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:** | 2 | **Last Rev Date:** | 07/21/2023 |
| **Reviewed By:** | Medicaid Medical Director | **Next Rev Date:** | 07/19/2024 |
| **Approved By:** | Medicaid Clinical Advisory Committee | **Approved Date:** | 07/15/2022 |

## Overview

| | |
|---|---|
| Medication: [1] | dostarlimab-gxly |
| Brand Name: | Jemperli® |
| Pharmacologic Category: | Programmed death receptor-1 (PD-1)–blocking antibody |
| FDA-Approved Indication(s): | Treatment of adult patients with mismatch repair deficient (dMMR)[≠] recurrent or advanced:<br>• Endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen; or<br>• Solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.<br>► 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).<br>[≠] 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.<br>• Doses 1 through 4: 500 mg every 3 weeks.<br>• Dose 5 and ongoing (beginning 3 weeks after dose 4): 1000 mg every 6 weeks.<br>Treat until disease progression or unacceptable toxicity. |
| 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.

## Definitions

Adjuvant therapy: Additional cancer treatment given after the primary treatment to lower the risk that the cancer will come back. Adjuvant therapy may include chemotherapy, radiation therapy, hormone therapy, targeted therapy, or biological therapy.

Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2.

Line of therapy:

- First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
- Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
- Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second-line therapy) are not effective or there is disease progression.

Maintenance therapy: Designed to maintain a condition to prevent a relapse.

Programmed death (PD)-1 proteins: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body.

Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks.

## 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:

- NCCN Guidelines® for Uterine Neoplasms (Version 2.2023 – April 28, 2023). [3]

| NCCN Guidelines® Recommendation(s) for dostarlimab-gxly (Jemperli®) in Endometrial Carcinoma |
|---|
| (1) Primary or Adjuvant Therapy<br>A. Stage III – IV tumors<br>i. Jemperli® + carboplatin + paclitaxel: Category 1, preferred [a]<br>(2) Recurrent Disease<br>A. First-line therapy for recurrent disease<br>i. Jemperli® + carboplatin + paclitaxel: Category 1, preferred<br>ii. Jemperli®: Category 2A, "useful in certain circumstances" in dMMR/MSI-H tumors [b]<br>B. Second-line or subsequent therapy for recurrent disease<br>i. Jemperli®: Category 2A, "useful in certain circumstances" in dMMR/MSI-H tumors [c]<br><br>[a] 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.<br>[b] Biomarker directed: after prior platinum-based therapy including neoadjuvant and adjuvant.<br>[c] Biomarker directed. |

NCCN provides additional recommendation with a category 2A level of evidence for the use of Jemperli® for various recurrent or advanced dMMR solid state tumors, including ampullary adenocarcinoma, breast cancer, colon cancer, esophageal and esophagogastric junction cancers, gastric cancer, ovarian cancer, rectal cancer, and small bowel adenocarcinomas for those who have progressed on, or following, prior treatment and who have no other satisfactory treatment options.

| **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, Mismatch Repair Deficient

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

1. Diagnosis of recurrent or advanced endometrial carcinoma; **AND**
2. Disease is mismatch repair deficient (dMMR,[≠] indicative of MMR gene mutation or loss of expression); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has confirmed disease progression on or after prior treatment with a platinum-containing regimen; **AND**
5. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
6. Prescribed by, or in consultation with, an oncologist; **AND**
7. Jemperli® will be used as monotherapy; **AND**
8. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage 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 recurrent or advanced solid tumor (e.g., breast cancer, colon cancer, gastric cancer, hepatobiliary cancer, ovarian/fallopian tube/primary peritoneal cancer, rectal cancer, small bowel adenocarcinoma, occult primary cancer); **AND**
2. Disease is mismatch repair deficient (dMMR[≠], indicative of MMR gene mutation or loss of expression); **AND**
3. Member is 18 years of age or older; **AND**
4. Member has confirmed disease progression on or following prior treatment with no other satisfactory alternative treatment options; [Δ] **AND**
5. Member has a current Eastern Cooperative Oncology Group (ECOG) Performance Status of 0, 1, or 2; **AND**
6. Prescribed by, or in consultation with, an oncologist; **AND**
7. Jemperli® will be used as monotherapy; **AND**
8. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling.

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

[Δ] Patients with dMMR endometrial cancer must have progressed on or after treatment with a platinum-containing regimen. Patients with dMMR colorectal cancer must have progressed after or been intolerant to a fluoropyrimidine, oxaliplatin, and irinotecan.

## 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. The regimen prescribed is within the FDA-approved labeling. If dose or schedule exceeds the FDA-approved labeling, therapy regimen (including dosage) must be supported by clinical practice guidelines (i.e., must be recommended in the NCCN Clinical Practice Guidelines®). Supporting clinical documentation must be provided with any request for which the regimen or dosage prescribed does not align with FDA-approved labeling.

## Approval Duration and Quantity Limits

| | Initial Authorization | Subsequent Authorization(s) |
|---|---|---|
| Approval Duration | 6 months | 12 months |
| Quantity Limits | 500 mg per infusion.<br>Up to 7 infusions on initial authorization. | 500 mg per infusion.<br>Up to 10 infusions on subsequent authorizations (one infusion every 6 weeks). |

## 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 | Labeler | Dosage | Pkg Size | Pkg Qty | Units/Pkg |
|---|---|---|---|---|---|
| 00173-0898-03 | GlaxoSmithKline | 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 (02/2023). GlaxoSmithKline LLC: Durham, NC. Available online at www.jemperlihcp.com. Accessed July 10, 2023.

[2] National Comprehensive Cancer Network (NCCN). Development and Update of Guidelines. Available online at www.nccn.org. Accessed January 19, 2023.

[3] Referenced from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Uterine Neoplasms V.2.2023 – April 28, 2023. Accessed July 10, 2023. 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 NCCN.org.

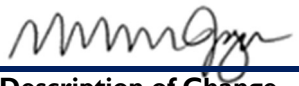
[4] Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655. PMID 7165009.

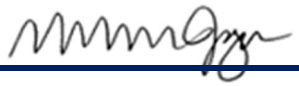
Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published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

## Criteria Change History

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| | CAC | | |
| **Signature** | | | |

| Change Date | Changed By | Description of Change | Version |
|---|---|---|---|
| | CAC | | |
| **Signature** | | | |

| 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**<br>William (Bill) Jagiello, DO | |  | |

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

CAC = Medicaid Clinical Advisory Committee