Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope
Dostarlimab-gxly (Jemperli®)	MP-RX-FP-119-24	☒ MMM MA ☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B Drugs

Service Description

This document addresses the use of *Dostarlimab-gxly (Jemperli®),* a programmed death receptor-1 (PD-1)–blocking antibody, approved by the Food and Drug Administration (FDA) for the treatment of Endometrial Cancer and Mismatch Repair Deficient Recurrent or Advance Solid Tumors.

Background Information

Dostarlimab is a human programmed death receptor-1 (PD-1) blocking antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response.

Jemperli is indicated 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), 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, and 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 on or following prior treatment and who have no satisfactory alternative treatment options.

Jemperli (dostarlimab-gxly) was approved under the FDA's accelerated approval program, and continued approval is contingent upon verification of clinical benefit in confirmatory trials.

The National Comprehensive Cancer Network (NCCN) provides additional recommendation with a category 2A level of evidence for the use of Jemperli for various recurrent or advanced dMMR or MSI-H solid state tumors including, Ampullary adenocarcinoma, breast cancer, colon cancer, esophageal and esophagogastric junction cancers, gastric cancer, ovarian cancer, occult primary/rectal cancer, pancreatic cancer, and small bowel adenocarcinomas for those who have progressed on, or following, prior treatment and who have no other satisfactory treatment options.

Jemperli also has a NCCN 1 recommendation with carboplatin and paclitaxel, followed by Jemperli as a single agent, for the treatment of adult patients with primary advanced or recurrent (stage III-IV) endometrial cancer (EC) that is mismatch repair deficient (dMMR), or microsatellite instability-high (MSI-H) (except for first-line therapy for isolated metastases).

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Jemperli also has 2A recommendations from NCCN for use as a single agent, in those with dMMR or MSI-H recurrent or advanced endometrial cancer, that has progressed on or following prior treatment with a platinum-containing regimen in any setting (except for first-line therapy for isolated metastases) and are not candidates for curative surgery or radiation.

Definitions and Measures

- Chemotherapy: Medical treatment of a disease, particularly cancer, with drugs or other chemicals.
- Disease-free survival (DFS): The interval between a complete disappearance of the cancer (complete response) and the time of relapse.
- Disease Progression: Cancer that continues to grow or spread.
- ECOG or Eastern Cooperative Oncology Group Performance Status: A scale and criteria used by doctors and researchers to assess how an individual's disease is progressing, assess how the disease affects the daily living abilities of the individual, and determine appropriate treatment and prognosis. This scale may also be referred to as the WHO (World Health Organization) or Zubrod score which is based on the following scale:
    - 0 = Fully active, able to carry on all pre-disease performance without restriction
    - 1 = Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, for example, light house work, office work
    - 2 = Ambulatory and capable of all self-care but unable to carry out any work activities. Up and about more than 50% of waking hours
    - 3 = Capable of only limited self-care, confined to bed or chair more than 50% of waking hours
    - 4 = Completely disabled. Cannot carry on any self-care. Totally confined to bed or chair
    - 5 = Dead
- Immune checkpoint inhibitor: A type of drug that blocks certain proteins made by some types of immune system cells, such as T cells, and some cancer cells. When these proteins are blocked, the "brakes" on the immune system are released and T cells are able to kill cancer cells better. Examples of checkpoint proteins found on T cells or cancer cells include programmed death (PD)-1, PD-ligand 1 (PD-L1), and cytotoxic T-lymphocyte–associated antigen (CTLA)-4/B7-1/B7-2.
- Line of Therapy:
    - First-line therapy: The first or primary treatment for the diagnosis, which may include surgery, chemotherapy, radiation therapy or a combination of these therapies.
    - Second-line therapy: Treatment given when initial treatment (first-line therapy) is not effective or there is disease progression.
    - Third-line therapy: Treatment given when both initial (first-line therapy) and subsequent treatment (second- line therapy) are not effective or there is disease progression.
- Locally advanced cancer: Cancer that has spread only to nearby tissues or lymph nodes. Maintenance therapy: Designed to maintain a condition to prevent a relapse.

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- Malignant: Cancerous. Malignant cells can invade and destroy nearby tissue and spread to other parts of the body.
- Metastasis: The spread of cancer from one part of the body to another; a metastatic tumor contains cells that are like those in the original (primary) tumor and have spread.
- Programmed death (PD)-1 proteins: PD-1 proteins are found on T-cells and attach to PD ligands (PD-L1) found on normal (and cancer) cells (see immune checkpoint inhibitor above). Normally, this process keeps T-cells from attacking other cells in the body. However, this can also prevent T-cells from attacking cancer cells in the body. Examples of FDA approved anti-PD-1 agents include Keytruda (pembrolizumab), Opdivo (nivolumab), and Libtayo (cemiplimab).
- Programmed death ligand (PD-L)-1: The ligands found on normal (and cancer) cells to which the PD-1 proteins attach (see immune checkpoint inhibitor above). Cancer cells can have large amounts of PD-L1 on their surface, which helps them to avoid immune attacks. Examples of FDA approved anti-PD-L1 agents include Bavencio (avelumab), Tecentriq (atezolizumab), and Imfinzi (durvalumab).
- Progressive Disease (PD): Cancer that is growing, spreading, or getting worse.

