

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 Endometrial Cancer (EC); **AND**
 - A. Individual has recurrent or advanced, mismatch repair deficient (dMMR) disease or microsatellite instability high (MSI-H) disease; **AND**
 - B. Individual is using as monotherapy following disease progression with a platinum-containing regimen; **AND**
 - C. Individual is not a candidate for curative surgery or radiation; **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;

OR

- II. Individual has a diagnosis of Solid Tumors; **AND**
 - A. Individual has recurrent or advanced, mismatch repair deficient (dMMR) disease; **AND**
 - B. Individual has disease progression following prior treatment with no other satisfactory alternative treatment options; **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; **AND**
 - E. Individual is not receiving therapy for an autoimmune disease or chronic condition requiring treatment with a systemic immunosuppressant;

OR

- III. Individual has a diagnosis of dMMR/MSI-H resectable metastatic colorectal cancer (NCCN 2A); **AND**
 - A. Individual is using in one of the following ways:
 1. As initial therapy; **OR**
 2. Neoadjuvant therapy;

AND

B. Individual has not had previous checkpoint inhibitor immunotherapy (e.g. pembrolizumab, nivolumab, nivolumab plus ipilimumab, or dostarlimab-gxly);

OR

IV. Individual has a diagnosis of stage III or IV Endometrial Cancer (Label, NCCN 1); **AND**

A. Individual has recurrent or primary advanced mismatch repair deficient disease (dMMR) or microsatellite instability high (MSI-H) disease; **AND**

B. Individual is using in combination with carboplatin and paclitaxel; **AND**

C. Individual has not received treatment with another anti-PD-1 or anti-PD-L1 agent; **AND**

D. 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. 2023. 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 12, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 12, 2023
 - a. Ampullary Adenocarcinoma. V1.2023. Revised April 27, 2023.
 - b. Breast Cancer. V4.2023. Revised March 23, 2023.
 - c. Colon Cancer. V2.2023. Revised April 25, 2023.
 - d. Esophageal and Esophagogastric Junction Cancers. V2.2023. Revised March 10, 2023.
 - e. Gastric Cancer. V2.2023. Revised March 10, 2023.
 - f. Occult Primary. V3.2023. Revised December 21, 2022.
 - g. Ovarian Cancer. V2.2023. Revised June 2, 2023.
 - h. Rectal Cancer. V3.2023. Revised May 26, 2023.
 - i. Small Bowel Adenocarcinoma. V1.2023. Revised January 9, 2023.
 - j. Uterine Neoplasms. V2.2023. Revised April 28, 2023.
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>.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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