STATE OF IOWA DEPARTMENT OF
Health AND Human
SERVICES

Jemperli (dostarlimab-gxly)
PAM–046

Iowa Medicaid Program:	Prior Authorization	**Effective Date:**	10/01/2021
Revision Number:	3	**Last Rev Date:**	07/19/2024
Reviewed By:	Medicaid Medical Director	**Next Rev Date:**	07/18/2025
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 that is mismatch repair deficient (dMMR≠) or microsatellite instability high (MSI-H). 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. ► **NEW** Indication: FDA-approved 7/31/2023 **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. Treat until disease progression or unacceptable toxicity.

Indication	Recommended Dosage	Duration/Timing
Combination Therapy dMMR/MSI-H primary advanced or recurrent EC	500 mg every 3 weeks for 6 doses (in combination with carboplatin and paclitaxel), followed by 1,000 mg monotherapy every 6 weeks	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 every 3 weeks for 4 doses, followed by 1,000 mg every 6 weeks	Until disease progression or unacceptable toxicity

dMMR = mismatch repair deficient MSI-H = microsatellite instability-high EC = endometrial cancer

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

As new and emerging therapies are rapidly coming to market, oncology treatment recommendations and guidelines are constantly changing. To keep up with these changes, the National Comprehensive Cancer Network (NCCN) publishes guidelines which are developed and updated by 60 individual panels, comprising over 1,660 clinicians and oncology researchers from the 31 NCCN Member Institutions.[2]

The NCCN Clinical Practice Guidelines in Oncology (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 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.

The information referenced at the time of this policy writing/revision is from:[3]

- NCCN Guidelines® for Ampullary Adenocarcinoma (Version 1.2024 – December 13, 2023)
- NCCN Guidelines® for Breast Cancer (Version 2.2024 – March 11, 2024)
- NCCN Guidelines® for Colon Cancer (Version 3.2024 – May 24, 2024)
- NCCN Guidelines® for Esophageal and Esophagogastric Junction Cancers (Version 3.2024 – April 26, 2024)
- NCCN Guidelines® for Gastric Cancer (Version 2.2024 – May 29, 2024)
- NCCN Guidelines® for Occult Primary (Cancer of Unknown Primary [CUP]) (Version 2.2024 – April 29, 2024)
- NCCN Guidelines® for Ovarian Cancer, including Fallopian Tube Cancer and Primary Peritoneal Cancer (Version 2.2024 – May 13, 2024)
- NCCN Guidelines® for Rectal Cancer (Version 2.2024 – April 30, 2024)
- NCCN Guidelines® for Small Bowel Adenocarcinoma (Version 3.2024 – April 30, 2024)
- NCCN Guidelines® for Uterine Neoplasms (Version 2.2024 – March 6, 2024)

NCCN Guidelines® Recommendation(s) for dostarlimab-gxly (Jemperli®) in endometrial carcinoma
(1) Primary or Adjuvant Therapy A. Stage III – IV tumors i. Dostarlimab-gxly + carboplatin + paclitaxel: Category 1, preferred [a, b] (2) Recurrent Disease A. First-line therapy for recurrent disease [c] i. Dostarlimab-gxly + carboplatin + paclitaxel: Category 1, preferred [a, b] ii. Biomarker-directed therapy: after platinum-based therapy including neoadjuvant and adjuvant 1. Dostarlimab-gxly: Category 2A, "useful in certain circumstances" in dMMR/MSI-H tumors [d] B. Second-line or subsequent therapy for recurrent disease (biomarker-directed therapy) i. Dostarlimab-gxly: Category 2A, "useful in certain circumstances" in dMMR/MSI-H tumors [c] [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 stage IIIA, IIIB, or IIIC1 with measurable disease, 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] These agents can be used as second-line or subsequent therapy as clinically appropriate. [d] For recurrent endometrial cancer, NCCN recommends MSI-H or dMMR testing if not previously done.

NCCN Guidelines® recommendation(s) for dostarlimab-gxly (Jemperli®) in dMMR solid state tumors		
NCCN Guidelines® provide additional recommendation with a category 2A level of evidence for the use of Jemperli® for 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[4]

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 themself, 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 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 house work, 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 that is mismatch repair deficient (dMMR[≠]) or microsatellite instability high (MSI-H[≠]); **OR**
   b. Disease is 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 dMMR/MSI-H primary advanced or recurrent EC and dose does not exceed 500 mg every 3 weeks for 6 doses (administered in combination with carboplatin and paclitaxel), followed by 1,000 mg as monotherapy every 6 weeks; **OR**
   b. Diagnosis of dMMR recurrent or advanced EC and dose (as monotherapy) does not exceed 500 mg every 3 weeks for 4 doses, followed by 1,000 mg every 6 weeks; **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 and MSI-H 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 doses, followed by 1,000 mg every 6 weeks; **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. Prescribed as monotherapy and dose does not exceed 1,000 mg every 6 weeks; **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

- Mismatch repair deficient (dMMR) or microsatellite instability high (MSI-H) 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 doses, then 1,000 mg every 6 weeks	1,000 mg every 6 weeks

- Mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer; 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 doses, 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 this 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 (03/2024). GlaxoSmithKline LLC: Durham, NC. Available online at: www.jemperlihcp.com. Accessed May 24, 2024.

[2] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed October 11, 2023.

[3] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). Accessed June 7, 2024. 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 of the guideline, go online to www.nccn.org.

- NCCN Guidelines® for Ampullary Adenocarcinoma (Version 1.2024 – December 13, 2023)
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- NCCN Guidelines® for Small Bowel Adenocarcinoma (Version 3.2024 – April 30, 2024)
- NCCN Guidelines® for Uterine Neoplasms (Version 2.2024 – March 6, 2024)

[4] 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.

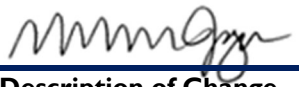
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published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

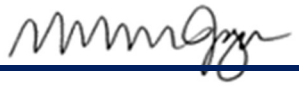
Criteria Change History

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
07/19/2024	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