>90 capsules per 90 days</td>
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</tbody>
</table>

**Duration**
6 months

**Prior – Approval Renewal Limits**
Strength | Quantity limit per 90 days
--- | ---
0.25 mg capsule | 270 capsules per 90 days OR
1 mg capsule | 90 capsules per 90 days

Duration 12 months

Rationale

Summary
Talzenna (talazoparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1 and PARP2 which play a role in DNA repair. Talazoparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, decreased cell proliferation, and apoptosis. Talazoparib anti-tumor activity was observed in human patient-derived xenograft breast cancer tumor models that expressed mutated or wild-type BRCA 1 and 2. The safety and effectiveness of Talzenna in pediatric patients have not been established (1).

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

References

Policy History
<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
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<tbody>
<tr>
<td>November 2018</td>
<td>Annual review, Addition to PA</td>
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<tr>
<td>March 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.