Pertuzumab (Perjeta®)	Place of Service Office Administration Outpatient Facility Infusion Administration Infusion Center Administration HCPCS: J9306 per 1 mg

Condition(s) listed in policy (*see criteria for details*)

- Breast cancer (HER2-positive)
- Colorectal cancer (HER2-positive)
- Head and neck cancer, salivary gland tumors (HER2-positive)
- Hepatobiliary cancers - Cholangiocarcinoma and gallbladder cancer (HER2-positive)

AHFS therapeutic class: Antineoplastic Agent

Mechanism of action: Pertuzumab is an anti-HER2 receptor monoclonal antibody

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Perjeta® (pertuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer (HER-2 positive)

1. Patient is HER2-positive, **AND**
2. One of the following:
    a. For neoadjuvant or adjuvant therapy and will be used in combination with trastuzumab, **OR**
    b. For recurrent unresectable or metastatic disease, and meets one of the following:
        i. For first line treatment and Patient has not received prior anti-HER2 therapy (e.g., trastuzumab, pertuzumab, or lapatinib) or chemotherapy for metastatic disease, and will be used in combination with trastuzumab and either docetaxel or paclitaxel, OR
        ii. For subsequent treatment and Patient has received trastuzumab and not Perjeta, and will be using Perjeta in combination with trastuzumab with or without chemotherapy

Covered Doses
Up to 840 mg IV as a one-time loading dose, then up to 420 mg IV every 3 weeks thereafter

Coverage Period
Neoadjuvant/adjuvant:
Cover maximum of 18 doses (1 year)

Metastatic:
Cover indefinitely

ICD-10:
C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

Colorectal cancer (HER2-positive)

1. Patient is HER2-positive, **AND**
2. Being used for advanced, metastatic, unresectable, inoperable, or recurrent disease, **AND**
3. Patient has not been previously treated with HER2 inhibitor, **AND**
4. Patient is RAS (KRAS/NRAS) and BRAF wild-type (negative for mutation), **AND**
5. Being used in combination with trastuzumab

Covered Doses
Up to 840 mg IV for the first dose, followed by up to 420 mg IV every 3 weeks

Coverage Period
Indefinite

ICD-10:

C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C19, C20, C21.8, C78.00-C78.02, C78.6, C78.7, Z85.038, Z85.068

Head and neck cancer, salivary gland tumors (HER2-positive)

1. Diagnosis of salivary gland tumor, **AND**
2. Recurrent, unresectable, or metastatic disease, **AND**
3. Patient is HER2-positive, **AND**
4. Being used in combination with trastuzumab

Covered Doses
Up to 840 mg IV for the first dose, followed by up to 420 mg IV every 3 weeks

Coverage Period
Indefinite

ICD-10:
C06.9, C07, C08.0, C08.1, C08.9

Hepatobiliary cancers - Cholangiocarcinoma and gallbladder cancer

1. Being used for unresectable or metastatic disease, **AND**
2. Patient is HER2-positive, **AND**
3. Given in combination with trastuzumab

Covered Doses
Up to 840 mg IV for the first dose, followed by up to 420 mg IV every 3 weeks

Coverage Period
Indefinite

ICD-10:
C22.1, C23, C24.0, C24.8, C24

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Perjeta® (pertuzumab) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
420 mg (single-use vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network. Biliary tract cancers (Volume 2.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Breast cancer (Volume 4.2023). Available at http://www.nccn.org.
- National Comprehensive Cancer Network. Colon cancer (Volume 2.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Head and neck cancer (Volume 2.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Rectal cancer (Volume 3.2023). Available at www.nccn.org.
- Perjeta® (pertuzumab) [prescribing information]. South San Francisco, CA: Genentech Inc./ Roche Group; 2/2021.

(7) Policy Update

Date of last review: 3Q2023
Date of next review: 3Q2024
Changes from previous policy version:

- No changes to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee