Reference number(s)
4723-A

STANDARD MEDICARE PART B MANAGEMENT

JEMPERLI (dostarlimab-gxly)

POLICY

I. 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.

A. FDA-Approved Indications

Jemperli is indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced:

1. Endometrial cancer (EC), as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.
2. 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.

B. Compendial Uses

1. Breast cancer
2. Colorectal cancer
3. Esophageal and esophagogastric junction cancers
4. Gastric cancer
5. Occult primary cancer
6. Ovarian cancer
    a. Epithelial ovarian cancer
    b. Fallopian tube cancer
    c. Primary peritoneal cancer
    d. Carcinosarcoma (malignant mixed Mullerian tumors)
    e. Clear cell carcinoma of the ovary
    f. Mucinous carcinoma of the ovary
    g. Grade 1 endometrioid carcinoma
    h. Low-grade serous carcinoma/ovarian borderline epithelial tumors
7. Endometrial carcinoma
8. Small bowel adenocarcinoma
9. Ampullary adenocarcinoma
10. Hepatobiliary cancer
    a. Hepatocellular carcinoma
    b. Intrahepatic cholangiocarcinoma
    c. Gallbladder cancer
    d. Extrahepatic cholangiocarcinoma

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

II. DOCUMENTATION

The following documentation must be available, upon request, for all initial requests:
Documentation of laboratory report confirming microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumor status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Endometrial cancer (EC)
Authorization of 12 months may be granted 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.

B. Solid tumors
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.

C. Breast cancer
Authorization of 12 months may be granted as a single agent for treatment of 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.

D. Colorectal cancer
Authorization of 12 months may be granted as a single agent for subsequent treatment of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma, that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), following previous oxaliplatin- irinotecan- and/or fluoropyrimidine-based therapy, if no previous treatment with a checkpoint inhibitor.

E. Esophageal, esophagogastric junction and gastric cancer
Authorization of 12 months may be granted for treatment of esophageal, esophagogastric junction, or gastric carcinoma when all of the following criteria are met:
1. The requested medication will be used as a single agent.
2. The requested medication will be used for subsequent treatment as palliative therapy for patients who are not surgical candidates or have unresectable locally advanced, recurrent, or metastatic disease.
3. The requested medication will be used for microsatellite instability-high (MSI-H) or deficient mismatch repair (dMMR) tumors.
4. The requested medication will be used in patients whose cancer is progressing on or following prior treatment and who have no satisfactory alternative treatment options.
5. The member has not received prior use of immuno-oncology therapy.

F. Occult primary cancer
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.

G. Ovarian cancer
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.

H. Small bowel adenocarcinoma
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) or mismatch repair deficient (dMMR) tumors if no previous treatment with a checkpoint inhibitor.

I. Ampullary adenocarcinoma
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.

J. Hepatobiliary cancer
Authorization of 12 months may be granted as a single agent for subsequent treatment of hepatocellular carcinoma, intrahepatic cholangiocarcinoma, gallbladder cancer, 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.

IV. 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:
A. The member is currently receiving therapy with the requested medication.
B. The requested medication is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy. Benefit is defined as:
    1. No evidence of unacceptable toxicity while on the current regimen and
    2. No evidence of disease progression while on the current regimen

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Jemperli.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. NCCN Guideline: Small bowel adenocarcinoma

4. NCCN Guideline: Breast cancer
5. NCCN Guideline: Hepatocellular carcinoma
6. NCCN Guideline: Occult primary
7. NCCN Guideline: Biliary tract cancers
8. NCCN Guideline: Ovarian cancer, fallopian tube cancer, and primary peritoneal cancer
9. NCCN Guideline: Uterine neoplasms
10. NCCN Guideline: Ampullary adenocarcinoma
11. NCCN Guideline: Pancreatic adenocarcinoma
12. NCCN Guideline: Colon cancer
13. NCCN Guideline: Rectal cancer
14. NCCN Guideline: Esophageal and esophagogastric junction cancers
15. 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:

1. Breast cancer
2. Colorectal cancer
3. Esophageal and esophagogastric junction cancers
4. Gastric cancer
5. Occult primary cancer
6. Ovarian cancer
    a. Epithelial ovarian cancer
    b. Fallopian tube cancer
    c. Primary peritoneal cancer
    d. Carcinosarcoma (malignant mixed Mullerian tumors)
    e. Clear cell carcinoma of the ovary
    f. Mucinous carcinoma of the ovary
    g. Grade 1 endometrioid carcinoma
    h. Low-grade serous carcinoma/ovarian borderline epithelial tumors
7. Endometrial carcinoma
8. Small bowel adenocarcinoma
9. Ampullary adenocarcinoma
10. Hepatobiliary cancer
    a. Hepatocellular carcinoma
    b. Intrahepatic cholangiocarcinoma
    c. Gallbladder cancer
    d. Extrahepatic cholangiocarcinoma

VI. 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 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).

VII. REFERENCES

1. Jemperli [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2022.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed September 13, 2022.