**09-J4000-03**

**Original Effective Date: 09/15/21**

**Reviewed: 09/10/25**

**Revised: 10/15/25**

# Subject: Dostarlimab-gxly (Jemperli)

**THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.**



## DESCRIPTION:

Dostarlimab-gxly (Jemperli) is a monoclonal antibody that works by targeting the programmed death-1 receptor (PD-1), which is involved in T-cell immune surveillance of tumors. Binding of the PD-1 receptor results in blockade of the PD-1 and PD-2 ligands which generates an anti-tumor immune response and decreased tumor growth. Mismatch repair deficient (dMMR) tumors are expressed in various cancers and have high mutation rates due to the inability to repair DNA replication errors. These tumors have higher levels of neoantigens and have been found to be responsive to PD-1 targeted immunotherapy. Dostarlimab is a PD-1 inhibitor FDA-approved for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC), that has progressed on or following prior treatment with a platinum-containing regimen, and are not candidates for curative surgery or radiation. It is also approved for recurrent or advanced mismatch repair deficient solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options. Continued approval of use for dMMR solid tumors is contingent upon verification of clinical benefit in confirmatory trials. It was also FDA approved for use in combination with carboplatin and paclitaxel followed by use as a single agent for primary advanced or recurrent endometrial cancer.

The efficacy of dostarlimab was assessed in an open-label study in 71 patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer who had progressed on or after treatment with a platinum-containing regimen. Half of the patients had received treatment for metastatic disease and 90% had previously undergone surgery. All patients previously received a platinum-containing regimen and 40% had received 2 lines or more of treatment. Patients were excluded if they had previously received immune checkpoint inhibitor therapy. The overall response rate (ORR) with dostarlimab was 42% (95% CI 30.6, 54.6). The ORR consisted of 13% of patients with a complete response and 30% with a partial response at a median follow up of 11.2 months. The median progression-free survival was 8.1 months and the median overall survival was not reached. The most

frequently reported adverse effects were asthenia, diarrhea, fatigue, nausea, anemia, and constipation. Dose interruption occurred in 23% of patients as a result of anemia, diarrhea, increased lipase, or pyrexia. Dostarlimab was permanently discontinued in 5% of patients due to elevated transaminases, sepsis, bronchitis, and pneumonitis.

The National Comprehensive Cancer Network (NCCN) Guidelines provide recommendations for the use of dostarlimab for the treatment of various types of cancer.

## POSITION STATEMENT:

Initiation of dostarlimab-gxly (Jemperli) **meets the definition of medical necessity** for members diagnosed with **ALL** of the following are met:

I. **ONE** of the following to support clinical use is met:

A. **ALL** of the following are met regarding FDA labeling or NCCN Compendium:

i. **ONE** of the following (indication and usage):

1. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

2. Indication is recognized in NCCN Drugs and Biologics Compendium **AND** usage as a Category 1 or 2A recommendation (Table 1).

ii. **ONE** of the following (diagnostic testing¶):

1. **ALL** of the following:

a. The requested indication requires genetic/specific diagnostic testing per FDA labeling or NCCN Compendium for the requested agent

b. Genetic/specific diagnostic testing has been completed

c. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate.

2. The requested indication does **NOT** require specific genetic/diagnostic testing per FDA labeling or NCCN Compendium.

B. Requested product is designated as an orphan drug by the FDA for the requested indication **AND** the indication is not included in the FDA labeling or the NCCN compendium as a 1 or 2A recommendation (i.e., "Designated/Approved", "Designated") (Orphan drug designations can be found at http://www.accessdata.fda.gov/scripts/opdlisting/oopd/)

C. The indication **AND** usage of the requested product is supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article.

NOTE:

- Case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support for use.

- Clinical studies must be supportive of use for a similar patient population (e.g., indication, diagnosis, disease severity, genetic or tumor mutations) and for the intended treatment plan, including any concomitant therapy.

