Perjeta® (pertuzumab)
(Intravenous)

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I. Length of Authorization [1,2]

Coverage is provided for 6 months and may be renewed (unless otherwise specified).

- Neoadjuvant and adjuvant treatment in Breast Cancer may be authorized up to a maximum of 1 year of treatment [18 cycles].

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

Perjeta 420 mg/14 mL solution for injection:

- Loading Dose: 2 vials
- Maintenance Dose: 1 vial every 21 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- Loading Dose: 840 billable units x 1 dose
- Maintenance Dose: 420 billable units every 21 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; AND

Universal Criteria [1]

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; AND

- Patient has human epidermal growth factor receptor 2 (HER2)-positive* disease as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Therapy will not be used in combination with pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**

Breast Cancer † ‡ [1-3,5-8,13]

- Used as neoadjuvant or preoperative therapy; **AND**
  - Patient has locally advanced, node positive, or inflammatory disease; **AND**
  - Used in combination with trastuzumab and chemotherapy; **OR**
- Used as adjuvant therapy; **AND**
  - Patient has locally advanced, node positive, or inflammatory disease; **AND**
    - Used in combination with trastuzumab and chemotherapy; **OR**
    - Used in combination with trastuzumab; **OR**
- Used for recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used as first-line therapy in combination with trastuzumab AND either paclitaxel or docetaxel; **OR**
  - Used as subsequent therapy in combination with trastuzumab with or without cytotoxic therapy ‡; **AND**
    - Patient was previously treated with trastuzumab and chemotherapy; **AND**
    - Patient has not previously received pertuzumab

Central Nervous System (CNS) Cancers ‡ [2]

- Used for the treatment of brain metastases in patients with breast cancer; **AND**
- Used in combination with trastuzumab; **AND**
  - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
  - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; **OR**
  - Patient has recurrent limited brain metastases; **OR**
  - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options

Colorectal Cancer (CRC) ‡ [2,9-12]

- Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; **AND**
  - Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CapeOX within the past 12 months; **AND**
    - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**

- Used as primary treatment for unresectable (or medically inoperable), or metastatic disease if intensive therapy is not recommended; **AND**
  - Patient has not previously received HER2-targeted therapy; **AND**
  - Used in one of the following:
    - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
    - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta [POLE/POLD1] mutation; **AND**
      - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; **OR**
- Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or unresectable (or medically inoperable) <u>rectal</u> cancer if intensive therapy is not recommended; **AND**
  - Used if resection is contraindicated following total neoadjuvant therapy; **AND**
    - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
    - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
      - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; **OR**
  - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **AND**
    - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; **OR**
- Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
  - Patient has not previously received HER2-targeted therapy; **AND**
  - Used in one of the following:
    - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
    - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta [POLE/POLD1] mutation; **AND**
      - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

Appendiceal Adenocarcinoma – Colon Cancer ‡ [2,10]

- Used for RAS and BRAF wild-type (WT) disease in combination with trastuzumab; **AND**
- Patient has not previously received HER2-targeted therapy; **AND**

- Used for one of the following:
  - Used as initial therapy for advanced or metastatic disease if intensive therapy is not recommended; **OR**
  - Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
- Used in one of the following:
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta [POLE/POLD1] mutation; **AND**
    - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

Head and Neck Cancers ‡ [2,14,15]

- Patient has salivary gland tumors; **AND**
- Used in combination with trastuzumab; **AND**
- Used for one of the following:
  - Recurrent disease with distant metastases
  - Unresectable locoregional recurrence with prior radiation therapy (RT)
  - Unresectable second primary with prior RT

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡ [2,16,17]

- Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease; **AND**
- Used in combination with trastuzumab

***HER2-positive overexpression criteria**
Breast, CNS, and Head and Neck: [3,4]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR**
• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

Colorectal Cancer and Appendiceal Adenocarcinoma: [10,11]
• Immunohistochemistry (IHC) assay 3+; **OR** • Fluorescence in situ hybridization (FISH) HER2/CEP17 ratio ≥ 2 AND concurrent IHC 2+; **OR**

• Next-generation sequencing (NGS) panel HER2 amplification
Biliary Tract Cancer: [17]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR**
• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+; **OR**
• Next-generation sequencing (NGS) panel HER2 amplification

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: left ventricular dysfunction, severe infusion-related reactions, hypersensitivity reactions/anaphylaxis, etc.; **AND**
- Left ventricular ejection fraction (LVEF) obtained within the previous 3 months as follows:
  - Neoadjuvant and adjuvant treatment of breast cancer: LVEF is ≥ 50% OR LVEF has had an absolute decrease of < 10% from baseline
  - All other indications: LVEF is > 45% OR LVEF is 40% to 45% and absolute decrease is < 10% from baseline

Breast Cancer (neoadjuvant or adjuvant therapy) [1,2]

- Patient has not exceeded a maximum of 1 year of treatment (total of 18 cycles)

V. Dosage/Administration [1,10-13,15,16,18]

Indication	Dose
Breast Cancer	Administer 840 mg intravenously x 1 dose, then 420 mg intravenously every 21 days thereafter until disease progression or unmanageable toxicity. • Neoadjuvant therapy consists of 3 to 6 cycles prior to surgery. • Use for neoadjuvant and adjuvant treatment is limited to a total of 1 year of treatment (total of 18 cycles). **Note: When used for recurrent or metastatic breast cancer, therapy may be continued until disease progression or unmanageable toxicity.*
All other indications	Administer 840 mg intravenously x 1 dose, then 420 mg intravenously every 21 days thereafter until disease progression or unmanageable toxicity.

VI. Billing Code/Availability Information

HCPCS Code:

- J9306 – Injection, pertuzumab, 1 mg; 1 mg = 1 billable unit

NDC:

- Perjeta 420 mg/14 mL single-dose vial for injection: 50242-0145-xx

VII. References

1. Perjeta [package insert]. South San Francisco, CA; Genentech, Inc.; February 2021. Accessed January 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pertuzumab. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer, Version 1.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2024.
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10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer, Version 1.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2024.
11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer, Version 1.2024. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2024.
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17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Biliary Tract Cancers, Version 3.2023. National Comprehensive Cancer Network, 2024. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed January 2024.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C06.9	Malignant neoplasm of mouth, unspecified
C07	Malignant neoplasm of parotid gland
C08.0	Malignant neoplasm of submandibular gland
C08.1	Malignant neoplasm of sublingual gland
C08.9	Malignant neoplasm of major salivary gland, unspecified
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of large intestines
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.1	Intrahepatic bile duct carcinoma

ICD-10	ICD-10 Description
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast

ICD-10	ICD-10 Description
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.31	Secondary malignant neoplasm of brain
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.3	Personal history of malignant neoplasm of breast

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC