Jemperli (dostarlimab-gxly)
PAM – 046

Iowa Medicaid Program	Prior Authorization	**Effective Date**	10/01/2021
Revision Number	4	**Last Reviewed**	07/18/2025
Reviewed By	Medicaid Medical Director	**Next Review**	07/17/2026
Approved By	Medicaid Clinical Advisory Committee	**Approved Date**	07/15/2022

Overview

Medication: [1]	dostarlimab-gxly
Brand Name:	Jemperli®
Pharmacologic Category:	Antineoplastic; programmed death receptor-1 (PD-1)–blocking antibody

FDA-Approved Indication(s):

1. Endometrial Cancer
   - A. In combination with carboplatin and paclitaxel, followed by Jemperli® as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer.
     - ▶ **REVISED** indication: FDA-approved expanded indication 8/1/2024 to include all adult patients with endometrial cancer, regardless of mismatch repair status
   - B. As a single agent for the treatment of adult patients with dMMR≠ recurrent or advanced endometrial cancer that has progressed on or following treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation.
2. Mismatch Repair Deficient Recurrent or Advanced Solid Tumors
   - A. As a single agent for the treatment of adult patients with dMMR≠ recurrent or advanced solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.
     - ▶ Accelerated Approval: This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

≠ dMMR determined by an FDA-approved test

How Supplied:	Single-dose vial containing 500 mg/10 mL (50 mg/mL) solution
Dosage and Administration:	• Administered as an intravenous (IV) infusion. • Select patients for treatment with Jemperli® as a single agent based on the presence of dMMR in tumor specimens in recurrent or advanced EC and in recurrent or advanced solid tumors.

Recommended Dosages

Indication	Recommended Dosage	Duration/Timing of Treatment
Combination Therapy primary advanced or recurrent EC	500 mg Jemperli® every 3 weeks for 6 cycles (in combination with carboplatin and paclitaxel), followed by 1,000 mg Jemperli® as monotherapy every 6 weeks for all cycles thereafter.	Until disease progression, unacceptable toxicity, *or up to 3 years*
Monotherapy dMMR recurrent or advanced EC and dMMR recurrent or advanced solid tumors	500 mg Jemperli® every 3 weeks for 4 cycles, followed by 1,000 mg Jemperli® every 6 weeks for all cycles thereafter	Until disease progression, unacceptable toxicity

EC = endometrial carcinoma dMMR = mismatch repair deficient

Benefit Category: Medical

Descriptive Narrative

Binding of the programmed death protein 1 (PD-1) ligands 1 and 2 (PD-L1 and PD-L2) to the PD-1 receptor found on T cells inhibits T cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. Jemperli® is a humanized monoclonal antibody of the IgG4 isotype that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. In syngeneic mouse tumor models, blocking PD-1 activity resulted in decreased tumor growth.

Guidelines

The National Comprehensive Cancer Network (NCCN) publishes guidelines for the prevention, diagnosis, and management of malignancies across the continuum of care. The NCCN Guidelines® are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97 percent of cancers affecting patients in the United States. The guidelines are developed and updated by 61 individual panels, comprising over 1,700 clinicians and oncology researchers from the 33 NCCN Member Institutions.

Guidelines are reviewed and updated on a continual basis to ensure that the recommendations take into account the most current evidence. To view the most recent and complete version of the guidelines, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.[2,3]

The information referenced at the time of this policy writing/revision is from the NCCN Guidelines® for (note version number and effective date):[4]

- Ampullary Adenocarcinoma (v.2.2025 – January 10, 2025)
- Breast Cancer (v.4.2025 – April 17, 2025)
- Colon Cancer (v.3.2025 – April 24, 2025)
- Esophageal and Esophagogastric Junction Cancers (v.3.2025 – April 22, 2025)
- Gastric Cancer (v.2.2025 – April 4, 2025)
- Occult Primary (Cancer of Unknown Primary [CUP]) (v.2.2025 – September 11, 2024)
- Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (v.2.2025 – May 23, 2025)
- Rectal Cancer (v.2.2025 – March 31, 2025)
- Small Bowel Adenocarcinoma (v.3.2025 – March 31, 2025)
- Uterine Neoplasms (v.3.2025 – March 7, 2025)

NCCN Guidelines® Recommendation(s) – Endometrial Carcinoma

(1) Primary or Adjuvant Therapy
  a. Systemic Therapy
    i. Dostarlimab-gxly + carboplatin + paclitaxel (for stage III-IV tumors): Category 1, Preferred Regimen [a, b]

(2) Recurrent Disease [c, d]
  a. First-Line Therapy for Recurrent Disease [e]
    i. Preferred Regimens
      1. Dostarlimab-gxly + carboplatin + paclitaxel: Category 1 [a, f]
    ii. Useful in Certain Circumstances (biomarker-directed therapy: after platinum-based therapy including neoadjuvant and adjuvant)
      1. MSI-H/dMMR tumors [g]: Dostarlimab-gxly: Category 2A
  b. Second-Line or Subsequent Therapy [e]
    i. Useful in Certain Circumstances (biomarker-directed therapy)
      1. MSI-H/dMMR tumors [g]: Dostarlimab-gxly: Category 2A

a Checkpoint inhibitors and/or monoclonal antibodies included in this regimen may be continued as maintenance therapy. Refer to the original study protocol for maintenance therapy dosing schedules.
b For adult patients with primary advanced endometrial carcinoma: stage IIIA, IIIB, or IIIC1 with measurable disease post-surgery, stage IIIC1 with carcinosarcoma, clear-cell, serous, or mixed histology regardless of the presence of measurable disease, and stage IIIC2 or stage IV regardless of the presence of measurable disease.
c Cisplatin, carboplatin, liposomal doxorubicin, paclitaxel, and docetaxel may cause drug reactions (see NCCN Guidelines for Ovarian Cancer–Management of Drug Reactions [OV-D]).
d Chemotherapy regimens can be used for all carcinoma histologies. Carcinosarcomas are now considered and treated as high-grade carcinomas.
e If not used previously, these agents can be used as second-line or subsequent therapy as clinically appropriate.
f For adult patients with recurrent endometrial carcinoma with or without measurable disease.
g For recurrent endometrial cancer, NCCN recommends MSI-H or dMMR testing if not previously done.

NCCN Guidelines® Recommendation(s) – dMMR Solid State Tumors

NCCN Guidelines® provide additional recommendation with a category 2A level of evidence for the use of Jemperli® in the treatment of various recurrent or advanced dMMR solid state tumors for those who have progressed on, or following, prior treatment and who have no other satisfactory treatment options, including:

• ampullary adenocarcinoma	• esophageal and esophagogastric junction cancers	• occult primary cancer (CUP)
• breast cancer	• gastric cancer	• rectal cancer
• colon cancer	• ovarian cancer	• small bowel adenocarcinoma

NCCN Categories of Evidence and Consensus (all recommendations are category 2A unless otherwise indicated)	
Category 1	Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2A	Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
Category 2B	Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate.
Category 3	Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

NCCN Categories of Preference (all recommendations are considered appropriate)	
Preferred intervention	Interventions that are based on superior efficacy, safety, and evidence; and, when appropriate, affordability.
Other recommended intervention	Other interventions that may be somewhat less efficacious, more toxic, or based on less mature data; or significantly less affordable for similar outcomes.
Useful in certain circumstances	Other interventions that may be used for select patient populations (defined with recommendation).

Eastern Cooperative Oncology Group (ECOG) Performance Status Scale [5]

Developed by the Eastern Cooperative Oncology Group (ECOG), now part of the ECOG-ACRIN Cancer Research Group, and published in 1982, the ECOG Performance Status Scale describes a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.). It is used by doctors and researchers to assess how a patient's disease is progressing, how the disease affects the daily living abilities of the patient, and to determine appropriate treatment and prognosis.