II. Dostarlimab will be used as monotherapy with the following exceptions:

A. Combination therapy for the indication is supported by FDA labeling, NCCN Compendium, or standard reference compendia (Table 2)

B. Combination therapy for the indication is supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article.

i. **NOTE**: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

III. The dose does not exceed the maximum FDA-approved dose and frequency* with the following exceptions:

A. Dose and frequency for indication are supported by NCCN Compendium or standard reference compendia (Table 2)

B. Dose and frequency for indication are supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article

**NOTE**: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

**Approval duration**: 6 months

Continuation of dostarlimab (Jemperli) meets the definition of medical necessity for members meeting ALL of the following criteria:

1. The member has been previously approved by Florida Blue or another health plan in the past 2 years, **OR** the member has previously met all indication-specific criteria for coverage
2. Member's disease has not progressed during treatment with dostarlimab
3. Dostarlimab will be used as monotherapy with the following exceptions:
   a. Combination therapy for the indication is supported by FDA labeling, NCCN Compendium, or standard reference compendia (Table 2)
   b. Combination therapy for indication is supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article
      i. **NOTE**: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use
4. The dose does not exceed the maximum FDA-approved dose and frequency* with the following exceptions:
   a. Dose and frequency for the indication is supported by NCCN Compendium or standard reference compendia (Table 1 or Table 2)
   b. Dose and frequency for indication is supported by the results of **TWO** or more published clinical studies – prescriber must submit full text copies of each article

i. **NOTE**: Dose ranging studies, case reports, posters, and abstracts (including published meeting abstracts) are not accepted as evidence to support use

**Approval duration**: 1 year

*__NOTE__: The maximum FDA approved dose as a single agent is 500 mg every 3 weeks for dose 1 through dose 4 and 1000 mg every 6 weeks for dose 5 and onward. Dose 5 is administered 3 weeks after dose 4. The maximum FDA approved dose in combination with carboplatin and paclitaxel is 500 mg every 3 weeks for dose 1 through dose 6 and 1000 mg every 6 weeks for dose 7 and onward. Dose 7 is administered 3 weeks after dose 6.

### Table 1 - NCCN Categories of Evidence Consensus

| | |
|---|---|
| Category 1 | Based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate |
| Category 2A | Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate |
| Category 2B | Based upon lower-level evidence, there NCCN consensus that the intervention is appropriate |
| Category 3 | Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate |

### Table 2 - Other compendia

| Compendium | Covered Uses† |
|---|---|
| AHFS-DI | Narrative text is supportive |
| Clinical Pharmacology | Narrative text is supportive |
| Lexicomp | Evidence rating A, B or G |
| Thomson Micromedex DrugDex | Meets requirements for BOTH of the following:<br>• Strength of recommendation: Class I (Recommended) or IIa (Recommended, In Most Cases)<br>• Efficacy: Class I (Effective) or IIa (Evidence Favors Efficacy) |
| †If covered use criteria are not met, the request should be denied.<br>AHFS-DI, American Hospital Formulary Service Drug Information; For additional information regarding designated compendia, please refer to the “Definitions” section. | |

## DOSAGE/ADMINISTRATION:

**THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER’S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.**

**FDA-approved**

- In combination with carboplatin and paclitaxel, for primary advanced or recurrent endometrial carcinoma: 500 mg IV every 3 weeks for 6 cycles; then 1,000 mg IV every 6 weeks until disease progression. Administer as an IV infusion over 30 minutes. Treat until disease progression of unacceptable toxicity.
- As a single agent for mismatch repair deficient (dMMR) recurrent or advanced endometrial carcinoma or advanced solid tumors: 500 mg IV every 3 weeks for 4 cycles; then 1,000 mg IV every 6 weeks

until disease progression. Administer as an IV infusion over 30 minutes. Treat until disease progression of unacceptable toxicity.

- Select patients based on the presence of dMMR in tumor specimens using a companion diagnostic test at https://www.fda.gov/companiondiagnostics.
- Because of the effect of prior chemotherapy on test results for dMMR in patients with high-grade gliomas is unclear, it is recommended to test for this marker in the primary tumor specimen obtained prior to initiation of temozolomide chemotherapy in patients with high-grade gliomas.

**Dose Adjustments**

- Therapy may need to be temporarily withheld or permanently discontinued in patients who develop immune-related reactions. See prescribing information for dose adjustments or discontinuation.

