Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 05/01/2021**
Policy Number: PA.CP.PHAR.227	**Effective Date: 01/2018** **Revision Date: 04/2021**
Policy Name: Pertuzumab (Perjeta)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL** - *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

2Q 2021 annual review: added requirement for BRAF wild-type disease for off-label indication of colorectal cancer per NCCN; added NCCN compendium-supported indication of salivary gland tumors and combined with colorectal cancer criteria; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Auren Weinberg, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Pertuzumab (Perjeta)

Reference Number: PA.CP.PHAR.227
Effective Date: 01/18
Last Review Date: 04/2021 Revision Log

Description
Pertuzumab (Perjeta®) is a human epidermal growth factor receptor 2 protein (HER2)/neu receptor antagonist.

FDA Approved Indication(s)
Perjeta is indicated for:

- Use in combination with trastuzumab and docetaxel for the treatment of patients with HER2-positive metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.
- Use in combination with trastuzumab and chemotherapy as:
  - 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 of patients with HER2-positive early breast cancer at high risk of recurrence.

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness® that Perjeta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of HER2-positive breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as combination therapy (*see Appendix B*);
5. Request meets one of the following (a, or b):
   a. Initial dose: 840 mg, followed by maintenance dose: 420 mg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

B. Additional NCCN Recommended Uses (off-label) (must meet all):

1. Diagnosis of one of the following (a or b):
   a. Recurrent HER2-positive salivary gland tumor;
   b. Advanced or metastatic colorectal cancer and disease is all of the following (i , ii, and iii):
      i. HER2 positive;

ii. Wild-type *RAS* (defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test for this use);
iii. Wild-type *BRAF*;

c. Meets conditions of other NCCN category 1, 2A, or 2B recommendation;

2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For colorectal cancer: No previous use of a HER2 inhibitor therapy (e.g., trastuzumab, Kadcyla®, Tykerb®, Perjeta);
5. Prescribed in combination with trastuzumab;*
   **Prior authorization may be required.*
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 420 mg every 3 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months
(Up to 18 total cycles if neoadjuvant or adjuvant therapy)

B. Other diagnoses/indications (1 or 2)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
KRAS: Kirsten rat sarcoma 2 viral oncogene homologue
NRAS: neuroblastoma RAS viral oncogene homologue

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Examples of drugs that may be used with Perjeta for breast cancer: • Chemotherapeutic agents: carboplatin, cyclophosphamide, doxocrubicin • HER2-targeted agents: docetaxel (Taxotere®), paclitaxel, Herceptin® (trastuzumab) • Endocrine therapy: tamoxifen; aromatase inhibitors: anastrozole (Arimidex®), letrozole (Femara®), exemestane (Aromasin®).	Regimens are dependent on a variety of factors including menopausal status, treatment/progression history, clinical stage, histology, mutational and receptor status, treatment purpose (e.g., adjuvant and neoadjuvant treatment, treatment for metastatic disease).	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): Known hypersensitivity to pertuzumab or to any of its excipients
- Boxed warning(s): Left ventricular dysfunction, embryo-fetal toxicity

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	Initial dose of 840 mg IV, followed by maintenance dose of 420 mg IV every 3 weeks *For metastatic disease*, Perjeta should be administered as outlined above. *For neoadjuvant treatment*, Perjeta should be administered for 3-6 cycles. Following surgery, patients should continue to receive Perjeta to complete 1 year of treatment (up to 18 cycles) *For adjuvant treatment*, Perjeta should be administered for a total of 1 year (up to 18 cycles) or until disease recurrence or unmanageable toxicity.	See regimens

V. Product Availability

Single-dose vial for injection: 420 mg/14 mL

VI. References

1. Perjeta Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2020. Available at https://www.gene.com/download/pdf/perjeta_prescribing.pdf. Accessed February 4, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 5, 2021.
3. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 1.2021. Available at www.nccn.org. Accessed February 5, 2021.
4. National Comprehensive Cancer Network Guidelines. Colon Cancer Version 2.2021. Available at www.nccn.org. Accessed February 5, 2021.
5. National Comprehensive Cancer Network Guidelines. Rectal Cancer Version 1.2021. Available at www.nccn.org. Accessed February 5, 2021.

Reviews, Revisions, and Approvals	Date	Approval Date
2Q 2018 annual review: summarized NCCN and FDA approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	04.07.18	
2Q 2019 annual review: added appendices/dosage and administration information/product availability; references reviewed and updated.	04/19	
2Q 2020 annual review: added NCCN compendium-supported use of colorectal cancer; references reviewed and updated.	04/2020	
2Q 2021 annual review: added requirement for BRAF wild-type disease for off-label indication of colorectal cancer per NCCN; added NCCN compendium-supported indication of salivary gland tumors and combined with colorectal cancer criteria; references reviewed and updated.	04/2021	