

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 **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 and either of the following (Label, NCCN 2A):

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1. Docetaxel with or without carboplatin; **OR**
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. For treatment of individuals who do not meet the criteria listed above; **OR**
- II. If it is administered after trastuzumab is discontinued or as part of a regimen without trastuzumab; **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).

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: April 13, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 13, 2019.
 - a. Breast Cancer (V.1.2019). Revised March 14, 2019.
 - b. Colon Cancer (V.1.2019). Revised March 15, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.