**Drug Availability**

- Intravenous Solution: 500 mg/ 10 mL (50 MG/1 ML) in a single dose vial

## PRECAUTIONS:

**Boxed Warning**

- none

**Contraindications**

- none

**Precautions/Warnings**

- Monitor for immune-mediated adverse reactions: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-meditiated hepatitis, immune-mediated nephritis with renal dysfunction, immune-mediated dermatologic adverse reactions, and solid organ transplant rejection. Monitor for signs and symptoms of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver enzymes, creatinine, and thyroid function, at baseline and periodically during treatment. Withhold or permanently discontinue and administer corticosteroids based on the severity of reaction.
- Infusion-related reactions: Interrupt, slow the rate of infusion, or permanently discontinue based on severity of reaction.
- Complications of allogeneic HSCT after PD-1/L-1–blocking antibody: Follow patients closely for evidence of transplant-related complications and intervene promptly.
- Embryo-fetal toxicity: Can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

## BILLING/CODING INFORMATION:

The following codes may be used to describe:

### HCPCS Coding

| | |
|---|---|
| J9272 | Injection, dostarlimab-gxly, 10 mg |

### ICD-10 Diagnosis Codes That Support Medical Necessity

| | |
|---|---|
| C15.3 – C15.9 | Malignant neoplasm of esophagus |
| C16.0 – C16.9 | Malignant neoplasm of stomach |
| C17.0 – C17.9 | Malignant neoplasm of small intestine |
| C18.0 – C18.9 | Malignant neoplasm of colon |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C21.0 – C21.8 | Malignant neoplasm of overlapping sites of rectum, anus and anal canal |
| C24.0 – C24.9 | Malignant neoplasm of other and unspecified parts of biliary tract |
| C25.0 – C25.9 | Malignant neoplasm of head of pancreas |
| C48.1 – C48.8 | Malignant neoplasm of retroperitoneum and peritoneum |
| C50.011 – C50.929 | Malignant neoplasm of breast |
| C54.0 – C54.9 | Malignant neoplasm of corpus uteri |
| C55 | Malignant neoplasm of uterus, part unspecified |
| C56.1 – C56.9 | Malignant neoplasm of ovary |
| C57.00 – C57.9 | Malignant neoplasm of other and unspecified female genital organs |
| C78.00 – C78.89 | Secondary malignant neoplasm of respiratory and digestive organs |
| C80.0 – C80.1 | Malignant neoplasm without specification of site |
| D37.1 | Neoplasm of uncertain behavior of stomach |
| D37.8, D37.9 | Neoplasm of uncertain behavior of other digestive organ |

## REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

## PROGRAM EXCEPTIONS:

**Federal Employee Program (FEP):** Follow FEP guidelines.

**State Account Organization (SAO):** Follow SAO guidelines.

**Medicare Part D:** BCBSF has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

**Medicare Advantage:** No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

## DEFINITIONS:

None

## RELATED GUIDELINES:

**Nivolumab (Opdivo®), 09-J2000-33**

**Pembrolizumab (Keytruda®) Injection, 09-J2000-22**

## OTHER:

None

## REFERENCES:


1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.;2025. URL www.clinicalpharmacilogy-ip.com Accessed 08/30/25.
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3. Micromedex® Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 08/30/25.
4. NCCN Drugs & Biologics Compendium [Internet]. Fort Washington (PA): National Comprehensive Cancer Network;2025. Available from: http://www.nccn.org/professionals/drug_compendium/content/contents.asp/. Accessed 08/30/25.
5. Oaknin A, Tinker AV, Gilbert L et al. Clinical activity and safety of the anti-programmed death 1 monoclonal antibody dostarlimab for patients with recurrent or advanced mismatch repair-deficient endometrial cancer: a nonrandomized phase 1 clinical trial. JAMA Oncol. 2020; 6(11): 1766-1772.


## COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 09/10/25.

## GUIDELINE UPDATE INFORMATION:

| | |
|---|---|
| 09/15/21 | New Medical Coverage Guideline. |
| 10/01/21 | Revision: Added HCPCS code C9082. |
| 10/15/21 | Revision to policy including updates to the position statement, description, coding, and references. |
| 01/01/22 | Revision: Added HCPCS code J9272 and deleted codes C9082 and J9999. |
| 01/15/23 | Review and revision to guideline; consisting of revising the position statement to include NCCN covered indications, and update to coding and references. |
| 08/15/23 | Review and revision to guideline; consisting of revising the position statement to include FDA label and NCCN covered indications. Update to coding and references. |
| 10/15/25 | Review and revision to guideline; consisting of updating description, dosing, warnings, and references. |