Draft Revised Policy: Do Not Implement

Dostarlimab-gxly (Jemperli®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

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

- 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) ~~.that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).~~
- 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 in any setting and are not candidates for curative surgery or radiation.
- 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.

Compendial Uses

- 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
- Pancreatic adenocarcinoma

All other indications are considered experimental/investigational and not medically necessary.

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

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

EXCLUSIONS

Coverage will not be provided for members who have experienced disease progression while on PD-1 or PD-L1 inhibitor therapy.

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

Endometrial Carcinoma

- Authorization of 6 months may be granted as a single agent for treatment of recurrent or advanced microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial cancer that has progressed on or following prior treatment with a platinum-containing regimen.
- Authorization of 6 months may be granted for ~~primary or adjuvant~~ 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

Authorization of 6 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

Authorization of 6 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

Authorization of 6 months may be granted as a single agent for treatment of ~~advanced or metastatic~~ colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, with ~~that is~~ microsatellite instability-high (MSI-H), ~~or~~ mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors.

Esophageal, Esophagogastric Junction and Gastric Cancer
Authorization of 6 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.
- ~~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.~~

Authorization of 6 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.

Authorization of 6 months may be granted as single agent induction therapy for relieving dysphagia in members with esophageal cancer or esophagogastric junction cancer who are surgical candidates with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

Occult Primary Cancer

Authorization of 6 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

Authorization of 6 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

Authorization of 6 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, or polymerase epsilon/delta (POLE/POLD1) tumors.

Ampullary Adenocarcinoma

Authorization of 6 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.

Pancreatic Adenocarcinoma

Authorization of 6 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 when member has ECOG 0-2.

CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section ~~IV~~ when there is no evidence of unacceptable toxicity or 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.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Jemperli [package insert]. Philadelphia, PA ~~Research Triangle Park, NC~~: 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.

EFFECTIVE DATE

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