Perjeta® (pertuzumab)
(Intravenous)

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I. Length of Authorization [1,2]

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days), unless otherwise specified.
  - Neoadjuvant and adjuvant treatment in Breast Cancer may be renewed up to a maximum of 1 year of treatment [18 cycles].

II. Dosing Limits

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]

Prior authorization validity is provided in the following conditions:

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

Breast Cancer † ‡ [1-3,5-8,13,19]

- Used as neoadjuvant or preoperative therapy; **AND**

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- Member has ≥ T1c disease, node positive disease, or inflammatory disease; **AND**
- Used in combination with trastuzumab and chemotherapy; **OR**

- Used as adjuvant therapy; **AND**
  - Member has ≥ T1 disease, node positive disease, or inflammatory disease (unless otherwise specified); **AND**
    - Used in combination with trastuzumab and chemotherapy (pT2-3 and pN0 or pN+ ONLY); **OR**
    - Used in combination with trastuzumab; **OR**
  - Used after completion of planned chemotherapy and following mastectomy or breast-conserving surgery; **AND**
    - Member has ≥ ypT0N0 or pCR disease by axillary staging; **AND**
    - Used in combination with trastuzumab; **OR**
- Used for recurrent unresectable (local or regional) or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
  - Used in combination with one of the following:
    - Trastuzumab and endocrine therapy, with or without palbociclib as first-line maintenance therapy following induction treatment with chemotherapy, trastuzumab, and with or without pertzumab; **AND**
      - Member has hormone receptor-positive disease; **AND**
        - Member is postmenopausal; **OR**
        - Member is premenopausal and is treated with ovarian ablation/suppression; **OR**
        - Member is a male (sex assigned at birth) **¥**
    - Trastuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy
    - Trastuzumab with or without cytotoxic therapy as subsequent therapy in members previously treated with chemotherapy and trastuzumab (without pertuzumab)
    - Fam-trastuzumab deruxtecan as first-line therapy

***¥** When an aromatase inhibitor is used in males, suppression of testicular steroidogenesis with a GnRH analog is required.*

Central Nervous System (CNS) Cancers ‡ [2]

- Member has brain metastases from breast cancer; **AND**
- Used in combination with trastuzumab

Colorectal Cancer (CRC) λ ‡ [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; **OR**

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- Used as primary treatment for unresectable (or medically inoperable), or metastatic disease; **AND**
  - Member has not previously received HER2-targeted therapy; **OR**
- Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or locally unresectable (or medically inoperable) rectal cancer; **AND**
  - Used if resection is contraindicated following total neoadjuvant therapy; **OR**
  - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
- Used as subsequent therapy; **AND**
  - Member has not previously received HER2-targeted therapy

λ *Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed members. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the member is a candidate.*

Head and Neck Cancers ‡ [2,14,15]

- Member has salivary gland tumors; **AND**
- Used in combination with trastuzumab; **AND**
- Member has recurrent disease with one of the following:
  - 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, gross residual (R2), or metastatic disease; **AND**
- Used in combination with trastuzumab

Appendiceal Neoplasms and Cancers ‡ [2,21]

- Member has RAS and BRAF wild-type (WT) disease; **AND**
- Used in combination with trastuzumab; **AND**
- Used as subsequent therapy (if not previously given) for recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease

Small Bowel Adenocarcinoma ‡ [2,22]

- Member has RAS and BRAF wild-type (WT) disease; **AND**
- Used in combination with trastuzumab; **AND**
- Used as subsequent therapy for advanced or metastatic disease (if not previously given)

***HER2-positive overexpression criteria**

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Breast, CNS, and Head and Neck: [3,4]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Dual-probe in situ hybridization (ISH) assay HER2 *(ERBB2)*/CEP17 ratio ≥ 2.0 AND average HER2 *(ERBB2)* copy number ≥ 4.0 signals/cell; **OR**
• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2 *(ERBB2)*/CEP17 ratio ≥ 2.0 AND average HER2 *(ERBB2)* copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  ○ HER2 *(ERBB2)*/CEP17 ratio < 2.0 AND average HER2 *(ERBB2)* copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**
  ○ HER2 *(ERBB2)*/CEP17 ratio < 2.0 AND average HER2 *(ERBB2)* copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

Colorectal Cancer, Appendiceal Neoplasms and Cancers, and Small Bowel Adenocarcinoma: [10,11,21,22]
• Immunohistochemistry (IHC) assay 3+; **OR** • Fluorescence in situ hybridization (FISH) HER2 *(ERBB2)*/CEP17 ratio ≥ 2 AND concurrent IHC 2+; **OR** • Next-generation sequencing (NGS) panel HER2 *(ERBB2)* amplification
Biliary Tract Cancer: [17]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Dual-probe in situ hybridization (ISH) assay HER2 *(ERBB2)*/CEP17 ratio ≥ 2.0 AND average HER2 *(ERBB2)* copy number ≥ 4.0 signals/cell; **OR**
• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2 *(ERBB2)*/CEP17 ratio ≥ 2.0 AND average HER2 *(ERBB2)* copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  ○ HER2 *(ERBB2)*/CEP17 ratio < 2.0 AND average HER2 *(ERBB2)* copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**
  ○ HER2 *(ERBB2)*/CEP17 ratio < 2.0 AND average HER2 *(ERBB2)* copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+; **OR**
• Next-generation sequencing (NGS) panel HER2 *(ERBB2)* 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]

Prior authorization validity may be renewed based upon the following criteria:

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- Member 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**
- Duration of authorization has not been exceeded *(refer to Section I)*; **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

V. Dosage/Administration [1-3,10-13,15,16,18,20]

Indication	Dose
Breast Cancer	**Initial Dose** Administer 840 mg intravenously x 1 dose **Maintenance Dose** Administer 420 mg intravenously every 21 days thereafter until disease progression or unmanageable toxicity (unless otherwise specified below). • Neoadjuvant/preoperative therapy consists of 3 to 9 cycles prior to surgery. • Use for neoadjuvant/preoperative and adjuvant treatment is limited to a total of 1 year of treatment (total of 18 cycles).
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 billable unit = 1 mg

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.; April 2026. Accessed July 2026.

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Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

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
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant

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ICD-10	ICD-10 Description
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, 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
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

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ICD-10	ICD-10 Description
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
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

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ICD-10	ICD-10 Description
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C50.A0	Malignant inflammatory neoplasm of unspecified breast
C50.A1	Malignant inflammatory neoplasm of right breast
C50.A2	Malignant inflammatory neoplasm of left 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
D37.031	Neoplasm of uncertain behavior of the sublingual salivary glands
D37.032	Neoplasm of uncertain behavior of the submandibular salivary glands
D37.039	Neoplasm of uncertain behavior of the submandibular salivary glands
D37.3	Neoplasm of uncertain behavior of appendix
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small 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)

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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

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