

# Jemperli® (dostarlimab-gxly) (Intravenous)

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04/2024, 08/2024

## I. Length of Authorization $^{\Delta 1}$

Coverage will be provided for 6 months and may be renewed, unless otherwise specified.

 Endometrial Carcinoma (Uterine Neoplasms) and MSI-H/dMMR Endometrial Cancer: Use in combination with carboplatin and paclitaxel may be renewed for up to a maximum of 3 years of therapy (30 doses).

## II. Dosing Limits

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

- Jemperli 500 mg/10 mL single-dose vial:
  - Initial: 1 vial every 21 days for 6 doses
  - Subsequent: 2 vials every 42 days

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

Indication	Billable Units (BU)	Per unit time (days)
Endometrial Cancer	Initial: 50 BU	21 days x 6 doses
	Subsequent: 100 BU	42 days
All other indications	Initial: 50 BU	21 days x 4 doses
	Subsequent: 100 BU	42 days

## III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

Patient is at least 18 years of age; AND

#### **Universal Criteria**

• Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., cemiplimab, avelumab, nivolumab, atezolizumab, durvalumab, pembrolizumab,



nivolumab/relatlimab, retifanlimab, tislelizumab, toripalimab, etc.), unless otherwise specified  $^{\Delta}$ ;

#### Endometrial Carcinoma (Uterine Neoplasms) ‡ 2,3,10

- Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; AND
  - Used as primary treatment for patients with stage III-IV tumors; OR
  - Used as adjuvant therapy for patients with stage III-IV tumors; OR
  - Used as first-line therapy for recurrent disease; AND
    - Patient does not have isolated metastases

#### Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer † ‡ 1-4,9,10

- - Used in combination with carboplatin and paclitaxel, followed by single agent therapy; AND
    - Patient has primary advanced or first recurrent endometrial cancer †; OR
  - Used as a single agent; AND
    - Used as subsequent therapy for unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic disease; AND
      - Patient has endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen in any setting; OR
      - Patient has solid tumors that have progressed on or following prior treatment (excluding colorectal cancer); AND
        - Patient has no satisfactory alternative treatment options; OR
      - Patient has colorectal cancer and disease has progressed on oxaliplatin-, irinotecan- and fluoropyrimidine-based therapy; AND
        - Patient has no satisfactory alternative treatment options

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

- ❖ If confirmed using an FDA approved assay <a href="http://www.fda.gov/companiondiagnostics">http://www.fda.gov/companiondiagnostics</a>
- † FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); ♠ Orphan Drug



### IV. Renewal Criteria <sup>41</sup>

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the 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-related reactions, severe immune-mediated adverse reactions (e.g., pneumonitis, hepatitis, colitis, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions/rash, etc.), complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; AND

Endometrial Carcinoma (Uterine Neoplasms) and MSI-H/dMMR Endometrial Cancer (in combination with carboplatin and paclitaxel) <sup>1,10</sup>

Patient has not exceeded a maximum of three (3) years of therapy (30 doses)

## <sup>Δ</sup> Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 3 years of therapy) are eligible to re-initiate PD-directed therapy.
- Patients previously presenting with aggressive disease who are exhibiting stable disease on treatment as their best response (or if therapy improved performance status) may be eligible for continued therapy beyond the 3-year limit without interruption or discontinuation.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate PD-directed therapy and will be evaluated on a case-by-case basis.
- Patients diagnosed with Gastric, Esophageal, and Esophagogastric Junction Cancers who are
  not surgical candidates or have unresectable locally advanced, recurrent, or metastatic
  disease and who have received previous checkpoint inhibitor therapy are eligible for
  treatment with dostarlimab as first-line palliative therapy provided there has been no prior
  tumor progression while on therapy with a checkpoint inhibitor.



# V. Dosage/Administration Δ 1,3,10,11

Indication	Dose	
Endometrial	In combination with carboplatin and paclitaxel:	
Carcinoma	Administer 500 mg intravenously every 3 weeks for 6 doses in combination with carboplatin and	
(Uterine	paclitaxel, followed by 1,000 mg monotherapy every 6 weeks (dose 7 begins three weeks after the 6 <sup>th</sup>	
Neoplasms)	dose) for up to 3 years or until disease progression or unacceptable toxicity.	
MSI-H/dMMR	In combination with carboplatin and paclitaxel:	
Endometrial	Administer 500 mg intravenously every 3 weeks for 6 doses in combination with carboplatin and	
Cancer	paclitaxel, followed by 1,000 mg monotherapy every 6 weeks (dose 7 begins three weeks after the 6 <sup>th</sup>	
	dose) for up to 3 years or until disease progression or unacceptable toxicity.	
	Single agent:	
	Administer 500 mg intravenously every 3 weeks for 4 doses, followed by 1,000 mg every 6 weeks	
	(dose 5 begins three weeks after the 4 <sup>th</sup> dose) until disease progression or unacceptable toxicity.	
MSI-H/dMMR	Single agent:	
Solid Tumors	Administer 500 mg intravenously every three weeks for 4 doses, followed by 1,000 mg every 6 weeks	
	(dose 5 begins three weeks after the 4 <sup>th</sup> dose) until disease progression or unacceptable toxicity.	

