

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 hyaluronidasezzxf (Phesgo); AND

Breast Cancer † ‡ 1-3,5-8,13

- Used as neoadjuvant or preoperative therapy; AND
 - o Patient has locally advanced, node positive, or inflammatory disease; AND
 - o Used in combination with trastuzumab and chemotherapy; **OR**
- Used as adjuvant therapy; AND
 - o 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) Cancer ‡ 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
 - o 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 primary treatment for unresectable metachronous metastases and previous adjuvant FOLFOX or CapeOX within the past 12 months; **OR**
 - Used as primary treatment for unresectable (or medically inoperable), locally advanced,
 or metastatic disease if intensive therapy is not recommended; AND
 - Patient has not previously received HER2-targeted therapy; OR



- Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; AND
 - Patient has not previously received HER2-targeted therapy

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 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 after at least one prior line of treatment in the advanced or metastatic disease setting

Head and Neck Cancer ‡ 2,14,15

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

Hepatobiliary Cancers ‡ 2,16,17

- Patient has gallbladder cancer, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; **AND**
- Used as subsequent treatment for progression on or after systemic treatment for unresectable or metastatic disease; AND
- Used in combination with trastuzumab

*HER2-positive overexpression criteria

Breast, CNS, Head and Neck, and Hepatobiliary Cancer: 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:
 - o HER2/CEP17 ratio \geq 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



 \circ HER2/CEP17 ratio < 2.0 AND average HER2 copy number \geq 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
- ♦ 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:
 - o Neoadjuvant and adjuvant treatment of breast cancer: LVEF is \geq 50% OR LVEF has had an <u>absolute</u> decrease of < 10% from baseline
 - All other indications: LVEF is > 45% OR LVEF is 40% to 45% and <u>absolute</u> decrease is <
 10% from baseline

Breast Cancer (neoadjuvant or adjuvant therapy)

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	
	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). 	



Indication	Dose
	*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 2023.
- 2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pertuzumab. National Comprehensive Cancer Network, 2023. 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 2023.
- 3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer, Version 1.2023. National Comprehensive Cancer Network, 2023. 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 2023.
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- 5. Gianni L, Pienkowski T, Im YH, et al. Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): a randomised multicentre, open-label, phase 2 trial. Lancet Oncol. 2012 Jan;13(1):25-32.
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- 10. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer, Version 3.2022. National Comprehensive Cancer Network, 2023. 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 2023.
- 11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer, Version 4.2022. National Comprehensive Cancer Network, 2023. 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 2023.
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- 13. Swain SM, Ewer MS, Viale G, et al. Pertuzumab, trastuzumab, and standard anthracycline-and taxane-based chemotherapy for the neoadjuvant treatment of patients with HER2-positive localized breast cancer (BERENICE): a phase II, open-label, multicenter, multinational cardiac safety study. Ann Oncol. 2018;29(3):646-653. doi:10.1093/annonc/mdx773.
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- 17. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hepatobiliary Cancers, Version 5.2022. National Comprehensive Cancer Network, 2023. 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 2023.
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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	
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	

ICD-10	ICD-10 Description	
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	
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	



ICD-10	ICD-10 Description	
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)

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 Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications may be covered 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)	



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, 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		



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Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
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U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

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ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY:
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1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- · Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PIC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist PreferredOne Insurance Company PO Box 59212 Minneapolis, MN 55459-0212 Phone: 1.800.940.5049 (TTY: 763.847.4013) Fax: 763.847.4010 customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

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ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).
ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013)
LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).
XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).
CHÚ Ý: Nếu ban nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho ban. Goi số 1.800.940.5049 (TTY: 763.847.4013).
注意:如果您使用繁體中文,您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。
ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).
ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ
1.800.940.5049 (TTY: 763.847.4013).
ማስታወሻ: የሚናንሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049
(መስጣት ለተሳናቸው: 763.847.4013 ).
ဟ်သူ၌ဟ်သး– နမ့်ကတိ၊ ကညီ ကျို်အယိ, နမၤန္ရ၊ ကျို်အတါမၤစၤလ၊ တလက်ဘူဉ်လက်စ္၊ နီတမံးဘဉ်သုန္၌လီ၊. ကိႏ 1.800.940.5049 (TTY: 763.847.4013).
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