



Jemperli® (dostarlimab-gxly)

(Intravenous)

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I. Length of Authorization ¹

Coverage will be provided for six months and may be renewed.

II. Dosing Limits

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

- Jemperli 500 mg/10 mL single use vial:
 - Initial: 1 vial every 21 days for four doses only
 - Subsequent: 2 vials every 42 days

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

- Initial: 50 billable units (500 mg) every 21 days for four doses only
- Subsequent: 100 billable units (1000 mg) every 42 days

III. Initial Approval Criteria ^{1,2}

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ^{1,4,9}

- Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab, etc.), unless otherwise specified; **AND**
- Patient does not have uncontrolled central nervous system metastatic cancer; **AND**
- Patient does not have interstitial lung disease; **AND**

Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer † ^{1-4,9}

- Patient has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) cancer as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent; **AND**
- Patient has one of the following cancers:

- Endometrial Carcinoma †
 - Patient does not have endometrial sarcoma (*excluding carcinosarcoma*); **AND**
 - Patient has advanced or recurrent disease; **AND**
 - Disease has progressed on or following treatment with a platinum-containing regimen
- Breast Cancer ‡
 - Used for recurrent unresectable or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**
 - Patient has progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Colorectal Cancer † ‡
 - Used as subsequent therapy; **AND**
 - Used for advanced or metastatic disease that has progressed following treatment with oxaliplatin-, irinotecan- and/or fluoropyrimidine based chemotherapy
- Gastric Adenocarcinoma ‡
 - Used as subsequent therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease; **AND**
 - Patient has progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Ocult Primary/Cancer of Unknown Primary (CUP) ‡
 - Used in symptomatic patients with PS 1-2 OR asymptomatic patients with PS 0 and aggressive disease; **AND**
 - Patient has adenocarcinoma or carcinoma not otherwise specified; **AND**
 - Patient has one of the following:
 - Axillary involvement in men if clinically indicated
 - Lung nodules or breast marker-negative pleural effusion
 - Resectable liver disease
 - Peritoneal mass or ascites with non-ovarian histology
 - Retroperitoneal mass of non-germ cell histology in selected patients
 - Unresectable liver disease or disseminated metastases
- Ovarian Cancer (epithelial ovarian, fallopian tube, and primary peritoneal cancers) ‡
 - Patient has carcinosarcoma (i.e., malignant mixed Müllerian tumor [MMMT]), clear cell, endometrioid, mucinous, borderline epithelial, or serous histology; **AND**
 - Used for patients with persistent or recurrent disease; **AND**
 - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 with no radiographic evidence of disease); **AND**
 - Patient has progressed following prior treatment; **AND**
 - Patient has no satisfactory alternative treatment options
- Small Bowel Adenocarcinoma or Advanced Ampullary Cancer ‡
 - Used for advanced or metastatic disease; **AND**
 - Used as initial therapy; **OR**

- Used as subsequent therapy in patients without a contraindication to oxaliplatin

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

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

IV. Renewal Criteria ¹

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria 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 severe infusion reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis and renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic HSCT after immunotherapy, etc.

V. Dosage/Administration ¹

Indication	Dose
dMMR/MSI-H Cancer	Administer 500 mg intravenously every three weeks for doses 1 through 4, followed by subsequent doses of 1,000 mg every six weeks (dose 5 begins three weeks after the 4 th dose) until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not otherwise classified, antineoplastic drug (*Discontinue use on 01/01/2022*)
- J9272 – Injection, dostarlimab-gxly, 10 mg; 1 billable unit = 10mg (*Effective 01/01/2022*)
- C9082 – Injection, dostarlimab-gxly, 100 mg; 1 billable unit = 100 mg (*Discontinue use on 01/01/2022*)

NDC:

- Jemperli 500 mg/10 mL solution in a single-dose vial: 00173-0898-xx

VII. References

1. Jemperli [package insert]. Research Triangle Park, NC; GlaxoSmithKline, LLC; August 2021. Accessed October 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) dostarlimab. National Comprehensive Cancer Network, 2021. The NCCN

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3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Uterine Neoplasms. Version 4.2021. National Comprehensive Cancer Network, 2021. 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 October 2021.
4. Oaknin A, Tinker AV, Gilbert L, et al. Clinical Activity and Safety of the Anti-Programmed Death 1 Monoclonal Antibody Dostarlimab for Patients With Recurrent or Advanced Mismatch Repair-Deficient Endometrial Cancer: A Nonrandomized Phase 1 Clinical Trial. JAMA Oncol. 2020 Oct 1. doi: 10.1001/jamaoncol.2020.4515. [Epub ahead of print]
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9. Berton D, Banerjee S, Curigliano G, et al. Antitumor activity of dostarlimab in patients with mismatch repair-deficient/microsatellite instability–high tumors: A combined analysis of two cohorts in the GARNET study. Journal of Clinical Oncology. Volume 39, Issue 15_suppl. doi/abs/10.1200/JCO.2021.39.15_suppl.2564

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified

JEMPERLI® (dostarlimab-gxly) Prior Auth Criteria

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ICD-10	ICD-10 Description
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, 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
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 colon
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
C24.1	Malignant neoplasm of ampulla of Vater
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
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
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
D37.1	Neoplasm of uncertain behavior of stomach
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine

ICD-10	ICD-10 Description
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.43	Personal history of malignant neoplasm of ovary

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)
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