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Section:	Prescription Drugs	**Effective Date:**	July 1, 2022
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 14, 2021
Subject:	Jemperli	**Page:**	1 of 4

Last Review Date: June 16, 2022

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 indication: Jemperli is a programmed death receptor-1 (PD-1)-blocking antibody indicated for the treatment of adult patients with mismatch repair deficient (dMMR) recurrent or advanced: (1)

- endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen.
- 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 removed 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** in patients 18 years of age or older with recurrent or advanced endometrial cancer or recurrent or advanced solid tumors and if the conditions indicated below are met.

Jemperli may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

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

1. Recurrent or advanced endometrial cancer
    a. Disease has progressed on or following prior treatment with a platinum-containing regimen
2. Recurrent or advanced solid tumors

a. Disease has progressed on or following prior treatment and patient has no satisfactory alternative treatment options

AND ALL of the following:

a. Presence of dMMR in tumor specimens based on an FDA-approved test
b. Prescriber agrees to monitor liver enzymes, creatinine, and thyroid function tests
c. 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

Diagnosis

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
b. Prescriber agrees to monitor liver enzymes, creatinine, and thyroid function tests
c. 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; August 2021.
2. NCCN Drugs & Biologics Compendium® Dostarlimab-gxly 2022. National Comprehensive Cancer Network, Inc. Accessed on April 19, 2022.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 16, 2022 and is effective on July 1, 2022.