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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2025
<b>Subsection:</b>	Antineoplastic Agents	<b>Original Policy Date:</b>	May 14, 2021
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**Last Review Date:** December 13, 2024

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## Jemperli

### Description

#### Jemperli (dostarlimab-gxly)

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#### 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.
  - 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).

When used for the treatment of adults with primary advanced or recurrent EC, Jemperli's duration of treatment is until disease progression, unacceptable toxicity, or up to 3 years (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).

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## 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

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## Diagnoses

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

1. Primary advanced or recurrent endometrial cancer
  - a. Used in combination with carboplatin and paclitaxel, followed by Jemperli used as a single agent
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

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## 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

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**AND ALL** of the following:

- NO** disease progression or unacceptable toxicity
- Used as a single agent
- Prescriber agrees to monitor liver enzymes, creatinine, and thyroid function tests
- 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

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### 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

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1. Jemperli [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; August 2024.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Dostarlimab-gxly 2024. National Comprehensive Cancer Network, Inc. Accessed on October 10, 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
September 2024	Annual review and reference update
October 2024	Per PI update, removed requirement for dMMR or MSI-H for primary advanced or recurrent EC
December 2024	Annual review and reference update

## Keywords

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**This policy was approved by the FEP<sup>®</sup> Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.**