Grade	ECOG Performance Status [Synonyms: WHO/Zubrod score]
0	Fully active, able to carry on all pre-disease performance without restriction.
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work.
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours.
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair.
5	Dead.

Criteria

Prior authorization is required.

Endometrial Cancer

Jemperli® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of endometrial carcinoma (EC) that meets one of the following (either a or b):
    a. Disease is primary advanced or recurrent EC; **OR**
    b. Disease is mismatch repair deficient (dMMR≠) recurrent or advanced EC that has progressed on or following treatment with a platinum-containing regimen, and member is not a candidate for curative surgery or radiation; **AND**
2. Member is 18 years of age or older; **AND**
3. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
4. Prescribed by, or in consultation with, an oncologist; **AND**
5. Request meets one of the following (a, b, or c):
    a. Diagnosis of primary advanced or recurrent EC and:
        i. Jemperli® (500 mg dose) is given every 3 weeks for 6 cycles (in combination with carboplatin and paclitaxel);
        ii. Followed by Jemperli® (1,000 mg dose) given every 6 weeks for all subsequent cycles (as monotherapy); **OR**
    b. Diagnosis of dMMR recurrent or advanced EC and Jemperli® is given as monotherapy as follows:
        i. 500 mg dose every 3 weeks for 4 cycles, followed by:
        ii. 1,000 mg dose every 6 weeks for all subsequent cycles; **OR**
    c. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

≠ Genomic testing for dMMR may require a separate prior authorization.

Solid Tumor, Mismatch Repair Deficient

Jemperli® is considered medically necessary when **ALL** of the following are met:

1. Diagnosis of mismatch repair deficient (dMMR≠) recurrent or advanced solid tumor (e.g., ampullary adenocarcinoma, breast cancer, colon cancer, esophageal and esophagogastric junction cancers, gastric cancer, occult primary cancer, ovarian cancer, rectal cancer, small bowel adenocarcinoma); **AND**
2. Member has confirmed disease progression on or following prior treatment, and has no other satisfactory alternative treatment options; **AND**
3. Member is 18 years of age or older; **AND**
4. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
5. Prescribed by, or in consultation with, an oncologist; **AND**
6. Request meets one of the following (a or b):
    a. Prescribed as monotherapy and dose does not exceed 500 mg every 3 weeks for 4 cycles, followed by 1,000 mg every 6 weeks for all subsequent cycles; **OR**
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

≠ Genomic testing for dMMR may require a separate prior authorization.

Continuation Criteria (all above indications)

Jemperli® is considered medically necessary for continuation of therapy when **ALL** of the following are met:

1. Member is currently receiving medication through the Iowa Medicaid benefit or has previously met initial approval criteria; **AND**
2. Documentation of positive clinical response to therapy, as demonstrated by tumor response or lack of disease progression, and an acceptable toxicity profile; **AND**
3. Prescribed by, or in consultation with, an oncologist; **AND**
4. Request meets one of the following (a or b):
    a. Jemperli® is prescribed as monotherapy and (i and ii):
        i. Dose does not exceed 1,000 mg given every 6 weeks; **AND**
        ii. Therapy is administered until disease progression or unacceptable toxicity (or for up to 3 years in the treatment of primary advanced or recurrent endometrial carcinoma); or,
    b. Regimen is supported by clinical practice guidelines (i.e., must be recommended in NCCN Guidelines®). Supporting clinical documentation must be provided with any request for which regimen prescribed does not align with FDA-approved labeling.

Approval Duration and Quantity Limits

- Primary advanced or recurrent endometrial carcinoma

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months (maximum of 3 total years of therapy)
Quantity Limits	500 mg every 3 weeks for 6 cycles, then 1,000 mg every 6 weeks	1,000 mg every 6 weeks

- Mismatch repair deficient (dMMR) recurrent or advanced endometrial carcinoma; and
- Mismatch repair deficient (dMMR) recurrent or advanced solid tumors

	Initial Authorization	Subsequent Authorization(s)
Approval Duration	6 months	12 months
Quantity Limits	500 mg every 3 weeks for 4 cycles, then 1,000 mg every 6 weeks	12 months

Coding and Product Information

The following list(s) of codes and product information are provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS code is inappropriate.

