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| Section: | Prescription Drugs | Effective Date: | April 1, 2024 |
| Subsection: | Antineoplastic Agents | Original Policy Date: | May 14, 2021 |
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Last Review Date: March 8, 2024

Jemperli

Description

Jemperli (dostarlimab-gxly)

Background

Jemperli (dostarlimab-gxly) is a humanized monoclonal antibody of the IgG4 isotype that binds to the programmed death receptor-1 (PD-1) and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors (1).

Regulatory Status

FDA-approved indications: Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody indicated: (1)

- Endometrial Cancer (EC)
 - In combination with carboplatin and paclitaxel, followed by Jemperli as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MIS-H).
 - As a single agent for the treatment of adult patients with dMMR recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation.
- Mismatch Repair Deficient Recurrent or Advanced Solid Tumors

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- As a single agent for the treatment of adult patients with dMMR recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.

Jemperli's mechanism of action removes inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Immune-mediated adverse reactions can occur in any organ system or tissue and can occur at any time after starting the medication. Patients should be monitored closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Liver enzymes, creatinine, and thyroid function should be evaluated at baseline and periodically during treatment (1).

Jemperli may cause fetal harm when administered to a pregnant woman. Pregnant women should be advised of the potential risk to a fetus. Females of reproductive potential should be advised to use effective contraception during treatment with Jemperli and for 4 months after the last dose (1).

The safety and effectiveness of Jemperli have not been established in pediatric patients less than 18 years of age (1).

Related Policies

Keytruda

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Jemperli may be considered **medically necessary** if the conditions indicated below are met.

Jemperli may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

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1. Primary advanced or recurrent endometrial cancer
 - a. Used in combination with carboplatin and paclitaxel, followed by Jemperli used as a single agent
 - b. Presence of dMMR in tumor specimens based on an FDA-approved test **OR** tumor is microsatellite instability-high (MSI-H)
2. Recurrent or advanced endometrial cancer
 - a. Disease has progressed on or following prior treatment with a platinum-containing regimen in any setting
 - b. Used as a single agent
 - c. Patient is **NOT** a candidate for curative surgery or radiation
 - d. Presence of dMMR in tumor specimens based on an FDA-approved test
3. Recurrent or advanced solid tumors
 - a. Disease has progressed on or following prior treatment and patient has no satisfactory alternative treatment options
 - b. Used as a single agent
 - c. Presence of dMMR in tumor specimens based on an FDA-approved test

AND ALL of the following:

- a. Prescriber agrees to monitor liver enzymes, creatinine, and thyroid function tests
- b. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jemperli and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** the following:

1. Recurrent or advanced endometrial cancer
2. Recurrent or advanced solid tumors

AND ALL of the following:

- a. **NO** disease progression or unacceptable toxicity

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- b. Used as a single agent
- c. Prescriber agrees to monitor liver enzymes, creatinine, and thyroid function tests
- d. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Jemperli and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 20 vials

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Jemperli (dostarlimab-gxly) is a humanized monoclonal antibody of the IgG4 isotype that binds to the programmed death receptor-1 (PD-1) and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors. The safety and effectiveness of Jemperli have not been established in pediatric patients less than 18 years of age (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Jemperli while maintaining optimal therapeutic outcomes.

References

1. Jemperli [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; July 2023.

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2. NCCN Drugs & Biologics Compendium[®] Dostarlimab-gxly 2024. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2024.

Policy History

| Date | Action |
|----------------|---|
| May 2021 | Addition to PA |
| August 2021 | Addition of indication per PI: "recurrent or advanced solid tumors that have progressed on or following prior treatment and who have no satisfactory alternative treatment options" |
| September 2021 | Annual review |
| June 2022 | Annual review and reference update |
| September 2022 | Annual review and reference update |
| March 2023 | Per PI update, added endometrial cancer requirement for patient to not be a candidate for curative surgery or radiation |
| June 2023 | Annual review and reference update |
| August 2023 | Per PI update, added indication of primary advanced EC |
| September 2023 | Annual review |
| March 2024 | Annual review and reference update |

Keywords

This policy was approved by the FEP[®] Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.