Clinical Policy: Dostarlimab-gxly (Jemperli)

Reference Number: LA.PHAR.540
Effective Date: 09.29.23
Last Review Date: ~~05.01.23~~02.01.24
Line of Business: Medicaid

Revision Log

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

Please note: This policy is for medical benefit

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)

- 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 ~~(EC),~~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 ~~progressed~~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 Louisiana Healthcare Connections 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. ~~Disease has both~~One of the following ~~characteristics~~ (a or b):
   a. Prescribed in combination with carboplatin and ~~b):~~paclitaxel for stage III-IV or recurrent disease;
   b. ~~Recurrent~~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;

~~4.~~5. Request meets one of the following (a, b or ~~b~~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;
   ~~a.~~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;
   ~~b.~~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, ~~hepatobiliary cancer,~~ hepatocellular carcinoma, extra/intrahepatic cholangiocarcinoma, occult primary cancer, ovarian/fallopian tube/primary peritoneal cancer, pancreatic adenocarcinoma, rectal cancer, small bowel ~~adenocarcinoma, occult primary cancer, ampullary~~ 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):
   ~~c.~~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;

~~5.~~6. Prescribed as a single agent;
~~6.~~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 LA.PMN.255
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: LA.PMN.53 for Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Louisiana Healthcare Connections 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 LA.PMN.255
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: LA.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 – LA.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
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 as combination therapy	Dose 1 through 6: 500mg every 3 weeks in combination with carboplatin and paclitaxel Subsequent dosing beginning 3 weeks after Dose 6 (Dose 7 onwards): 1,000 mg monotherapy every 6 weeks	See dosing regimen
EC~~, solid~~ 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; ~~February~~July 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761174s003s004lbl.pdf. Accessed ~~February 27~~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 February 27~~compendiumAccessed 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	LDH Approval Date
Policy created.	05.01.23	08.28.23
For EC, added indication and 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.	02.01.24	

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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 LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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