## VI. Billing Code/Availability Information

#### **HCPCS Code:**

J9272 - Injection, dostarlimab-gxly, 10 mg; 1 billable unit = 10mg

#### NDC:

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

## VII. References (STANDARD)

- 1. Jemperli [package insert]. Durham, NC; GlaxoSmithKline, LLC; March 2024. Accessed June 2024.
- 2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) dostarlimab-gxly. 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 June 2024.
- Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Uterine Neoplasms. Version 2.2024. 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



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- 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]
- 5. Gupta S, Sonpavde G, Grivas P, et al. Defining "platinum-ineligible" patients with metastatic urothelial cancer (mUC). J Clin Oncol. 2019 Mar 1;37(7\_suppl):451.
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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.
- 10. Mirza M, Chase D, Slomovitz B, et al. Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer. March 27, 2023. doi: 10.1056/NEJMoa2216334.
- 11. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Small Bowel Adenocarcinoma. Version 3.2024. 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 June 2024.

## VIII. References (ENHANCED)

- 1e. Marabelle A, Le DT, Ascierto PA, et al. Efficacy of Pembrolizumab in Patients With Noncolorectal High Microsatellite Instability/Mismatch Repair-Deficient Cancer: Results From the Phase II KEYNOTE-158 Study. J Clin Oncol. 2020 Jan 1;38(1):1-10. doi: 10.1200/JCO.19.02105. Epub 2019 Nov 4.
- 2e. Azad NS, Gray RJ, Overman MJ, et al. Nivolumab Is Effective in Mismatch Repair-Deficient Noncolorectal Cancers: Results From Arm Z1D-A Subprotocol of the NCI-MATCH (EAY131) Study. J Clin Oncol. 2020 Jan 20;38(3):214-222.



- 3e. Marabelle A, Le DT, Ascierto PA, et al. Efficacy of Pembrolizumab in Patients With Noncolorectal High Microsatellite Instability/Mismatch Repair-Deficient Cancer: Results From the Phase II KEYNOTE-158 Study. J Clin Oncol. 2020 Jan 1;38(1):1-10. doi: 10.1200/JCO.19.02105. Epub 2019 Nov 4.
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- 6e. Overman MJ, McDermott R, Leach JL, et al. Nivolumab in patients with metastatic DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer (CheckMate 142): an open-label, multicentre, phase 2 study [published correction appears in Lancet Oncol. 2017 Sep;18(9):e510]. Lancet Oncol. 2017;18(9):1182-1191. doi:10.1016/S1470-2045(17)30422-9.
- 7e. Eskander RN, Sill MW, Beffa L, et al. Pembrolizumab plus Chemotherapy in Advanced Endometrial Cancer. N Engl J Med. 2023 Mar 27. doi: 10.1056/ NEJMoa2302312. Epub ahead of print. PMID: 36972022.
- 8e. Garmezy B, Gheeya J, Lin HY, et al. Clinical and Molecular Characterization of *POLE* Mutations as Predictive Biomarkers of Response to Immune Checkpoint Inhibitors in Advanced Cancers. JCO Precis Oncol. 2022 Feb;6:e2100267.
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## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description	
C15.3	Malignant neoplasm of upper third of esophagus	
C15.4	Malignant neoplasm of middle third of esophagus	
C15.5	Malignant neoplasm of lower third of esophagus	
C15.8	Malignant neoplasm of overlapping sites of esophagus	
C15.9	Malignant neoplasm of esophagus, unspecified	
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	



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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	
C25.0	Malignant neoplasm of head of pancreas	
C25.1	Malignant neoplasm of body of pancreas	
C25.2	Malignant neoplasm of tail of pancreas	
C25.3	Malignant neoplasm of pancreatic duct	
C25.7	Malignant neoplasm of other parts of pancreas	
C25.8	Malignant neoplasm of overlapping sites of pancreas	
C25.9	Malignant neoplasm of pancreas, unspecified	
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	
-	•	



ICD-10	ICD-10 Description	
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	
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	
C56.3	Malignant neoplasm of bilateral ovaries	
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	



ICD-10	ICD-10 Description	
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	
D37.8	Neoplasm of uncertain behavior of other specified digestive organs	
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified	
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ	
Z85.01	Personal history of malignant neoplasm of esophagus	
Z85.028	Personal history of other malignant neoplasm of stomach	
Z85.068	Personal history of other malignant neoplasm of small intestine	
Z85.07	Personal history of malignant neoplasm of pancreas	
Z85.09	Personal history of malignant neoplasm of other digestive organs	
Z85.3	Personal history of malignant neoplasm of breast	
Z85.42	Personal history of malignant neoplasm of other parts of uterus	
Z85.43	Personal history of malignant neoplasm of ovary	

# 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: <a href="https://www.cms.gov/medicare-coverage-database/search.aspx">https://www.cms.gov/medicare-coverage-database/search.aspx</a>. 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	
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	ку, он	CGS Administrators, LLC	