Perjeta

Description

Perjeta (pertuzumab)

Background
Perjeta (pertuzumab) is approved for use in combination with Herceptin (trastuzumab) and docetaxel in people with HER2-positive breast cancer that has spread to different parts of the body (metastatic). Perjeta is also approved for use as neoadjuvant or adjuvant HER2-positive breast cancer treatment. Perjeta works by attaching itself to the HER2 receptors on the surface of breast cancer cells and blocking them from receiving growth signals. In addition to blocking HER2 receptors, Perjeta can also help fight breast cancer by alerting the immune system to destroy cancer cells (1-3).

Regulatory Status
FDA-approved indication: Perjeta (pertuzumab) is a HER2/neu receptor antagonist indicated for: (1)

1. Use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease

2. Used in combination with trastuzumab and chemotherapy as:

   a. Neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer
b. Adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence

Limitations of Use:
The safety of Perjeta as part of a doxorubicin-containing regimen has not been established. The safety of Perjeta administered for greater than 6 cycles for early breast cancer has not been established (1).

Off-Label Uses: (2-3)
1. Treatment of recurrent disease

Perjeta should be withheld or discontinued if trastuzumab treatment is withheld or discontinued. If docetaxel is discontinued, treatment with Perjeta and trastuzumab may continue (1).

Perjeta carries a boxed warning for embryo-fetal toxicity when administered to a pregnant woman. Perjeta carries a pregnancy category D status based on treatment studies done on pregnant cynomolgus monkeys with pertuzumab which resulted in oligohydramnios, delayed fetal kidney development, and embryo-fetal death. It is important to verify pregnancy status prior to the initiation of Perjeta and to advise patients of the risks of embryo-fetal death and birth defects (1).

Pertuzumab has a boxed warning regarding cardiomyopathy. Perjeta can result in subclinical and clinical cardiac failure manifesting as congestive heart failure (CHF), and decreased left ventricular ejection fraction (LVEF). Perjeta has not been studied in patients with a pretreatment LVEF value of less than 50%, a prior history of CHF, decreases in LVEF to less than 50%. Assess cardiac function and LVEF prior to initiation of Perjeta and at regular intervals during treatment to ensure that LVEF is within the institution’s normal limits (1).

Pertuzumab may cause infusion-related or hypersensitivity reactions and should be monitored for signs and symptoms (1).

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

Related policies
Afinitor, Ibrance, Kadcyla, Trastuzumab, Tykerb
Perjeta may be considered medically necessary for patients 18 years of age or older for the treatment of metastatic or recurrent HER2-positive breast cancer; or neoadjuvant HER2-positive locally advanced, inflammatory, or early stage breast cancer; or adjuvant therapy for HER2-positive early stage breast cancer; and if the conditions indicated below are met.

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

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have ONE of the following:

1. Metastatic or recurrent HER2-positive breast cancer
   a. Used initially in combination with trastuzumab (required) and docetaxel (if tolerated)
   b. NOT have a history of prior anti-HER2 therapy or chemotherapy for metastatic disease

2. Neoadjuvant treatment for HER2-positive locally advanced, inflammatory, or early stage breast cancer
   a. Used in combination with trastuzumab and chemotherapy
   b. Greater than 2 cm in diameter OR node positive

3. Adjuvant therapy for HER2-positive early stage breast cancer
   a. Used in combination with trastuzumab and chemotherapy

AND ALL of the following:

a. Females of childbearing potential should have pregnancy excluded before the start of treatment with Perjeta, prevented during therapy and for 7 month after treatment cessation
b. Left ventricular ejection fraction (LVEF) is above 50%
Prior – Approval *Renewal* Requirements

**Age**
18 years of age or older

**Diagnosis**

Patient must have the following:

1. Metastatic or recurrent HER2-positive breast cancer
   a. Used in combination with trastuzumab (required) and docetaxel (if tolerated)
   b. Left ventricular ejection fraction (LVEF) is above 50%

**Policy Guidelines**

**Pre – PA Allowance**

None

**Prior - Approval Limits**

**Duration**
12 months

**Prior – Approval *Renewal* Limits**

Same as above

**Rationale**

**Summary**

Perjeta (pertuzumab) is approved for use in combination with Herceptin (trastuzumab) and docetaxel in people with HER2-positive breast cancer that has spread to different parts of the body (metastatic). Perjeta is also approved for use as neoadjuvant or adjuvant HER2-positive breast cancer. Perjeta use can result in decreased left ventricular ejection fraction (LVEF). Perjeta carries a boxed warning for embryo-fetal toxicity when administered to a pregnant woman (1-3).
Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Perjeta while maintaining optimal therapeutic outcomes.

References


Policy History

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<tbody>
<tr>
<td>July 2012</td>
<td>New Addition</td>
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<tr>
<td>September 2012</td>
<td>Annual editorial and reference update</td>
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<td>March 2013</td>
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<tr>
<td>June 2013</td>
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<tr>
<td>October 2013</td>
<td>Addition of new FDA indication of neoadjuvant therapy for the treatment of HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a combined therapy with trastuzumab and docetaxel</td>
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<td>September 2014</td>
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<td>July 2017</td>
<td>Policy number change from 5.04.20 to 5.21.20</td>
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<tr>
<td>January 2018</td>
<td>Annual editorial review and reference update</td>
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<td>Addition of new indication: adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence and recurrent HER2-positive breast cancer</td>
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<td>Removal of the requirement “not to have a history of prior anti-HER2 therapy or chemotherapy for metastastic disease. (Prior anti-HER2 therapy as adjuvant or neoadjuvant therapy is acceptable.)”</td>
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<td>Removal of the quantity requirement</td>
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<td>Addition of the requirement for females of childbearing potential should have pregnancy excluded before the start of treatment with Perjeta, prevented during therapy and for 7 month after treatment cessation and addition of left ventricular ejection fraction (LVEF) is above 50%</td>
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<td>March 2018</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.