Market Applicability/Effective Date															
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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Perjeta (pertuzumab)

CG-DRUG-72

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Perjeta (pertuzumab)

APPROVAL CRITERIA

Requests for Perjeta (pertuzumab) may be approved for treatment of individuals who meet criteria I. and either II., or III. below:

I. The breast tumor is HER2 positive (HER2+) as documented by ONE of the following:
   A. Immunohistochemistry (IHC) is 3+; **OR**
   B. In situ hybridization (ISH) positive by any of the following
      1. Single probe average HER2 copy number greater than or equal to 6.0 signals/cell; **OR**
      2. Dual-probe HER2/CEP17 ratio greater than or equal to 2.0; **OR**
      3. Dual-probe HER2/CEP17 ratio less than 2.0 with an average HER2 copy number greater than or equal to 6.0 signals/cell;

   AND

II. The individual has metastatic breast cancer and both of the following:
   A. Perjeta (pertuzumab) will be used in combination with trastuzumab **AND** either docetaxel **or** paclitaxel*****; **AND**
   B. The combination chemotherapy with Perjeta (pertuzumab) 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. The individual has early stage, locally advanced, or inflammatory breast cancer and **ALL** of the following are met:
   A. Will undergo *neoadjuvant* (prior to surgery) therapy or adjuvant systemic therapy; **AND**
   B. 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. ECOG performance status 0-2; **AND**
   D. Used in combination therapy with trastuzumab and one of the following:
      1. Docetaxel with or without carboplatin; **OR**

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Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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2. Paclitaxel;

AND

E. Pertuzumab is used for a maximum of 18 cycles (12 month course).

Requests for Perjeta (pertuzumab) may **not** be approved for:

I. 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 N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

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Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

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