Reference number(s)
4723-A

Standard Medicare Part B Management Jemperli

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Jemperli	dostarlimab-gxly

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- 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).
- Jemperli is indicated as a single agent for the treatment of adult patients with mismatch repair deficient dMMR recurrent or advanced endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.
- Jemperli is indicated as a single agent for the treatment of adult patients with mismatch repair deficient (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.

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Compendial Uses[2]

- Breast cancer
- Colorectal cancer
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Occult primary cancer
- Ovarian cancer
    - Epithelial ovarian cancer
    - Fallopian tube cancer
    - Primary peritoneal cancer
    - Carcinosarcoma (malignant mixed Mullerian tumors)
    - Clear cell carcinoma of the ovary
    - Mucinous carcinoma of the ovary
    - Grade 1 endometrioid carcinoma
    - Low-grade serous carcinoma/ovarian borderline epithelial tumors
- Endometrial carcinoma
- Small bowel adenocarcinoma
- Ampullary adenocarcinoma
- Hepatocellular Carcinoma
- Biliary Tract cancers
    - Intrahepatic cholangiocarcinoma
    - Gallbladder cancer
    - Extrahepatic cholangiocarcinoma
- Pancreatic Adenocarcinoma

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Documentation

The following documentation must be available, upon request, for all initial requests:

Documentation of laboratory report confirming microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumor status, where applicable.

Coverage Criteria

Endometrial Cancer (EC)[1,2]

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- Authorization of 12 months may be granted as a single agent for treatment of microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer (EC) that has progressed on or following prior treatment with a platinum-containing regimen.
- Authorization of 12 months may be granted for treatment of endometrial carcinoma in combination with carboplatin and paclitaxel (for up to 6 doses of combination therapy followed by Jemperli monotherapy) in members with stage III-IV or recurrent disease.

Solid Tumors[1]

Authorization of 12 months may be granted as a single agent for treatment of mismatch repair deficient (dMMR) solid tumors in members with recurrent or advanced disease that have progressed on or following prior treatment and for whom there are no satisfactory alternative treatment options.

Breast Cancer[2]

Authorization of 12 months may be granted as a single agent in members with no response to preoperative systemic therapy, recurrent unresectable or stage IV breast cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and has progressed on or following prior treatment and has no satisfactory alternative treatment options.

Colorectal Cancer[2,3]

Authorization of 12 months may be granted as a single agent for subsequent treatment of colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, with microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors.

Esophageal, Esophagogastric Junction and Gastric Cancer[2]

Authorization of 12 months may be granted for treatment of esophageal cancer, esophagogastric junction cancer, or gastric adenocarcinoma when all of the following criteria are met:

- The requested medication will be used as a single agent.
- The requested medication will be used as palliative therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease.
- The requested medication will be used for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.

Authorization of 12 months may be granted for treatment of gastric adenocarcinoma if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) in members who have early-stage disease or are medically fit for surgery with surgically unresectable locoregional disease.

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Authorization of 12 months may be granted as single agent induction therapy for relieving dysphagia in members with esophageal cancer or esophagogastric junction cancer in members who are surgical candidates with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

Occult Primary Cancer[2]

Authorization of 12 months may be granted as a single agent for treatment of occult primary cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) and has progressed on or following prior treatment and has no satisfactory alternative treatment options.

Ovarian Cancer[2]

Authorization of 12 months may be granted as a single agent for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, carcinosarcoma (malignant mixed Mullerian tumors), clear cell carcinoma of the ovary, mucinous carcinoma of the ovary, grade 1 endometrioid carcinoma, and low-grade serous carcinoma/ovarian borderline epithelial tumors for recurrent, persistent, or advanced microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

Small Bowel Adenocarcinoma[2]

Authorization of 12 months may be granted as a single agent for treatment of advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors if no previous treatment with a checkpoint inhibitor.

Ampullary Adenocarcinoma[2]

Authorization of 12 months may be granted as a single agent for subsequent treatment of recurrent or advanced microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) ampullary adenocarcinoma that has progressed on or following prior treatment and has no satisfactory alternative treatment options.

Biliary Tract Cancers[2]

Authorization of 12 months may be granted as a single agent for subsequent treatment of unresectable, resected gross residual (R2) disease, or metastatic gallbladder cancer, intrahepatic cholangiocarcinoma and extrahepatic cholangiocarcinoma that is microsatellite instability-high (MSI-H) and/or mismatch repair deficient (dMMR), if no previous treatment with a checkpoint inhibitor and no satisfactory alternative treatment options.

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Hepatocellular Carcinoma[2]

Authorization of 12 months may be granted as a single agent for subsequent treatment of hepatocellular carcinoma that is microsatellite instability-high (MSI-H) and/or mismatch repair deficient (dMMR), if no previous treatment with a checkpoint inhibitor and no satisfactory alternative treatment options.

Pancreatic Adenocarcinoma[2]

Authorization of 12 months may be granted as a single agent for treatment of recurrent, locally advanced, metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) pancreatic adenocarcinoma.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent. Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested medication.
- The requested medication is being used to treat an indication listed in the coverage criteria section.
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen

Treatment as monotherapy after combination use with carboplatin and paclitaxel for endometrial carcinoma will not be approved beyond 36 months total therapy.

Summary of Evidence

The contents listed in these criteria were created after examining the following resources:

- The prescribing information for Jemperli.
- The available compendium
    - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    - Micromedex DrugDex
    - American Hospital Formulary Service- Drug Information (AHFS-DI)
    - Lexi-Drugs
    - Clinical Pharmacology
- NCCN Guideline: Small bowel adenocarcinoma
- NCCN Guideline: Breast cancer
- NCCN Guideline: Hepatocellular carcinoma

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- NCCN Guideline: Occult primary
- NCCN Guideline: Biliary tract cancers
- NCCN Guideline: Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
- NCCN Guideline: Uterine neoplasms
- NCCN Guideline: Ampullary adenocarcinoma
- NCCN Guideline: Pancreatic adenocarcinoma
- NCCN Guideline: Colon cancer
- NCCN Guideline: Rectal cancer
- NCCN Guideline: Esophageal and esophagogastric junction cancers
- NCCN Guideline: Gastric cancer

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Jemperli are covered in addition to the following:

- Breast cancer
- Colorectal cancer
- Esophageal and esophagogastric junction cancers
- Gastric cancer
- Occult primary cancer
- Ovarian cancer
    - Epithelial ovarian cancer
    - Fallopian tube cancer
    - Primary peritoneal cancer
    - Carcinosarcoma (malignant mixed Mullerian tumors)
    - Clear cell carcinoma of the ovary
    - Mucinous carcinoma of the ovary
    - Grade 1 endometrioid carcinoma
    - Low-grade serous carcinoma/ovarian borderline epithelial tumors
- Endometrial carcinoma
- Small bowel adenocarcinoma
- Ampullary adenocarcinoma
- Hepatobiliary cancer
    - Hepatocellular carcinoma
    - Intrahepatic cholangiocarcinoma
    - Gallbladder cancer
    - Extrahepatic cholangiocarcinoma

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Jemperli to treat the compendial indications listed in section V can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics

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Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Jemperli [package insert]. Philadelphia, PA: GlaxoSmithKline; August 2024.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed September 3, 2024.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf Accessed September 3, 2024

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