Perjeta (pertuzumab)

Line(s) of Business: HMO; PPO; QUEST Integration
Medicare Advantage

Original Effective Date: 10/01/2015
Current Effective Date: 01/01/2018

POLICY

A. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

- Metastatic breast cancer
  - In combination with trastuzumab and docetaxel for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease

- Neoadjuvant treatment of breast cancer
  - In combination with trastuzumab and docetaxel chemotherapy for the 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.

- Adjuvant treatment
  - In combination with trastuzumab and chemotherapy as 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 six cycles for early breast cancer has not been established.

Compendial Uses

- Preoperative systemic therapy for patients with human epidermal growth factor receptor 2 (HER2)-positive tumors clinical stage T0-1, N1, M0 or T2-3, N0-1, M0 stage IIA (T2, N0, M0), stage IIB (T2, N1, M0 or T3, N0, M0) or stage IIIA (T3, N1, M0) tumors disease who desire breast preservation and fulfill criteria for breast-conserving surgery except for tumor size, or for those who have node-positive disease likely to become node-negative with preoperative systemic
therapy, or for locally advanced clinical stage T0-3, N2, M0; T4, N0-2, M0 or any T, N3, M0 disease (stage IIIA, IIIB, or IIIC)

- In combination with trastuzumab and paclitaxel (preferred regimen) or trastuzumab and docetaxel-following AC (doxorubicin and cyclophosphamide) regimen
- In combination with trastuzumab and docetaxel following AC (doxorubicin and cyclophosphamide) regimen
- In combination with TCH (docetaxel, carboplatin, and trastuzumab) regimen (preferred regimen)
- In combination with trastuzumab and paclitaxel or trastuzumab and docetaxel prior to or following FEC (fluorouracil, epirubicin, and cyclophosphamide) regimen

- Adjuvant systemic therapy for patients with ≥T2 or ≥N1 node positive HER2-positive early stage or locally advanced breast cancer if a pertuzumab-containing regimen was not used as neoadjuvant therapy tumors
  - In combination with trastuzumab and paclitaxel (preferred regimen) or trastuzumab and docetaxel-following AC (doxorubicin and cyclophosphamide) regimen
  - In combination with trastuzumab and docetaxel following AC (doxorubicin and cyclophosphamide) regimen
  - In combination with TCH (docetaxel, carboplatin, and trastuzumab) regimen (preferred regimen)
  - In combination with trastuzumab and paclitaxel or trastuzumab and docetaxel prior to or following FEC (fluorouracil, epirubicin, and cyclophosphamide) regimen
  - Six to eight cycles of chemotherapy (anthracycline or non-anthracycline-containing regimen) with pertuzumab and trastuzumab, followed by pertuzumab and trastuzumab every three weeks for a total of one year (52 weeks) of treatment

- Recurrent or metastatic HER2-positive breast cancer that is either hormone receptor (HR)-negative, or HR-positive and endocrine therapy refractory, or with symptomatic visceral disease, or a visceral crisis:
  - In combination with trastuzumab with docetaxel or paclitaxel as preferred first-line therapy
  - In combination with trastuzumab with or without cytotoxic therapy (e.g., vinorelbine or taxane) for one line of therapy beyond first-line therapy in patients previously treated with chemotherapy and trastuzumab in the absence of pertuzumab

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:

- **For initial therapy**
  - Current oncology notes, clinical notes (including previous treatment history), treatment plans, and any pertinent pathology reports and/or imaging studies
  - HER2 test result
  - HR test result (if applicable)
  - Cancer staging (if applicable)
- **For continuation of therapy**
  - Documentation demonstrating lack of disease progression on therapy (e.g., clinical notes, laboratory tests, and any pertinent pathology reports and/or imaging studies)
C. PRESCRIBER RESTRICTION
Perjeta must be prescribed by an oncologist.

D. INITIAL CRITERIA FOR APPROVAL
Breast cancer
1. Member must have HER2-positive breast cancer.
2. Authorization of 3 months may be granted to members who are prescribed Perjeta as neoadjuvant therapy for the treatment of breast cancer when ALL of the following criteria are met:
   a. Member has locally advanced, inflammatory, or early-stage breast cancer (either greater than 2 cm in diameter or node positive) AND
   b. Perjeta must be used in combination with ONE of the following regimens:
      i. Trastuzumab and docetaxel
      ii. Trastuzumab and paclitaxel
      iii. TCH (docetaxel, carboplatin, and trastuzumab) regimen

4.3. Authorization of 3 months may be granted to members who are prescribed Perjeta as adjuvant therapy for the treatment of breast cancer when ALL of the following criteria are met:
   a. A Perjeta-containing regimen was not used as neoadjuvant therapy AND
   b. Disease must be ≥T2 or ≥N1 early stage or locally advanced breast cancer node positive AND
   c. Perjeta must be used in combination with ONE of the following regimens:
      i. Trastuzumab and docetaxel
      ii. Trastuzumab and paclitaxel
      iii. TCH (docetaxel, carboplatin, and trastuzumab) regimen
      iv. Trastuzumab and paclitaxel prior to or following FEC (fluorouracil, epirubicin, and cyclophosphamide)
      v. Trastuzumab, following 6-8 prior cycles with chemotherapy and trastuzumab for a total of one year (52 weeks) of treatment

6.4. Authorization of 3 months may be granted for the treatment of recurrent or metastatic breast cancer when ALL of the following criteria are met:
   a. Disease is classified as one of the following:
      i. HR-negative disease
      ii. HR-positive disease refractory to endocrine therapy
      iii. Symptomatic visceral disease
      iv. Disease with visceral crisis
   b. Perjeta must be used in combination with ONE of the following regimens:
      i. For members who have NOT experienced prior progression on trastuzumab-based therapy, Perjeta will be used with trastuzumab and a taxane (e.g., paclitaxel, docetaxel, or albumin-bound paclitaxel)
      ii. For members who have experienced prior progression on trastuzumab-based therapy AND who have NOT been previously treated with a regimen containing Perjeta, Perjeta will be used with trastuzumab with or without cytotoxic therapy (e.g., vinorelbine or taxane).

E. CONTINUATION OF THERAPY
1. No previous authorization/precertification:
All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section D.

2. Reauthorization:

Members who were previously approved for Perjeta by HMSA/CVS may request reauthorization after their initial approval. Approval for an additional Authorization of 3 months may be granted when the following documentation shows no progression of disease:

- A current oncology note documenting the patient’s response to treatment showing no progression of disease
- Current laboratory reports or other objective measures showing no progression of disease when compared with previous results

F. DOSAGE AND ADMINISTRATION

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

G. ADMINISTRATIVE GUIDELINES

Prior authorization is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA/CVS’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES


Document History

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