Clinical Policy: Dostarlimab-gxly (Jemperli)

Reference Number: PA.CP.PHAR.540
Effective Date: 10/2021
Last Review Date: 07/2025

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

FDA Approved Indication(s)
Jemperli is indicated for:

- **Endometrial cancer (EC)**
  - In combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent EC;
  - As a single agent for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced 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
- **dMMR recurrent or advanced solid tumors**
  - As a single agent for the treatment of adult patients with dMMR recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progress 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, b or c):
   a. Prescribed in combination with carboplatin and paclitaxel for advanced (i.e., stage III-IV) or recurrent disease, followed by use as single agent maintenance therapy;
   b. All of the following (i-iv):
      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);

iv. Member is not a candidate for curative surgery or radiation;
c. Other category 1, 2A, or 2B NCCN-recommended uses not listed;

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 4 cycles, followed by 1,000 mg every 6 weeks starting 3 weeks after cycle 4;
   b. For combination therapy: dose does not exceed 500 mg every 3 weeks for 6 cycles 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. One of the following (a-e):
   a. Disease is metastatic, recurrent, or advanced;
   b. Gastric cancer only: Disease is surgically unresectable, or member is not a surgical candidate;
   c. Colon (including appendiceal adenocarcinoma) cancer or rectal cancer, or small bowel adenocarcinoma only: Disease is locally unresectable or medically inoperable;
   d. Esophageal or esophagogastric junction cancer only: Member is not a surgical candidate;
   e. Other category 1, 2A, or 2B NCCN-recommended uses not listed;
5. One of the following (a-d):
   a. Disease is dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression);
   b. Disease is MSI-H;
   c. Colon (including appendiceal adenocarcinoma) cancer, rectal cancer, or small bowel adenocarcinoma only: Disease is positive for polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype (e.g., tumor mutational burden [TMB] > 50 mut/Mb);
   d. Other category 1, 2A, or 2B NCCN-recommended uses not listed;
6. One of the following (a, b, c or d):
   a. Disease has progressed on or following prior treatment and who have no satisfactory alternative options;
   b. Request is for palliative therapy for gastric, esophageal, or esophagogastric junction cancer;
   c. Request is for colon cancer (including appendiceal adenocarcinoma), esophageal or esophagogastric junction cancer with a planned esophagectomy, gastric cancer

that is either early stage or surgically unresectable, pancreatic adenocarcinoma, rectal cancer, or small bowel adenocarcinoma;
   d. Other category 1, 2A, or 2B NCCN-recommended uses not listed;
7. Prescribed as a single agent;
8. Request meets one of the following (a or b):
   a. Dose does not exceed 500 mg every 3 weeks for 4 cycles, followed by 1,000 mg every 6 weeks starting 3 weeks after cycle 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. Anal Carcinoma (off-label) (must meet all)**:**
1. Diagnosis of anal carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. One of the following (a or b):
   a. Disease is metastatic, and both of the following (i and ii):
      i. Prescribed as second-line or subsequent therapy;
      ii. Member has not previously received immunotherapy (e.g., nivolumab, pembrolizumab, retifanlimabdlwr, cemiplimab-rwlc, tislelizumab-jsgr, toripalimab-tpzi);
   b. Disease is locally recurrent and progressive, and (i):
      i. Member will undergo abdominoperineal resection;
6. 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

D. 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.PHARM.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.PHARM.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
POLE/POLD1: polymerase epsilon/delta
TMB: tumor mutational burden

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 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 as combination therapy	500 mg IV every 3 weeks for 6 cycles in combination with carboplatin and paclitaxel, followed by 1,000 mg IV as monotherapy every 6 weeks for all cycles thereafter until disease progression, unacceptable toxicity, or up to 3 years	See dosing regimen
EC as single agent therapy; solid tumors	500 mg IV every 3 weeks for 4 cycles followed by 1,000 mg IV every 6 weeks for all cycles thereafter until disease progression or unacceptable toxicity	See dosing regimen

VI. Product Availability

Single-dose vial: 500 mg/10 mL

VII. References

1. Jemperli Prescribing Information. Philadelphia, PA: GlaxoSmithKline LLC; August 2024. Available at: https://jemperli.com/. Accessed April 17, 2025.
2. Dostarlimab-hxly In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed May 13, 2025.
3. Mirza MR, Chase DM, Slomovitz BM, et al. Dostarlimab for primary advanced or recurrent endometrial cancer. N Engl J Med. 2023 Jun 8;388(23):2145-2158. doi: 10.1056/NEJMoa2216334. Epub 2023 Mar 27. PMID: 36972026.

Reviews, Revisions, and Approvals	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
3Q 2024 annual review: revised solid tumors criteria per NCCN – added additional disease qualifiers of early stage or unresectable for gastric cancer and locally unresectable or medically inoperable for colon and rectal cancers, added pathway to allow members who are not surgical candidates for gastric and esophageal/esophagogastric junction cancers, added POLE/POLD1 mutation for colon and rectal cancers, and added bypass of prior therapies for	07/2024

Reviews, Revisions, and Approvals	Date
colon cancer, esophageal/esophagogastric junction cancer with planned esophagectomy or if request is for palliative therapy, gastric cancer that is early stage or surgically unresectable or if request is for palliative therapy, and rectal cancer; references reviewed and updated.	
3Q 2025 annual review: for EC, added that combination use with carboplatin/paclitaxel for advanced/recurrent disease may be followed by single agent use per FDA labeling and NCCN; for solid tumors, removed option for early-stage gastric cancer, added option for locally unresectable, medically inoperable, or POLE/POLD1 mutated small bowel adenocarcinoma, and clarified that POLE/POLD1 mutation should have ultra-hypermutated phenotype per NCCN; added off-label criteria for anal carcinoma per NCCN; references reviewed and updated.	07/2025