# Clinical Policy: Dostarlimab-gxly (Jemperli)

Reference Number: PA.CP.PHAR.540
Effective Date: 10/2021
Last Review Date: 07/2023

Revision Log

**Description**
Dostarlimab-gxly (Jemperli™) is a programmed death receptor-1 (PD-1)–blocking antibody.

**FDA Approved Indication(s)**
Jemperli is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced:

- Endometrial cancer (EC), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H) in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent
- Endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation
- Solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options*

*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).

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Jemperli is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Endometrial Carcinoma** (must meet all)**:**

1. Diagnosis of EC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
   a. Prescribed in combination with carboplatin and paclitaxel for stage III-IV or recurrent disease;
   b. All of the following (i, ii, and iii):
      i. Disease is recurrent or advanced;
      ii. Disease is dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression) or microsatellite instability-high (MSI-H);
      iii. Disease has progressed following prior treatment with a platinum-containing regimen (e.g., carboplatin/cisplatin);
5. Request meets one of the following (a, b or c):

a. For single agent: dose does not exceed 500 mg every 3 weeks for dose 1 through 4, followed by 1,000 mg every 6 weeks starting 3 weeks after dose 4;
b. For combination with carboplatin and paclitaxel: dose does not exceed 500 mg every 3 weeks for 6 doses followed by 1,000 mg monotherapy every 6 weeks;
c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**B. Solid Tumor** (must meet all):
1. Diagnosis of solid tumor (e.g., ampullary adenocarcinoma, breast cancer, colon cancer [including appendiceal adenocarcinoma], esophageal and esophagogastric junction cancers, gallbladder cancer, gastric cancer, hepatocellular carcinoma, extra/intrahepatic cholangiocarcinoma, occult primary cancer, ovarian/fallopian tube/primary peritoneal cancer, pancreatic adenocarcinoma, rectal cancer, small bowel adenocarcinoma);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease has both of the following characteristics (a and b):
   a. Metastatic, recurrent, or advanced;
   b. dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression) or MSI-H;
5. One of the following (a or b):
   a. Disease has progressed on or following prior treatment and who have no satisfactory alternative options;
   b. Request is for small bowel adenocarcinoma, pancreatic adenocarcinoma, colon cancer, appendiceal adenocarcinoma, or rectal cancer;
6. Prescribed as a single agent;
7. Request meets one of the following (a or b):
   a. Dose does not exceed 500 mg every 3 weeks for dose 1 through 4, followed by 1,000 mg every 6 weeks starting 3 weeks after dose 4;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 6 months**

**C. Other diagnoses/indications**
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## II. Continued Therapy

**A. All Indications in Section I** (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 1,000 mg every 6 weeks;

b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

dMMR: mismatch repair deficient
EC: endometrial carcinoma
FDA: Food and Drug Administration
MSI-H: microsatellite instability-high
NCCN: National Comprehensive Cancer Network

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **EC systemic therapies**: carboplatin, cisplatin, carboplatin/paclitaxel, cisplatin/docetaxel, cisplatin/doxorubicin, cisplatin/doxorubicin/paclitaxel, carboplatin/paclitaxel/bevacizumab, carboplatin/paclitaxel/trastuzumab, cisplatin/ifosfamide | Varies | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

None reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| EC, solid tumors | Dose 1 through 4: 500 mg every 3 weeks<br><br>Subsequent dosing beginning 3 weeks after Dose 4 (Dose 5 onwards): 1,000 mg every 6 weeks | See dosing regimen |

## VI. Product Availability

Single-dose vial: 500 mg/10 mL

## VII. References

1. Jemperli Prescribing Information. Philadelphia, PA: GlaxoSmithKline LLC; February 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761174s003s004lbl.pdf. Accessed April 14, 2023.
2. Dostarlimab-hxly In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 17, 2023.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| Policy created. | 10/2021 | |
| 3Q 2022 annual review: per NCCN – for all indications, added that cancer can also be MSI-H; for solid tumors, added that cancer can also be metastatic, added additional examples of solid tumors that are eligible for coverage, and added requirement for use as a single agent; references reviewed and updated. | 07/2022 | |
| RT4: updated previously accelerated approved indication that was converted to full approval for dMMR EC with additional wording stating “not candidates for curative surgery or radiation.” | 04/2023 | |
| 3Q 2023 annual review: for EC, added pathway for first-line use when prescribed in combination with carboplatin and paclitaxel for stage III-IV or recurrent disease; for solid tumors, added gallbladder cancer and pancreatic cancer, specified types of hepatobiliary cancers, and added bypass of prior therapies for small bowel adenocarcinoma or pancreatic adenocarcinoma per NCCN; references reviewed and updated. | 07/2023 | |