Medical Drug Clinical Criteria

Subject:	Jemperli (dostarlimab-gxly)		
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Table of Contents

Overview

This document addresses the use of Jemperli (dostarlimab-gxly). Jemperli is a human programmed death receptor-1 (PD-1) blocking antibody, indicated for the treatment of endometrial cancer.

The FDA approved indication for Jemperli is for the treatment of adult patients:

- in combination with carboplatin and paclitaxel, followed by Jemperli as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), or microsatellite instability-high (MSI-H)
- As a single agent, is indicated 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.

Jemperli is also indication for recurrent or advanced dMMR solid tumors that have progressed on or following prior treatment, and who have no other satisfactory 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).

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.

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.

Clinical Criteria

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.

Jemperli (dostarlimab-gxly)

Requests for Jemperli (dostarlimab-gxly) may be approved if the following criteria are met:

I. Individual has a diagnosis of metastatic Anal Carcinoma (NCCN 2A); **AND**

A. Individual is using Jemperli as a single agent; **AND**
B. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
D. Individual has a current ECOG performance status of 0-2;

OR

II. Individual has a diagnosis of recurrent, unresectable or metastatic breast cancer (NCCN 2A); **AND**
A. Individual is using Jemperli as a single agent; **AND**
B. Individual has microsatellite instability-high/mismatch repair deficient (MSI-H/dMMR) disease; **AND**
C. Individual has disease progression following prior treatment with no other satisfactory alternative treatment options;

OR

III. Individual has a diagnosis of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma (NCCN 2A); **AND**
A. Individual has mismatch repair deficient (dMMR) disease and/or microsatellite instability-high (MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated phenotype (e.g. TMB > 50 mut/MB) mutation; **AND**
B. Individual is using Jemperli as a single agent; **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;

OR

IV. Individual has a diagnosis of Endometrial Cancer (EC); **AND**
A. Individual has primary advanced (stage III-IV) or recurrent EC disease (Label, NCCN 1, 2A); **AND**
1. Individual is using Jemperli in combination with carboplatin and paclitaxel; **OR**
2. Individual continues to use Jemperli as a single agent for maintenance therapy;
AND
3. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
4. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
5. Individual has a current ECOG performance status of 0-2;

OR

B. Individual has microsatellite instability-high/mismatch repair deficient (MSI-H/dMMR) recurrent or advanced EC disease (Label, NCCN 1); **AND**
1. Individual is using Jemperli as monotherapy; **AND**
2. Individual has progressed on or following prior treatment with a platinum-containing regimen in any setting including neoadjuvant or adjuvant therapy; **AND**
3. Individual is not a candidate for curative surgery or radiation; **AND**
4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
6. Individual has a current ECOG performance status of 0-2;

OR

V. Individual has a diagnosis of Gastric Cancer or Esophageal and esophagogastric junction cancer (NCCN 2A); **AND**
A. Individual is using Jemperli as a single agent; **AND**
B. Individual has mismatch repair deficient (dMMR) disease or microsatellite instability-high (MSI-H) disease;

OR

VI. Individual has a diagnosis of Ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (NCCN 2A); **AND**
A. Individual is using Jemperli as a single agent; **AND**
B. Individual has mismatch repair deficient (dMMR) disease or microsatellite instability-high (MSI-H) disease; **AND**
C. Individual has recurrent or advanced tumors;

OR

VII. Individual has a diagnosis of Small bowel adenocarcinoma (NCCN 2A); **AND**
- A. Individual is using Jemperli as a single agent; **AND**
- B. Individual has deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H] or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, tumor mutational burden (TMB) > 50 mut/Mb]); **AND**
- C. Individual has advanced or metastatic disease;

OR

VIII. Individual has a diagnosis of Solid Tumors (Label); **AND**
- A. Individual has recurrent or advanced, mismatch repair deficient (dMMR) disease and/or microsatellite instability-high (MSI-H);
- B. **AND**
- C. Individual is using dostarlimab-gxly as a single agent; **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.

Jemperli (dostarlimab) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

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

ICD-10 Diagnosis

C00.0-C76.8	Malignant neoplasm at various anatomical sites
Z15.09	Genetic susceptibility to other malignant neoplasm

Document History

Revised: 03/10/2025
Document History:
- 03/10/2025 – Select Review: Separate NCCN and FDA criteria. Clarify Jemperli use in solid state tumors according to NCCN recommendations. Wording and formatting updates. Coding Reviewed: Removed duplicate line item for C54.0-C54.9.
- 11/15/2024 – Select Review: Simplifying and merging the endometrial cancer criteria. Add ECOG score to use in Stege III or IV endometrial cancer. Clarify use in solid tumors as a single agent. Clarify mutations for use in colorectal cancer. Coding Reviewed: No changes.
- 08/16/2024 – Annual Review: 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. Wording and formatting updates. Coding Reviewed: No changes.
- 12/11/2023 – Select Review: Update existing criteria for use in endometrial cancer to avoid repetitive criteria. Coding Reviewed: No changes.
- 08/18/2023 – Annual Review: Add criteria for use in endometrial cancer, recurrent stage III or IV (NCCN 1, FDA) and initial or neoadjuvant therapy in dMMR/MSI-H resectable metastatic colorectal cancer (NCCN 2A). Coding Reviewed: No changes.
- 03/13/2023 – Select Review: Update criteria due to FDA label update for endometrial cancer. Minor wording and formatting changes. Coding Reviewed No changes.

- 08/19/2022 – Annual Review: Update references. No criteria changes. Updates from NCCN guidelines reiterate FDA approved usage in dMMR solid state tumors. Coding reviewed: No changes.
- 09/13/2021 – Selected Review: Update criteria to add new indication for dMMR solid tumors per label. Wording and formatting changes. Coding reviewed: Added HCPCS C9082. Added ICD-10-CM, C00.0-C76.08, C54.0-C54.9, Z15.09. Coding Reviewed: 1/1/2022 Added HCPCS J9272. Removed C9082, J3490, J3590, J9999. Removed all diagnoses pend.
- 05/21/2021 – Annual Review: Add new clinical criteria document for Jemperli. Coding Reviewed: Added J3490, J3590, J9999. All diagnosis pend.

References

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3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on July 1, 2024.
    a. Ampullary Adenocarcinoma. V2.2024. Revised August 02.2024.
    b. Biliary Tract Cancers. V4.2024. Revised August 29, 2024
    c. Breast Cancer. V4.2024. Revised July 3, 2024.
    d. Colon Cancer. V5.2024. Revised August 22, 2024
    e. Esophageal and Esophagogastric Junction Cancers. V4.2024. Revised July 30, 2024.
    f. Gastric Cancer. V4.2024. Revised August 12, 2024.
    g. Hepatocellular Carcinoma. V3.2024. Revised September 24, 2024.
    h. Occult Primary. V2.2025. September 11, 2024.
    i. Ovarian Cancer. V3.2024. Revised July 15, 2024.
    j. Pancreatic Cancer. V3.2024. Revised August 02, 2024.
    k. Rectal Cancer. V4.2024. Revised August 22, 2024.
    l. Small Bowel Adenocarcinoma. V5.2024. Revised September 13, 2024.
    m. Uterine Neoplasms. V3.2024. Revised September 20, 2024.
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.