Clinical Policy: Dostarlimab-gxly (Jemperli)

Reference Number: CP.PHAR.540
Effective Date: 09.01.21
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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
- **Microsatellite instability-high (MSI-H) or dMMR locally advanced rectal cancer (LARC)**
  - As a single agent for the treatment of adult patients with Stage II/III LARC that is MSI-H or dMMR, as determined by an FDA-authorized test for solid tumors*
    **This indication is approved under accelerated approval based on sustained clinical complete response for 12 months. The long-term risk of relapse is unknown, with additional follow-up expected. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).*
- **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-authorized 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 health plans affiliated with Centene Corporation® 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 advanced (i.e., stage III-IV) or recurrent disease, followed by use as single agent maintenance therapy;
   b. All of the following (i, ii, iii, and 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 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;
5. Request meets one of the following (a, b, or c):*
   a. Combination therapy: Dose does not exceed 500 mg every 3 weeks for 6 cycles, in combination with carboplatin and paclitaxel, followed by 1,000 mg monotherapy every 6 weeks starting 3 weeks after cycle 6;
   b. Single-agent use: 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;
   c. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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);
   **If request is for LARC, please refer to criteria set I.C below*
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a, b, c, d, or e):
   a. Disease is metastatic, recurrent, or advanced;
   b. Gastric cancer only: One of the following (i or ii):
      i. Disease is surgically unresectable or member is not a surgical candidate;
      ii. Prescribed as neoadjuvant immunotherapy as primary treatment prior to surgery for potentially resectable locoregional disease;
   c. Colon cancer, rectal cancer, or small bowel adenocarcinoma only: One of the following (i or ii):
      i. Disease is locally unresectable or medically inoperable;
      ii. Prescribed as neoadjuvant therapy;
   d. Esophageal or esophagogastric junction cancer only: One of the following (i, ii, or iii):

i. Member is not a surgical candidate;
ii. Prescribed as neoadjuvant immunotherapy as primary treatment for adenocarcinoma;
iii. Prescribed as induction systemic therapy for relieving dysphagia in a member with planned esophagectomy;

e. Appendiceal cancer only: Prescribed as neoadjuvant systemic therapy for one of the following (i or ii):
i. Biopsy-proven recurrence of high-risk disease and no previous cytoreductive surgery;
ii. Metastatic peritoneal-only disease;

5. One of the following (a, b, or c):
a. Disease is dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression);
b. Disease is MSI-H;
c. Appendiceal cancer, colon 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);
6. One of the following (a, b, c, or d):
a. Disease has progressed on or following prior treatment, and there are no satisfactory alternative options;
b. Request is for neoadjuvant or palliative therapy for gastric, esophageal, or esophagogastric junction cancer;
c. Request is for subsequent therapy for pancreatic adenocarcinoma;
d. Request is for appendiceal cancer, colon cancer, esophageal or esophagogastric junction cancer with a planned esophagectomy, gastric cancer that is either early stage or surgically unresectable, rectal cancer, or small bowel adenocarcinoma;
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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

C. Locally Advanced Rectal Cancer (must meet all)**:**
1. Diagnosis of Stage II/III LARC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is one of the following (a or b):
a. dMMR (i.e., disease is indicative of MMR gene mutation or loss of expression);
b. MSI-H;
5. Prescribed as a single agent;

6. Request meets one of the following (a or b):*
   a. Dose does not exceed 500 mg every 3 weeks for up to a total of 9 cycles;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

D. 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. One of the following (a, b, or c):
   a. Disease is metastatic, and prescribed in one of the following ways (i or ii):
      i. As a single agent, and both of the following (1 and 2):
         1) Prescribed as second-line or subsequent therapy;
         2) Member has not previously received immunotherapy (e.g., nivolumab, pembrolizumab, retifanlimabdlwr, cemiplimab-rwlc, tislelizumab-jsgr, toripalimab-tpzi);
      ii. In combination with paclitaxel and carboplatin, and (1)
         1) Prescribed as first-line or primary treatment;
   b. Disease is locally recurrent and progressive, and both of the following (i and ii):
      i. Prescribed as a single agent;
      ii. Member will undergo abdominoperineal resection;
   c. Member has inguinal node recurrence, and (i):
      i. Prescribed in combination with paclitaxel and carboplatin;
5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

E. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Jemperli and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b, or c):*
   a. EC, solid tumors: New dose does not exceed 1,000 mg every 6 weeks (for up to a total of 3 years for primary advanced or recurrent EC);
   b. LARC: New dose does not exceed 500 mg every 3 weeks for up to a total of 9 cycles;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid/HIM/ICHRA – 12 months
Commercial – 6 months or to the member's renewal date, whichever is longer

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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 –

CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

dMMR: mismatch repair deficient
EC: endometrial carcinoma
FDA: Food and Drug Administration
LARC: locally advanced rectal cancer
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 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
Primary advanced or recurrent EC	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
dMMR recurrent or advanced EC; dMMR solid tumors	Monotherapy: 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
MSI-H/dMMR LARC	Monotherapy: 500 mg IV every 3 weeks until disease progression, unacceptable toxicity, or 9 cycles	See dosing regimen

VI. Product Availability

Single-dose vial: 500 mg/10 mL

VII. References

1. Jemperli Prescribing Information. Philadelphia, PA: GlaxoSmithKline LLC; October 2026. Available at: https://jemperli.com. Accessed October 29, 2026.
2. Dostarlimab-hxly In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed April 28, 2026.
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	P&T Approval Date
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.	04.04.22	08.22
Template changes applied to other diagnoses/indications.	10.05.22	
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.”	02.27.23	
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.	04.14.23	08.23
RT4: for EC, added newly approved indication to include first-line use when prescribed in combination with carboplatin and paclitaxel for stage III-IV or recurrent disease.	08.31.23	
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 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	05.16.24	08.24

Reviews, Revisions, and Approvals	Date	P&T Approval Date
palliative therapy, and rectal cancer; references reviewed and updated.		
RT4: for EC, updated FDA approved indication to remove requirement for disease to be dMMR/MSI-H when prescribed in combination with carboplatin and paclitaxel per expanded label, and clarified in criteria that stage III-IV is advanced.	08.08.24	
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.	05.13.25	08.25
3Q 2026 annual review: per NCCN – for solid tumors, revised to require use as subsequent therapy for pancreatic adenocarcinoma, added option for use as neoadjuvant therapy for gastric, colon, rectal, or small bowel adenocarcinoma, esophageal, esophagogastric junction, appendiceal cancers, and added option for use as induction systemic therapy for esophageal and esophagogastric junction cancers; for anal carcinoma, added options for use in combination with paclitaxel and carboplatin; added ICHRA line of business; for all indications, extended initial approval durations for Medicaid/HIM from 6 to 12 months and revised all approval durations for Commercial to "6 months or to the member's renewal date, whichever is longer"; references reviewed and updated.	04.29.26	08.26
RT4: added newly approved indication of MSI-H/dMMR Stage II/III LARC; for primary advanced or recurrent EC, added "up to a total of 3 years" to dosing requirement in continued criteria per PI.	10.29.26	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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