

# Jemperli (dostarlimab-gxly)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Jemperli (dostarlimab-gxly)

## APPROVAL CRITERIA

Requests for Jemperli (dostarlimab-gxly) may be approved if the following criteria are met:

- I. Individual has a diagnosis of metastatic Anal Carcinoma (NCCN 2A); **AND**
  - A. Individual is using Jemperli as a single agent; **AND**
  - B. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
  - C. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
  - D. Individual has a current ECOG performance status of 0-2;

**OR**

- II. Individual has a diagnosis of recurrent, unresectable or metastatic breast cancer (NCCN 2A); **AND**
  - A. Individual is using Jemperli as a single agent; **AND**
  - B. Individual has microsatellite instability-high/mismatch repair deficient (MSI-H/dMMR) disease; **AND**
  - C. Individual has disease progression following prior treatment with no other satisfactory alternative treatment options;

**OR**

- III. Individual has a diagnosis of advanced or metastatic colorectal cancer, including appendiceal adenocarcinoma (NCCN 2A); **AND**
  - A. Individual has mismatch repair deficient (dMMR) disease and/or microsatellite instability-high (MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) with ultra-hypermutated phenotype (e.g. TMB > 50 mut/MB) mutation; **AND**
  - B. Individual is using Jemperli as a single agent; **AND**
  - C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
  - D. Individual has a current ECOG performance status of 0-2;

**OR**

- IV. Individual has a diagnosis of Endometrial Cancer (EC); **AND**
  - A. Individual has primary advanced (stage III-IV) or recurrent EC disease (Label, NCCN 1, 2A); **AND**
    - 1. Individual is using Jemperli in combination with carboplatin and paclitaxel; **OR**
    - 2. Individual continues to use Jemperli as a single agent for maintenance therapy; **AND**
    - 3. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
    - 4. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
    - 5. Individual has a current ECOG performance status of 0-2;

**OR**

- B. Individual has microsatellite instability-high/mismatch repair deficient (MSI-H/dMMR) recurrent or advanced EC disease (Label, NCCN 1); **AND**
  - 1. Individual is using Jemperli as monotherapy; **AND**
  - 2. Individual has progressed on or following prior treatment with a platinum-containing regimen in any setting including neoadjuvant or adjuvant therapy; **AND**
  - 3. Individual is not a candidate for curative surgery or radiation; **AND**
  - 4. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
  - 5. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant; **AND**
  - 6. Individual has a current ECOG performance status of 0-2;

**OR**

- V. Individual has a diagnosis of Gastric Cancer or Esophageal and esophagogastric junction cancer (NCCN 2A); **AND**
  - A. Individual is using Jemperli as a single agent; **AND**
  - B. Individual has mismatch repair deficient (dMMR) disease or microsatellite instability-high (MSI-H) disease;

**OR**

- VI. Individual has a diagnosis of Ovarian cancer, fallopian tube cancer, or primary peritoneal cancer (NCCN 2A); **AND**
  - A. Individual is using Jemperli as a single agent; **AND**
  - B. Individual has mismatch repair deficient (dMMR) disease or microsatellite instability-high (MSI-H) disease; **AND**
  - C. Individual has recurrent or advanced tumors;

**OR**

- VII. Individual has a diagnosis of Small bowel adenocarcinoma (NCCN 2A); **AND**
  - A. Individual is using Jemperli as a single agent; **AND**
  - B. Individual has deficient mismatch repair/microsatellite instability-high [dMMR/MSI-H]

- or polymerase epsilon/delta [POLE/POLD1] mutation with ultra-hypermutated phenotype [eg, tumor mutational burden (TMB) > 50 mut/Mb]); **AND**
- C. Individual has advanced or metastatic disease;

**OR**

- VIII. Individual has a diagnosis of Solid Tumors (Label); **AND**
- A. Individual has recurrent or advanced, mismatch repair deficient (dMMR) disease and/or microsatellite instability-high (MSI-H); **AND**
- B. Individual has disease progression following prior treatment with no other satisfactory alternative treatment options; **AND**
- C. Individual is using dostarlimab-gxly as a single agent; **AND**
- D. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**
- E. Individual has a current ECOG performance status of 0-2; **AND**
- F. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant.

Jemperli (dostarlimab-gxly) may not be approved when the above criteria are not met and for all other indications.

**Key References:**

1. Clinical Pharmacology powered by ClinicalKey. Tampa (FL): Elsevier. 2024. Available from: <http://www.clinicalkey.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 2, 2024.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 1, 2024.
  - a. Ampullary Adenocarcinoma. V2.2024. Revised August 02.2024.
  - b. Biliary Tract Cancers. V4.2024. Revised August 29, 2024
  - c. Breast Cancer. V4.2024. Revised July 3, 2024.
  - d. Colon Cancer. V5.2024. Revised August 22, 2024
  - e. Esophageal and Esophagogastric Junction Cancers. V4.2024. Revised July 30, 2024.
  - f. Gastric Cancer. V4.2024. Revised August 12, 2024.
  - g. Hepatocellular Carcinoma. V3.2024. Revised September 24, 2024.
  - h. Occult Primary. V2.2025. September 11, 2024.
  - i. Ovarian Cancer. V3.2024. Revised July 15, 2024.
  - j. Pancreatic Cancer. V3.2024. Revised August 02, 2024.
  - k. Rectal Cancer. V4.2024. Revised August 22, 2024.
  - l. Small Bowel Adenocarcinoma. V5.2024. Revised September 13, 2024.
  - m. Uterine Neoplasms. V3.2024. Revised September 20, 2024.
6. Oaknin A, Tinker AV, Gilbert L, et al. Clinical Activity and Safety of the Anti-Programmed Death 1 Monoclonal Antibody Dostarlimab for Patients With Recurrent or Advanced Mismatch Repair-Deficient Endometrial Cancer: A Nonrandomized Phase 1 Clinical Trial [published online ahead of print, 2020 Oct 1]. *JAMA Oncol*. 2020;6(11):1-7. doi:10.1001/jamaoncol.2020.4515. Available at: <https://jamanetwork.com/journals/jamaoncology/fullarticle/2771011>.

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