Verzenio

Description

Verzenio (abemaciclib)

Background
Verzenio is a prescription medication that is a kinase inhibitor that works by blocking certain molecules (known as cyclin-dependent kinases 4 and 6), involved in promoting the growth of cancer cells. Verzenio provides a new targeted treatment option for certain patients with breast cancer who are not responding to treatment, and unlike other drugs in the class, it can be given as a stand-alone treatment to patients who were previously treated with endocrine therapy and chemotherapy. Verzenio can also be given in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with breast cancer (1).

Regulatory Status
FDA-approved indication: Verzenio is a kinase inhibitor indicated: (1)

1. In combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer.
2. In combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy
3. As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting
Increases in serum transaminase levels have been seen with the use of Verzenio. Perform LFTs before initiating therapy with Verzenio. Monitor LFTs every 2 weeks for first 2 months, monthly for the next 2 months. Based on severity of transaminase elevation, Verzenio may require dose interruption, reduction, or discontinuation (1).

Neutropenia was highly reported with the use of Verzenio. Perform Complete Blood Count (CBC) prior to initiating therapy with Verzenio. Monitor CBC every 2 weeks for first 2 months, monthly for the next 2 months, and as clinically indicated (1).

Diarrhea occurred in patients receiving Verzenio plus an aromatase inhibitor. Instruct patients at the first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their healthcare provider (1).

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

Related policies
Ibrance, Kisqali

Policy

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

Verzenio may be considered **medically necessary** for patients 18 years of age or older for advanced or metastatic breast cancer and if the conditions indicated below are met.

Verzenio is considered **investigational** for patients under the age of 18 years and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

Advanced or metastatic breast cancer

**AND ONE** of the following:
1. Used in combination with an aromatase inhibitor as initial endocrine-based
therapy in postmenopausal women
2. Used in combination with fulvestrant for the treatment of women with disease progression following endocrine therapy
3. Used as monotherapy for the treatment of adult patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

AND ALL of the following:
   a. Hormone receptor (HR) positive
   b. Human epidermal growth factor receptor 2 (HER2) – negative
   c. Prescriber agrees to monitor liver function tests (LFTs), and complete blood count (CBCs) prior to initiation of treatment and each month as clinically indicated

Prior – Approval Renewal Requirements

Age
18 years of age or older

Diagnosis

Patient must have the following:

Advanced or metastatic breast cancer

AND ONE of the following:
1. Used in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women
2. Used in combination with fulvestrant for the treatment of women with disease progression following endocrine therapy
3. Used as monotherapy for the treatment of adult patients with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting

AND ALL of the following:
   a. NO disease progression or unacceptable toxicity
   b. Prescriber agrees to monitor liver function tests (LFTs), and complete blood count (CBCs) each month as clinically indicated
Policy Guidelines

Pre – PA Allowance
None

Prior - Approval Limits

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 84 days</th>
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<tr>
<td>50 mg</td>
<td>168 tablets per 84 days OR</td>
</tr>
<tr>
<td>100 mg</td>
<td>168 tablets per 84 days OR</td>
</tr>
<tr>
<td>150 mg</td>
<td>168 tablets per 84 days OR</td>
</tr>
<tr>
<td>200 mg</td>
<td>168 tablets per 84 days</td>
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</table>

Duration 12 months

Prior – Approval Renewal Limits
Same as above

Rationale

Summary
Verzenio is a prescription medication that is a kinase inhibitor that works by blocking certain molecules (known as cyclin-dependent kinases 4 and 6), involved in promoting the growth of cancer cells. Verzenio provides a new targeted treatment option for certain patients with breast cancer who are not responding to treatment, and unlike other drugs in the class, it can be given as a stand-alone treatment to patients who were previously treated with endocrine therapy and chemotherapy. Verzenio can also be given in combination with an aromatase inhibitor as initial endocrine-based therapy for postmenopausal women with breast cancer. The safety and effectiveness of Verzenio have not been established in pediatric patients (1).

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

References

Policy History
**Section:** Prescription Drugs  
**Effective Date:** January 1, 2020  
**Subsection:** Antineoplastic Agents  
**Original Policy Date:** October 12, 2017  
**Subject:** Verzenio  
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<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>October 2017</td>
<td>New Addition to PA</td>
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<tr>
<td>December 2017</td>
<td>Annual review</td>
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<tr>
<td>April 2018</td>
<td>Addition of the indication “Used in combination with an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women” for the treatment of breast cancer</td>
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<tr>
<td>June 2018</td>
<td>Annual review</td>
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<tr>
<td>June 2019</td>
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<td>December 2019</td>
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**Keywords**

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