| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | X |

# Perjeta (pertuzumab)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization | 1 year |

| Medications |
|---|
| Perjeta (pertuzumab) |

## APPROVAL CRITERIA

Requests for Perjeta (pertuzumab) may be approved if the following criteria are met:

I. Individual has a diagnosis of HER2-positive (HER2+) breast cancer (NCCN 2A); **AND**
   A. Confirmed by one of the following:
      1. Immunohistochemistry (IHC) is 3+; **OR**
      2. In situ hybridization (ISH) positive;

**AND**

II. Individual has a diagnosis of metastatic breast cancer (Label, NCCN 2A); **AND**
   A. Individual is using in combination with trastuzumab (or trastuzumab biosimilars) **AND** either docetaxel **or** paclitaxel*****; **AND**
   B. The combination chemotherapy will be used as single-line anti-HER2 chemotherapy for metastatic disease until progression.

*****Note: If docetaxel or paclitaxel treatment is contraindicated upon initiation or discontinued (for example, related to toxicity), treatment with Perjeta (pertuzumab) and trastuzumab may continue.

**OR**

III. Individual has early stage, locally advanced, or inflammatory breast cancer; **AND**
   A. Individual will undergo neoadjuvant (prior to surgery) therapy or adjuvant systemic therapy; **AND**
   B. The primary tumor is larger than 2 cm in diameter or individual is lymph node positive (for neoadjuvant therapy: clinically evident by palpation or imaging); **AND**
   C. Individual has an Eastern Cooperative Oncology Group (ECOG) performance status 0-2; **AND**
   D. Individual is using in combination with trastuzumab (or trastuzumab biosimilars) and either of the following (Label, NCCN 2A):
      1. Docetaxel with or without carboplatin; **OR**

| Market Applicability | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Market** | **DC** | **GA** | **KY** | **MD** | **NJ** | **NY** | **WA** |
| **Applicable** | X | X | X | X | X | X | X |

2. Paclitaxel;

**AND**

E. Individual is using pertuzumab is used for a maximum of 18 cycles (12 month course) (NCCN 2A).

Requests for Perjeta (pertuzumab) may not be approved for the following:

I. When the above criteria are not met and for all other indications; **OR**
II. If it is administered after trastuzumab (or trastuzumab biosimilars) is discontinued or as part of a regimen without trastuzumab (or trastuzumab biosimilars); **OR**
III. Concomitant use with other targeted biologic agents not otherwise noted in the criteria above (including, but not limited to erlotinib, cetuximab, panitumumab, bevacizumab, and lapatinib).

**Key References**:


1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 27, 2020
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 27, 2020.
    a. Breast Cancer. V1.2020. Revised January 15, 2020.
    b. Colon Cancer. V1. 2020. Revised December 19, 2019.
    c. Rectal Cancer. V1. 2020. Revised December 19, 2019.