Reference number(s)
4705-A

Specialty Guideline 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 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[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
- Pancreatic adenocarcinoma
- Anal carcinoma
- Non-small cell lung cancer

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), mismatch repair deficient (dMMR), polymerase epsilon/delta (POLE/POLD1) tumor status, or human epidermal growth factor receptor 2 (HER2), 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

Endometrial Carcinoma[1,2]

- 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 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 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[2]

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 (M1) 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 when either of the following criteria is met:

- The requested medication will be used as third-line therapy or later and member has human epidermal growth factor receptor 2 (HER2)-negative disease
- The requested medication will be used as fourth-line or later and member has HER2-positive disease

Colorectal Cancer[2,3]

Authorization of 6 months may be granted as a single agent for 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 with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Esophageal, Esophagogastric Junction And Gastric Cancer[2]

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 members 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 6 months may be granted for treatment of gastric adenocarcinoma if tumor is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) 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 planned for esophagectomy with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) tumors.

Occult Primary Cancer[2]

Authorization of 6 months may be granted as a single agent for treatment of recurrent or advanced 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 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[2]

Authorization of 6 months may be granted as a single agent for treatment of locally unresectable, medically inoperable, advanced or metastatic small bowel adenocarcinoma for microsatellite instability-high (MSI-H), mismatch repair deficient (dMMR), or polymerase epsilon/delta (POLE/POLD1) tumors with ultra-hypermutated phenotype (e.g., tumor mutational burden (TMB) > 50 mut/Mb).

Ampullary Adenocarcinoma[2]

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[2]

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.

Anal Carcinoma[2]

Authorization of 6 months may be granted as a single agent for subsequent treatment of metastatic squamous cell anal carcinoma when member has not received prior immunotherapy.

Non-Small Cell Lung Cancer[4]

Authorization of 6 months may be granted in combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic nonsquamous non-small cell lung cancer without genomic aberrations.

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 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.

References

1. Jemperli [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; September 2025.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed September 10, 2025.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 4.2025. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf Accessed September 16, 2025.
4. Micromedex Solutions [database online]. Ann Arbor, MI: Merative. www.micromedexsolutions.com [available with subscription]. Accessed September 22, 2025.