Updated: 03/2018
DMMA Approved: 04/2018

Request for Prior Authorization for Perjeta® (pertuzumab)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Perjeta® (pertuzumab) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Perjeta® (pertuzumab) Prior Authorization Criteria:

Coverage may be provided when all of the following criteria is met:

- Perjeta® (pertuzumab) is considered medically necessary for the treatment of **metastatic breast cancer** when the member meets the following criteria:
  - The member is 18 years of age or older; **AND**
  - The member is not pregnant; **AND**
  - The prescriber is a hematologist/oncologist; **AND**
  - The prescriber attests the member is HER2-positive, confirmed by an FDA-approved test; **AND**
  - The member has not received prior anti-HER2 therapy or chemotherapy for metastatic disease; **AND**
  - Perjeta® (pertuzumab) will be used in combination with trastuzumab and a taxane; **AND**
  - The member has a baseline left ventricular ejection fraction within normal limits; **AND**
  - The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Perjeta® (pertuzumab) is considered medically necessary for the treatment of neoadjuvant treatment of breast cancer when the member meets the following criteria:
  - The member is 18 years or age older; **AND**
  - The member is not pregnant; **AND**
  - The prescriber is a hematologist/oncologist; **AND**
  - The prescriber attests the pmember is HER2-positive, confirmed by an FDA-approved test; **AND**
  - The member has locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive); **AND**
  - Perjeta will be used in combination with trastuzumab and a taxane agent (as part of a complete treatment regimen for early breast cancer); **AND**
  - The member has a baseline left ventricular ejection fraction within normal limits; **AND**
  - The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines

- **Initial Duration of Approval:**

  - For metastatic breast cancer, initial benefit is approved for 3 months.
  - For neoadjuvant treatment of breast cancer, benefit is approved for 18 weeks. (Efficacy of treatment beyond 18 weeks (6 cycles) has not been established in the neoadjuvant setting).
- **Reauthorization criteria:**
  - Documentation the member is tolerating and responding to treatment with Perjeta and there is ongoing monitoring of Left Ventricular Ejection Fraction (LVEF).
- **Reauthorization Duration of approval:** 12 months for a diagnosis of metastatic breast cancer only.

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.