Approved Indications

A. Endometrial Cancer
B. Mismatch Repair Deficient Recurrent or Advance Solid Tumors.

Other Uses

i. Colorectal cancer

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
J9272	Injection, dostarlimab-gxly, 10 mg, [Jemperli]

ICD-10	Description
C00.0-C76.8	Malignant neoplasm at various anatomical sites

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C54.0	Malignant neoplasm of corpus uteri
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
Z15.09	Genetic susceptibility to other malignant neoplasm

Medical Necessity Guidelines

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Dostarlimab-gxly (Jemperli®)

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

i. Individual has a diagnosis of *Endometrial Cancer (EC)* (Label, NCCN 2A); **AND**
   - A. Individual has recurrent or advanced, mismatch repair deficient (dMMR) disease or microsatellite instability high (MSI-H) disease; **AND**
   - B. Individual is using as monotherapy following disease progression with a platinum-containing regimen; **AND**
   - C. Individual is not a candidate for curative surgery or radiation; **AND**
   - D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   - E. Individual has a current ECOG performance status of 0-2; **AND**
   - F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

ii. Individual has a diagnosis of *Solid Tumors* (Label, NCCN 2A); **AND**
   - A. Individual has recurrent or advanced, mismatch repair deficient (dMMR) disease and/or microsatellite instability-high (MSI-H); **AND**
   - B. Individual has disease progression following prior treatment with no other satisfactory alternative treatment options; **AND**
   - C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
   - D. Individual has a current ECOG performance status of 0-2; **AND**
   - E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

iii. Individual has a diagnosis of *dMMR/MSI-H or polymerase epsilon/delta (POLE/POLD1) mutation resectable metastatic colorectal cancer* (NCCN 2A); **AND**

A. Individual is using in one of the following ways:

1. As initial therapy;

OR

2. Neoadjuvant therapy; **AND**

B. Individual has not had previous checkpoint inhibitor immunotherapy (e.g. pembrolizumab, nivolumab, nivolumab plus ipilimumab, or dostarlimab-gxly);

OR

iv. Individual has a diagnosis of *stage III or IV Endometrial Cancer* (Label, NCCN 1, 2A); **AND**

A. Individual has recurrent or primary advanced mismatch repair deficient disease (dMMR) or microsatellite instability high (MSI-H) disease; **AND**

B. Individual is using in combination with carboplatin and paclitaxel; **AND**

C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

D. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Dostarlimab-gxly (Jemperli®) therapy medically necessary in members requesting reauthorization for an indication listed in Section A above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen and the maximum duration of treatment has not been exceeded. The following information should be submitted for reauthorization:

A. A current oncology note documenting the patient's response to treatment showing no progression of disease.

B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

ii. Maximum duration of therapy

A. Adults with dMMR/MSI-H primary advanced or recurrent EC: Up to 3 years.

B. All other indications: until disease progression or unacceptable toxicity.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months

ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

i. Requests for Jemperli may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Dostarlimab-gxly (Jemperli®) 500 mg/10 mL (50 mg/mL) SDV

Indication	Recommended Dosage	Duration of Treatment
Combination Therapy with carboplatin and paclitaxel		
Primary advanced or recurrent Endometrial Cancer	500 mg every 3 weeks for 6 doses followed by 1,000 mg monotherapy every 6 weeks. Administer JEMPERLI prior to carboplatin and paclitaxel when given on the same day.	Until disease progression, unacceptable toxicity, or up **to 3 years**.
Monotherapy		
dMMR recurrent or advanced EC and dMMR recurrent or advanced solid tumors	500 mg every 3 weeks for 4 doses followed by 1,000 mg every 6 weeks (starting 3 weeks after fourth dose).	Until disease progression or unacceptable toxicity.
Locally advanced rectal cancer (as neoadjuvant therapy)	500 mg every 3 weeks.	6 months (9 cycles)
Exceptions		
• 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. • Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after being treated with a PD-1/PD-L1–blocking antibody.		

dMMR = Mismatch Repair Deficient; MSI-H = Microsatellite Instability-High; EC = endometrial cancer.

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Reference Information

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2023. Available from: http://www.clinicalkey.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 12, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 12, 2023
    a. Ampullary Adenocarcinoma. V1.2023. Revised April 27, 2023.
    b. Breast Cancer. V4.2023. Revised March 23, 2023.
    c. Colon Cancer. V2.2023. Revised April 25, 2023.
    d. Esophageal and Esophagogastric Junction Cancers. V2.2023. Revised March 10, 2023.
    e. Gastric Cancer. V2.2023. Revised March 10, 2023.
    f. Occult Primary. V3.2023. Revised December 21, 2022.
    g. Ovarian Cancer. V2.2023. Revised June 2, 2023.
    h. Rectal Cancer. V3.2023. Revised May 26, 2023.
    i. Small Bowel Adenocarcinoma. V1.2023. Revised January 9, 2023.
    j. Uterine Neoplasms. V2.2023. Revised April 28, 2023.
6. 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 [published online ahead of print, 2020 Oct 1]. *JAMA Oncol*. 2020;6(11):1-7. doi:10.1001/jamaoncol.2020.4515. Available at: https://jamanetwork.com/journals/jamaoncology/fullarticle/2771011.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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Revision Type	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Annual Review 12/23/2024	Modify existing criteria for monotherapy use in endometrial cancer of dostarlimab vs. combination therapy. Add NCCN criteria to include MSI-H mutations for use of dostarlimab-gxly in solid tumors. Add NCCN criteria to include polymerase epsilon/delta (POLE/POLD1) mutation for use with dostarlimab-gxly in colorectal cancer. Update quantity limits table: included dosage form and strength, added dose for rectal cancer, and added warnings and precautions per FDA label. Wording and formatting changes. Coding Reviewed: No changes.	3/20/2025	4/2/2025
Policy Inception 01/29/2024	New Medical Policy creation	4/18/2024	6/28/2024