HCPCS	Description
~~C9082~~	~~Injection, dostarlimab-gxly, 10 mg. *(effective 10/1/2021 – 12/31/2021)*~~
J9272	Injection, dostarlimab-gxly, 10 mg. *(effective 1/1/2022)*

ICD-10	Description
C00.0-C76.8	Malignant neoplasm at various anatomical sites
C54.1	Malignant neoplasm of endometrium
D07.0	Carcinoma in situ of endometrium

NDC (Strength)	Labeler	Dosage	Pkg Size	Pkg Qty	Units /Pkg
00173-0898-03 (500 mg/10 mL)	GlaxoSmithKline LLC (00173)	10 mg	1	EA	50

Compliance

1. Should conflict exist between the policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual or as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. Medical necessity guidelines are developed for selected physician-administered medications found to be safe and proven to be effective in a limited, defined population or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

[1] Jemperli® prescribing information (08/2024). GlaxoSmithKline LLC: Durham, NC. Available online: www.jemperlihcp.com. Accessed June 9, 2025.

[2] National Comprehensive Cancer Network (NCCN). Guidelines Process: About Clinical Practice Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[3] National Comprehensive Cancer Network (NCCN). Guidelines Process: Development and Update of Guidelines. Available online at www.nccn.org. Accessed July 29, 2024.

[4] NCCN Clinical Practice Guidelines in Oncology. The NCCN Guidelines® are a work in progress that may be refined as often as new significant data becomes available. To view the most recent and complete version, go online to NCCN.org. NCCN Guidelines® referenced (note version number and effective date):

- Ampullary Adenocarcinoma (v.2.2025 – January 10, 2025)
- Breast Cancer (v.4.2025 – April 17, 2025)
- Colon Cancer (v.3.2025 – April 24, 2025)
- Esophageal and Esophagogastric Junction Cancers (v.3.2025 – April 22, 2025)
- Gastric Cancer (v.2.2025 – April 4, 2025)
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- Rectal Cancer (v.2.2025 – March 31, 2025)
- Small Bowel Adenocarcinoma (v.3.2025 – March 31, 2025)
- Uterine Neoplasms (v.3.2025 – March 7, 2025)

[5] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

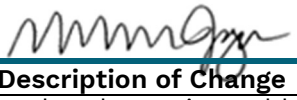
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

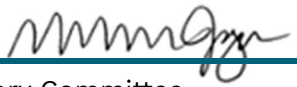
Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
[mm/dd/yyyy]	CAC		
Signature			

Change Date	Changed By	Description of Change	Version
07/18/2025	CAC	Annual review. Updated Overview table with REVISED indication for primary advanced or recurrent endometrial cancer (FDA-approved 8/1/2024); this approval expanded the indication to include all adults with endometrial cancer, regardless of mismatch repair status. Updated initial and continuation criteria for endometrial cancer to align with new indication. Reviewed and updated NCCN Guidelines®.	4
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/19/2024	CAC	Annual review. Updated NCCN Guidelines. Updated references. Updated Overview table – NEW indication (FDA-approved 7/31/2023): primary advanced or recurrent endometrial cancer that is dMMR or MSI-H. Updated criteria to include new indication. Added dosing to criteria and updated Approval Duration and Quantity Limits section.	3
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/21/2023	CAC	Updated overview table – indication for endometrial carcinoma received full FDA approval on 2/9/2023 (originally accelerated approval). Updated NCCN recommendations. In initial criteria, changed ECOG from “0 or 1” to “0, 1, or 2” to align with clinical trials. Added definitions as part of Descriptive Narrative. Added criterion “will be used as monotherapy.”	2
Signature William (Bill) Jagiello, DO			

Change Date	Changed By	Description of Change	Version
07/15/2022	CAC	Criteria implementation.	1
Signature William (Bill) Jagiello, DO			

CAC = Medicaid Clinical Advisory Committee