RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	pertuzumab
Policy Number:	RxA.249
Drug(s) Applied:	Perjeta®
Original Policy Date:	02/07/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

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

Perjeta is indicated for:

- Use in combination with trastuzumab and docetaxel for the treatment of patients with HER2positive 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.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Pertuzumab (Perjeta®)	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

Dosage Forms

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

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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
Commercial: 6 months
Medicaid: 6 months
HIM: 6 months

II. Continued Therapy Approval

A. Breast Cancer (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Perjeta for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively 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
Commercial: 12 months (Total of 18 cycles if neoadjuvant or adjuvant therapy)
Medicaid: 12 months (Total of 18 cycles if neoadjuvant or adjuvant therapy)
HIM: 12 months (Total of 18 cycles if neoadjuvant or adjuvant therapy)

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2

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: • 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

APPENDIX D: General Information

- Not applicable

References

1. Perjeta Prescribing Information. South San Francisco, CA: Genentech, Inc.; January 2020. Available at http://www.gene.com/download/pdf/perjeta_prescribing.pdf. Accessed July 8 2020
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed July 8, 2020.
3. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 4.2020 . Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed July 8, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Continued Therapy criteria II.A.1. was rephrased to “Currently receiving medication that has been authorized by RxAdvance..” 4. Initial approval criteria approval	07/08/2020	09/14/2020

Review/Revision History	Review/Revised Date	P&T Approval Date
duration was updated to include Commercial, Medicaid and HIM approval duration as 6 months. 5. Continued therapy approval duration was updated to include Commercial, Medicaid and HIM approval duration as 12 months. 6. References were reviewed and updated.		