

Jemperli (dostarlimab-gxly) (Intravenous)

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I. Length of Authorization ^{Δ 1,16,17}

- 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) thereafter, unless otherwise specified.
 - Endometrial Carcinoma (Uterine Neoplasms) - Use in combination with carboplatin and paclitaxel followed by single agent maintenance therapy: Prior authorization validity may be renewed for up to a maximum of 3 years (30 doses).
 - Gastric, Esophageal and Esophagogastric Junction Cancers neoadjuvant therapy: Prior authorization validity may be renewed for up to a maximum of 27 weeks total (9 cycles).
 - Anal carcinoma in combination with paclitaxel and carboplatin, then continued as a single agent: Prior authorization validity may be renewed for up to a maximum of 1 year.

II. Dosing Limits

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
Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer	Initial: 50 BU	21 days x 4 doses
	Subsequent: 100 BU	21 days x 5 doses then every 42 days
All other indications	Initial: 50 BU	21 days x 4 doses
	Subsequent: 100 BU	42 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

- Member has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy, unless otherwise specified ^Δ; **AND**

Endometrial Carcinoma (Uterine Neoplasms) † ‡ ¹⁻⁴

- Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; **AND**
 - Member has primary advanced or recurrent disease †; **OR**
 - Used as primary treatment for members with stage III-IV tumors ‡; **OR**
 - Used as adjuvant therapy for members with stage III-IV tumors ‡; **OR**
 - Used as first-line or subsequent therapy for recurrent disease ‡; **AND**
 - Will not be used for either of the following:
 - Therapy for locoregional recurrence in members with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
 - Therapy after surgical exploration for locoregional recurrence in members with disease confined to the vagina or paravaginal soft tissue

Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer † ‡ ^{1-3,11-14,16,17}

- Member has mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) cancer as determined by an FDA-approved or Clinical Laboratory Improvement Amendments (CLIA)-compliant test❖; **AND**
- Used as a single agent; **AND**
 - Used as subsequent therapy for unresectable or medically inoperable, advanced, recurrent, persistent, or metastatic disease; **AND**
 - Member has endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen in any setting †; **OR**
 - Member has solid tumors that have progressed on or following prior treatment; **OR**
 - Used as induction systemic therapy for relieving dysphagia; **AND**
 - Member has Esophageal or Esophagogastric Junction squamous cell carcinoma; **AND**
 - Member is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **OR**
 - Used as initial therapy ‡; **AND**
 - Member has one of the following cancers:
 - Recurrent, progressive, metastatic peritoneal-only, or extraperitoneal Appendiceal Neoplasms and Cancers
 - Locally unresectable or medically inoperable, advanced, or metastatic Colon Cancer

- Esophageal and Esophagogastric Junction Cancers in members with no prior checkpoint inhibitor therapy or no tumor progression while on therapy with a checkpoint inhibitor
- Gastric Cancer in members with no prior checkpoint inhibitor therapy or no tumor progression while on therapy with a checkpoint inhibitor
- Locally unresectable or medically inoperable, advanced, or metastatic Rectal Cancer
- Locally unresectable or medically inoperable, advanced, or metastatic Small Bowel Adenocarcinoma
- Recurrent Endometrial Carcinoma (Uterine Neoplasms) and will not be used for either of the following:
 - ❖ Therapy for locoregional recurrence in members with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
 - ❖ Therapy after surgical exploration for locoregional recurrence in members with disease confined to the vagina or paravaginal soft tissues
- Used as neoadjuvant therapy ‡; **AND**
 - Member has advanced or metastatic Colon Cancer or Rectal Cancer; **OR**
 - Member has Appendiceal Neoplasms and Cancers; **AND**
 - Used for biopsy-proven recurrence of high-risk disease and no previous cytoreductive surgery; **OR**
 - Used for metastatic disease in peritoneal-only; **OR**
 - Member has Esophageal or Esophagogastric Junction adenocarcinoma; **AND**
 - Member is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **OR**
 - Member has Gastric Cancer; **AND**
 - Member is medically fit for surgery and has potentially resectable locoregional disease (cT2 or higher, any N); **OR**
 - Member has advanced or metastatic Small Bowel Adenocarcinoma

Polymerase Epsilon/Delta (POLE/POLD1) Mutation Cancer ‡^{2,11-14,16}

- Used as a single agent; **AND**
- Member has disease with ultra-hypermutated phenotype [e.g., tumor mutational burden (TMB) > 50 mut/Mb]; **AND**
 - Member has Colon Cancer or Rectal Cancer; **AND**
 - Member has locally unresectable or medically inoperable, advanced, or metastatic disease; **OR**
 - Member has Appendiceal Neoplasms and Cancers; **AND**

- Member has recurrent, progressive, metastatic peritoneal-only, or extraperitoneal disease; **OR**
- Member has Small Bowel Adenocarcinoma; **AND**
 - Member has advanced or metastatic disease; **OR**
 - Member has locally unresectable or medically inoperable disease; **AND**
 - Used as primary treatment

Anal Carcinoma ‡^{2,14}

- Member has squamous cell carcinoma; **AND**
 - Used as a single agent as subsequent therapy for metastatic disease; **OR**
 - Used in combination with paclitaxel and carboplatin, then continued as a single agent; **AND**
 - Used for treatment of inguinal node recurrence; **OR**
 - Used as first-line treatment for metastatic disease

❖ If confirmed using an FDA approved assay – <http://www.fda.gov/companiondiagnostics>

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

IV. Renewal Criteria ^{Δ1}

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

- Member continues to meet the universal and other indication-specific relevant criteria 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: 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.

^Δ Notes:

- Members 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.
- Members 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.
- Members who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate PD-directed therapy for metastatic disease.
- Members 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.

V. Dosage/Administration ^{Δ 1,11-17}

Indication	Dose
Endometrial Carcinoma (Uterine Neoplasms)	Administer 500 mg intravenously every 3 weeks for 6 doses in combination with carboplatin and paclitaxel, followed by 1,000 mg monotherapy every 6 weeks (dose 7 begins three weeks after the 6 th dose) for up to 3 years or until disease progression or unacceptable toxicity.
MSI-H/dMMR Endometrial Cancer and Solid Tumors	Neoadjuvant therapy only for Gastric, Esophageal and Esophagogastric Junction Cancers: Administer 500 mg intravenously every 3 weeks for 9 cycles. All other regimens: 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 th dose) until disease progression or unacceptable toxicity.
POLE/POLD1 Mutation Tumors	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 th dose) until disease progression or unacceptable toxicity.
Anal Carcinoma	<u>Single agent:</u> Administer 500 mg intravenously every 3 weeks for 4 doses, followed by 1,000 mg every 6 weeks until disease progression or unacceptable toxicity. <u>In combination with carboplatin and paclitaxel:</u> Administer 500 mg intravenously every 3 weeks for 4 doses, followed by 1,000 mg every 6 weeks for up to a maximum of 1 year. <i>(Note: combination therapy may be administered for up to 24 weeks, followed by single agent maintenance therapy)</i>

VI. Billing Code/Availability Information

HCPCS Code:

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

NDC:

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

VII. References

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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	No: PA not a priority
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
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
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
C21.0	Malignant neoplasm of anus, unspecified
C21.1	Malignant neoplasm of anal canal
C21.2	Malignant neoplasm of cloacogenic zone

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium

ICD-10	ICD-10 Description
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
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
D37.3	Neoplasm of uncertain behavior of appendix
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

ICD-10	ICD-10 Description
Z85.038	Personal history of other malignant neoplasm of large intestine
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:

<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
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