Drug Policy:

Jemperli™ (dostarlimab-gxly)

POLICY NUMBER UM ONC_1433	SUBJECT Jemperli™ (dostarlimab-gxly)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 06/09/21, 09/08/21, 11/15/21, 03/09/22, 05/11/22, 03/08/23, 09/13/23, 10/11/23, 09/18/24	APPROVAL DATE September 18, 2024	EFFECTIVE DATE Septmeber 27, 2024	COMMITTEE APPROVAL DATES 06/09/21, 09/08/21, 11/15/21, 03/09/22, 05/11/22, 03/08/23, 09/13/23, 10/11/23, 09/18/24	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Jemperli (dostarlimab-gxly) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, AND
2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Endometrial Carcinoma

1. Jemperli (dostarlimab-gxly) may be used as a single agent for subsequent line systemic therapy of unresectable or metastatic dMMR (deficient Mis-Match Repair)/MSI-High (MicroSatellite Instability-High) endometrial carcinoma that has progressed following prior treatment with a platinum containing regimen AND the tumor is confirmed to be dMMR/MSI-High by any standard test.

2. Jemperli (dostarlimab-gxly) may be used with carboplatin and paclitaxel, followed by single-agent dostarlimab-gxly, as first/initial line therapy, for stage III/IV primary advanced or recurrent endometrial cancer (EC).

C. Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Solid Tumors

1. Jemperli (dostarlimab-gxly) may be used as monotherapy in members with recurrent, advanced, or metastatic solid tumors that have progressed following all satisfactory treatment alternatives and the solid tumor is positive for microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) as confirmed by any standard test.

D. Rectal Cancer

1. Jemperli (dostarlimab-gxly) may be used as monotherapy, for a period of 6 months, for members with locally advanced, treatment-naïve, mismatch repair deficiency(dMMR)/microsatellite instability-high(MSI-H) rectal cancer; this indication is for members with Stage II or III, non-metastatic rectal cancer.

III. EXCLUSION CRITERIA

A. Disease progression while on or after Jemperli (dostarlimab-gxly) or on prior immunotherapy (anti-PD-L1 or PD-1 inhibitor).

B. Treatment exceeds the maximum 6 months duration limit for Jemperli (dostarlimab-gxly) use in Stage III or lower stage rectal cancer.

C. Dosing exceeds single dose limit of Jemperli (dostarlimab-gxly) 500 mg every 3 weeks or 1,000 mg every 6 weeks.

D. Investigational use of Jemperli (dostarlimab-gxly) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:

1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Oaknin A, et al. GARNET trial: 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. JAMA Oncol. 2020 Nov 1;6(11):1766-1772.

B. Mirza MR, et al; RUBY Investigators. Dostarlimab for Primary Advanced or Recurrent Endometrial Cancer. N Engl J Med. 2023 Jun 8;388(23):2145-2158. doi: 10.1056/NEJMoa2216334

C. Cercek A, et al. PD-1 Blockade in Mismatch Repair-Deficient, Locally Advanced Rectal Cancer. N Engl J Med. 2022 Jun 23;386(25):2363-2376.

D. Jemperli PI prescribing information. GlaxoSmithKline LLC, Philadelphia, PA 2024.

E. Clinical Pharmacology Elsevier Gold Standard 2024.

F. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2024.

G. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.

H. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2024.

I. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

J. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf