

Clinical Policy: Dostarlimab-gxly (Jemperli)

Reference Number: CP.PHAR.540

Effective Date: 09.01.21

Last Review Date: 08.23

Line of Business: Commercial, HIM, 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:

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 endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H)
- As a single agent for the treatment of adult patients with dMMR recurrent or advanced endometrial cancer, 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

Mismatch Repair Deficient 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 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 stage III-IV or recurrent disease;

- 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 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;
5. Request meets one of the following (a, b or c):*
 - a. Dose does not exceed 500 mg every 3 weeks for dose 1 through 6, in combination with carboplatin and paclitaxel, followed by 1,000 mg monotherapy every 6 weeks starting 3 weeks after dose 6;
 - b. 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;
 - 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: 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 \geq 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 or pancreatic adenocarcinoma;
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*).

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

Approval duration: 6 months

C. 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) 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, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) 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, 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, 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 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*).
- *Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

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) 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, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace) 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, 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

Indication	Dosing Regimen	Maximum Dose
EC as single agent therapy; Solid tumors	Dose 1 through 4: 500 mg every 3 weeks 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; July 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761174s003s004lbl.pdf. Accessed August 31, 2023.
2. Dostarlimab-hxly In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium Accessed August 31, 2023.
3. Mirza MR, Chase DM, Slomovitz BM, dePont Christensen R, Novák Z, Black D, Gilbert L, Sharma S, Valabrega G, Landrum LM, Hanker LC, Stuckey A, Boere I, Gold MA, Auranen A, Pothuri B, Cibula D, McCourt C, Raspagliesi F, Shahin MS, Gill SE, Monk BJ, Buscema J, Herzog TJ, Copeland LJ, Tian M, He Z, Stevens S, Zografos E, Coleman RL, Powell MA; RUBY Investigators. 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
Policy created.	04.29.21	08.21
RT4: added newly approved indication for solid tumors.	09.26.21	
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

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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	

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.

©2021 Centene Corporation. All rights reserved. All materials are exclusively owned by Centene Corporation and are protected by United States copyright law and international copyright law. No part of this publication may be reproduced, copied, modified, distributed, displayed, stored in a retrieval system, transmitted in any form or by any means, or otherwise published without the prior written permission of Centene Corporation. You may not alter or remove any trademark, copyright or other notice contained herein. Centene[®] and Centene Corporation[®] are registered trademarks exclusively owned by Centene Corporation.