

Jemperli (dostarlimab-gxly)



Pharmacy Coverage Policy

Effective Date: August 01, 2021

Revision Date: September 28, 2022

Review Date: September 21, 2022

Line of Business: Medicare, Commercial, Medicaid - Ohio

Policy Type: Prior Authorization

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Disclaimer Description Coverage Determination

Background Medical Terms References

Disclaimer

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, take precedence over clinical policy and must be considered first in determining eligibility for coverage. Coverage may also differ for our Medicare and/or Medicaid members based on any applicable Centers for Medicare & Medicaid Services (CMS) coverage statements including National Coverage Determinations (NCD), Local Medical Review Policies (LMRP) and/or Local Coverage Determinations. See the CMS website at <http://www.cms.hhs.gov/>. The member's health plan benefits in effect on the date services are rendered must be used. Clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise without permission from Humana.

Description

Jemperli (dostarlimab-gxly) programmed death receptor-1 (PD-1)-blocking monoclonal antibody.

Jemperli (dostarlimab-gxly) is approved for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, after progression on or following a prior platinum-containing regimen[^].

[^] indication is approved under accelerated approval based on tumor response rate and durability of response; continued approval is contingent on confirmatory trial illustrating clinical benefit.

Dostarlimab-gxly is available as Jemperli in 500 mg/10 mL (50 mg/mL) single-dose vials.

Coverage Determination

Please note the following regarding medically accepted indications:

All reasonable efforts have been made to ensure consideration of medically accepted indications in this policy. Medically accepted indications are defined by CMS as those uses of a covered Part D drug that are approved under the federal Food, Drug and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act. These compendia guide review of off-label and off-evidence prescribing and are

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subject to minimum evidence standards for each compendium. Currently, this review includes the following references when applicable and may be subject to change per CMS:

- American Hospital Formulary Service-Drug Information (AHFS-DI)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
- Truven Health Analytics Micromedex DrugDEX
- Elsevier/Gold Standard Clinical Pharmacology
- Wolters Kluwer Lexi-Drugs

Jemperli (dostarlimab-gxly) will require prior authorization. This agent may be considered medically necessary when the following criteria are met:

Endometrial cancer

- The member has diagnosis of recurrent or advanced endometrial cancer **AND**
- The member has documented dMMR endometrial cancer **AND**
- The member has progressed on prior platinum containing regimen **AND**
- There is a medical reason why Keytruda (pembrolizumab) can not be initiated as subsequent therapy* **AND**
- Jemperli (dostarlimab-gxly) is administered as monotherapy as subsequent therapy

*For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Solid tumors (dMMR)

- The member has a diagnosis of unresectable or metastatic documented mismatch repair deficient (d-MMR) solid tumors **AND**
- The member has disease that has progressed on prior therapy with no alternative treatments **AND**

See the [DISCLAIMER](#). All Humana member health plan contracts are NOT the same. All legislation/regulations on this subject may not be included. This document is for informational purposes only.

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- The member has a medical reason why Keytruda (pembrolizumab) can not be initiated as subsequent therapy* **AND**
- Jemperli (dostarlimab-gxly) is administered as monotherapy

*For Medicare Part B requests, the step therapy requirement does not apply if the request is a continuation of prior therapy within the past 365 days.

Jemperli (dostarlimab-gxly) will be approved in six month durations or as determined through clinical review.

Coverage Limitations

Jemperli (dostarlimab-gxly) therapy is not considered medically necessary for members with the following concomitant conditions:

- Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g., nivolumab, pembrolizumab)
- Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

Background

This is a prior authorization policy about Jemperli (dostarlimab-gxly).

- Warnings/Precautions:
 - Immune mediated adverse reactions
 - Infusion related reactions
 - Complications of allogenic HSCT after PD-L1 therapy
 - Embryo-fetal toxicity

Please refer to current full Prescribing Information for further details and management.

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- Evaluation of disease progression while on or following immunotherapy will assess direct PD-1/PD-L1 treatment effects
 - Progressive disease off therapy is not equivalent to progressive disease while on therapy
- Assessment of treatment response will be evaluated on individual case basis utilizing various resources (e.g., NCCN Guidelines, iRECIST criteria)

Please refer to the Genetic Testing for further details:

http://apps.humana.com/TAD/TAD_NEW/Home.aspx

Provider Claims Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Jemperli; dostarlimab-gxly; dMMR; endometrial cancer; intravenous, pharmacy

References

Jemperli [package insert]. Research Triangle Park, NC: GlaxoSmithKline; April 2022 . National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2022.