SmartHealth Ascension

Pertuzumab

(Perjeta®) J9306 (1mg)

Covered with prior authorization

Pertuzumab (Perjeta®) may be authorized when the following criteria are met:

- Individual has a diagnosis of HER2-positive (HER2+) breast cancer (NCCN 2A); **AND**
- Diagnosis is confirmed by one of the following:
    - Immunohistochemistry (IHC) is 3+; **OR**
    - In situ hybridization (ISH) positive; **AND**
- Treatment plan is one of the following:
    - Individual has a diagnosis of **metastatic breast cancer**; **AND**
        - Pertuzumab is used in combination with trastuzumab (or trastuzumab biosimilars) and either docetaxel or paclitaxel:
            - Exception: if docetaxel or paclitaxel treatment is contraindicated upon initiation or discontinued due to toxicity or intolerance, treatment with pertuzumab and trastuzumab without docetaxel or paclitaxel may continue; **AND**
        - Combination chemotherapy will be used as single-line anti-HER2 chemotherapy for metastatic disease until progression;

    OR

    - Individual has **early stage, locally advanced, or inflammatory breast cancer**; **AND**
        - Individual will undergo neoadjuvant (prior to surgery) therapy or adjuvant systemic therapy; AND
        - 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**
        - Individual has a ECOG performance status of 0-2; **AND**
        - Pertuzumab is used in combination with trastuzumab (or trastuzumab biosimilars) and either of the following:
            - Docetaxel with or without carboplatin; **OR**
            - Paclitaxel; **AND**
        - Individual is using pertuzumab for a maximum of 18 cycles (12 month course);

OR

- Treatment plan for individual includes pertuzumab in combination with trastuzumab (or trastuzumab biosimilars) for 12 months after completing 6 cycles (18 weeks) of TCHP (docetaxel, carboplatin, trastuzumab (or trastuzumab biosimilars), pertuzumab) for early stage, locally advance, or inflammatory breast cancer;

AND

- Prescriber is an oncologist; **AND**

- Treatment follows an approved dosing regimen:
    - Initial dose is 840 mg, followed every 3 weeks thereafter by 420 mg;
    - MBC: pertuzumab, trastuzumab or trastuzumab hyaluronidase oysk, and docetaxel every 3 weeks;
    - Neoadjuvant: pertuzumab, trastuzumab or trastuzumab hyaluronidase-oysk, and chemotherapy preoperatively every 3 weeks for 3 to 6 cycles;
    - Adjuvant: pertuzumab, trastuzumab or trastuzumab hyaluronidase-oysk, and chemotherapy postoperatively every 3 weeks for a total of 1 year (up to 18 cycles).

Exclusion criteria:
Requests may not be approved for the following:

- Requests for treatment plans of pertuzumab after trastuzumab (or trastuzumab biosimilars) is discontinued or as part of a regimen without trastuzumab (or trastuzumab biosimilars);
- Concomitant use of pertuzumab with other targeted biologic agents not otherwise noted in the criteria above (including, but not limited to erlotinib, cetuximab, panitumumab, bevacizumab, lapatinib, and ziv-aflibercept);
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Perjeta® is a HER2/neu receptor antagonist indicated for:

- Use in combination with trastuzumab and docetaxel for treatment of patients with HER2-positive metastatic breast cancer (MBC) 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

References:

Dai, W. F., Beca, J. M., & et al. (2022, February 28). Comparative Effectiveness and Safety of Pertuzumab and Trastuzumab Plus Chemotherapy vs Trastuzumab Plus Chemotherapy for Treatment of Metastatic Breast Cancer. *JAMA Netw Open*, *5*(2), e2145460. doi:10.1001/jamanetworkopen.2021.45460
PERJETA® (pertuzumab). (2021, February). Genentech. Retrieved June 21, 2022, from https://www.gene.com/download/pdf/perjeta_prescribing.pdf
Perjeta (pertuzumab). (updated periodically). Medscape Reference. Retrieved June 21, 2022, from https://reference.medscape.com/drug/perjeta-pertuzumab-999749
Pertuzumab (Lexi-Drugs). (2022, April 19). Lexicomp. Retrieved June 21, 2022, from https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/3791605?cesid=asiF7Kk36dq&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3Dperjeta%26t%3Dname%26acs%3Dfalse%26acq%3Dperjeta

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.