Jemperli (dostarlimab-gxly)

Humana

Pharmacy Coverage Policy

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.

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 platinumcontaining 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 500mg (50mg/10mL) 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

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**

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

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.

- **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)

Provider Claims Codes	**Please refer to the Genetic Testing for further details: http://apps.humana.com/TAD/TAD_NEW/Home.aspx** **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**
References	**Jemperli [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2021.** **National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2021.**