Jemperli (dostarlimab-gxly)
(Intravenous)

-E-

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I. Length of Authorization Δ [1]

- 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).

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:

- 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, unless otherwise specified [Δ]; **AND**

Endometrial Carcinoma (Uterine Neoplasms) † ‡ [1-4,7e,8e]

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

Patients with dMMR tumors ONLY:
○ Use of dostarlimab will be restricted to patients with a contraindication or intolerance to durvalumab/carboplatin/paclitaxel

Mismatch Repair Deficient (dMMR)/Microsatellite Instability-High (MSI-H) Cancer † ‡ [1-3,11-13,14,16,17,1e,4e]

- Patient 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**
    - Patient has endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen in any setting †; **OR**
    - Patient has colorectal cancer; **AND**
      - Disease progressed on or was intolerant to oxaliplatin-, irinotecan- and fluoropyrimidine-based therapy; **AND**
      - Patient has no satisfactory alternative treatment options; **OR**
    - Patient has solid tumors that have progressed on or following prior treatment (*excluding endometrial and colorectal cancer*); **AND**
      - Patient has no satisfactory alternative treatment options; **OR**

- Used as induction systemic therapy for relieving dysphagia; **AND**
  - Patient has stage I-III Esophageal or Esophagogastric Junction squamous cell carcinoma; **AND**
  - Patient 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 for stage I-III disease ‡; **AND**
  - Patient has one of the following cancers:
    - Esophageal and Esophagogastric Junction Cancers [Δ]
    - Gastric Cancer [Δ]
    - Endometrial Carcinoma (Uterine Neoplasms) and will not be used for either of the following:
      - Therapy for locoregional recurrence in patients with no prior radiation therapy to site of recurrence, or previous vaginal brachytherapy only; **OR**
      - Therapy after surgical exploration for locoregional recurrence in patients with disease confined to the vagina or paravaginal soft tissues; **OR**
- Used as neoadjuvant therapy for stage I-III disease ‡; **AND**
  - Patient has Esophageal or Esophagogastric Junction adenocarcinoma; **AND**
    - Patient 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**
  - Patient has Gastric Cancer; **AND**
    - Patient is medically fit and planned for esophagectomy and has potentially rescectable locoregional disease (cT2 or higher, any N)

Polymerase Epsilon/Delta (POLE/POLD1) Mutation Cancer ‡ [2,11-13]

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

- Patient has Small Bowel Adenocarcinoma; **AND**
  - Patient has advanced or metastatic disease

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.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from prior authorization validity. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

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

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

IV. Renewal Criteria Δ 1

Prior authorization validity 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**
- 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:
- 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 palliative therapy provided there has been no prior tumor progression while on therapy with a checkpoint inhibitor.

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 6th 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 4th 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 4th 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)

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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
C24.1	Malignant neoplasm of ampulla of Vater

ICD-10	ICD-10 Description
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
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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