Reference number(s)
4705-A

SPECIALTY GUIDELINE 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. Gastric cancer
4. Occult primary cancer
5. Ovarian cancer
    a. Epithelial ovarian cancer
    b. Fallopian tube cancer
    c. Primary peritoneal cancer
    d. Carcinosarcoma (malignant mixed Mullerian tumors)
    e. Clear cell carcinoma
    f. Mucinous carcinoma
    g. Grade 1 endometrioid carcinoma
    h. Low-grade serous carcinoma/ ovarian borderline epithelial tumors (low malignant potential with invasive implants)
6. Endometrial Carcinoma
7. Small Bowel Adenocarcinoma

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

II. 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) tumor status, where applicable.

III. EXCLUSIONS

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

IV. CRITERIA FOR INITIAL APPROVAL

A. Endometrial cancer (EC)
Authorization of 6 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 6 months may be granted for treatment of mismatch repair deficient (dMMR) recurrent or advanced solid tumors that has progressed on or following prior treatment and for whom there are no satisfactory alternative treatment options, when used as a single agent.

C. Breast Cancer
Authorization of 6 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 6 months may be granted as a single agent for subsequent treatment of advanced or metastatic colon cancer that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) following previous oxaliplatin- irinotecan- and/or fluoropyrimidine-based therapy.

E. Gastric Cancer
Authorization of 6 months may be granted as a single agent for subsequent treatment of unresectable locally advanced, recurrent, or metastatic disease gastric 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.

F. Occult Primary
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).

G. Epithelial Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal 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, mucinous carcinoma, grade 1 endometrioid carcinoma, and low-grade serous carcinoma/ ovarian borderline epithelial tumors (low malignant potential with invasive implants) for recurrent or persistent microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors if there is disease progression and there are no satisfactory alternative treatment options.

H. Small Bowel Adenocarcinoma
Authorization of 6 months may be granted as a single agent for treatment of advanced or metastatic small bowel adenocarcinoma, including advanced ampullary cancer, for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section IV when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

VI. REFERENCES

1. Jemperli [package insert]. Research Triangle Park, NC: GlaxoSmithKline; August 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 1, 2021.