



ADDING JEMPERLI (DOSTARLIMAB-GXLY) TO AN EPIC[®] PROTOCOL

INDICATIONS

- JEMPERLI, in combination with carboplatin and paclitaxel, followed by JEMPERLI as a single agent, is indicated for the treatment of adult patients with primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with dMMR recurrent or advanced:
 - EC, 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, or
 - 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. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1 –blocking antibody, including JEMPERLI.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Please see additional [Important Safety Information](#) on pages 9-11 and full [Prescribing Information](#).

dMMR = mismatch repair deficient.

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Jemperli 
(dostarlimab-gxly) Injection 500 mg

ABOUT THIS GUIDE

This electronic medical record (EMR) guide is intended to help health care providers (HCPs) who want to create Protocols that include JEMPERLI (dostarlimab-gxly) or want to add JEMPERLI to an existing Protocol. Protocols group order sets for medications, lab testing, procedures, and other aspects of care based on the patient's diagnosis and condition. It is important to evaluate oncology protocols frequently as treatment options, such as JEMPERLI, become available.

This guide does not constitute guidance for treatment or medical advice. It is the responsibility of the healthcare provider to select a treatment based on their independent medical judgment and the needs of each individual patient.

The examples and instructions listed in this guide are based on the most recent version of Epic. Locations, illustrations, and terminology are subject to change with system updates. This guide is meant to serve as an overview only and should not replace detailed instructions provided to you by your internal or external EMR support resources. GSK makes no claims or warranties about the applicability or appropriateness of this information. This guide has not been reviewed or endorsed by Epic. GSK does not endorse or recommend any EMR system.

EMR PROTOCOLS HELP SIMPLIFY ONCOLOGY WORKFLOWS

Protocols, also known as Treatment Plans to the clinical staff, are commonly used to help facilitate the care of patients. After the initial release of a Protocol, the Epic EMR system should be updated periodically by the practice in conjunction with the health system. Refreshing Protocols is a common process and provides an opportunity to incorporate treatment updates and guideline changes. Protocols are typically updated at the health system level to help reduce practice variation. Typically, an oncology practice will conduct a clinical review process to confirm and approve a suggested Protocol update. Various stakeholders may participate in reviewing Protocol modification requests prior to the approval.

As treatment options such as JEMPERLI become available, it may be necessary to create a new Protocol or to update an existing Protocol to remove system obstacles to prescribe JEMPERLI for its approved indications. Updating relevant Protocols to include JEMPERLI communicates to the care team that it is available for appropriate patients.

NOTE: If JEMPERLI is not available for selection in Epic, the practice may need to run a drug database update. As a backup option, the practice EMR Support/IT team may be able to manually add JEMPERLI, subject to the practice's business rules for drug database maintenance.

Creating or Editing a Protocol

Upon request and approval from the Clinical Team, the Health System IT Team creates Protocols that include the necessary orders for a given course of treatment.

When an HCP assigns a Protocol to a patient, it becomes the patient's Treatment Plan. Treatment Plans are comprised of sets of orders, called **Order Groups** in Epic. Once the HCP has created a Treatment Plan specific to the patient, Epic enables users to save it as a preferred Treatment Plan. Treatment Plans can be saved in an HCP's individual library—and can optionally be shared publicly with others in the practice or in the entire health system.

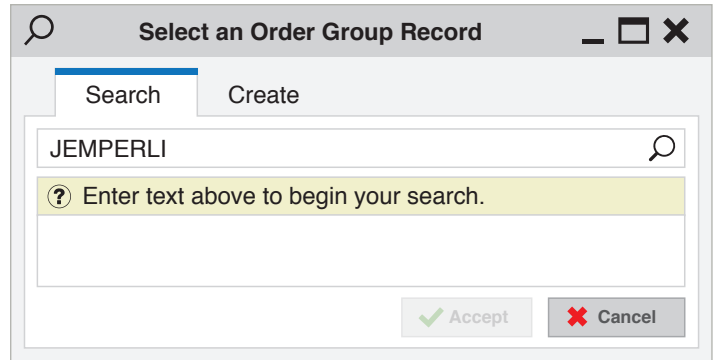
As a prerequisite to inclusion in a Protocol, Treatment Plan, or **Order Group**, JEMPERLI must be set up as an orderable item. It may be appropriate to validate that all treatments are appropriately set up as orderable items prior to beginning the setup of these **Order Groups**.

How to Set Up a New Order Group for JEMPERLI in Epic

The first step in the process of setting up a Protocol for JEMPERLI is to create an **Order Group**. After you create the **Order Group**, you can add it to the Protocol.

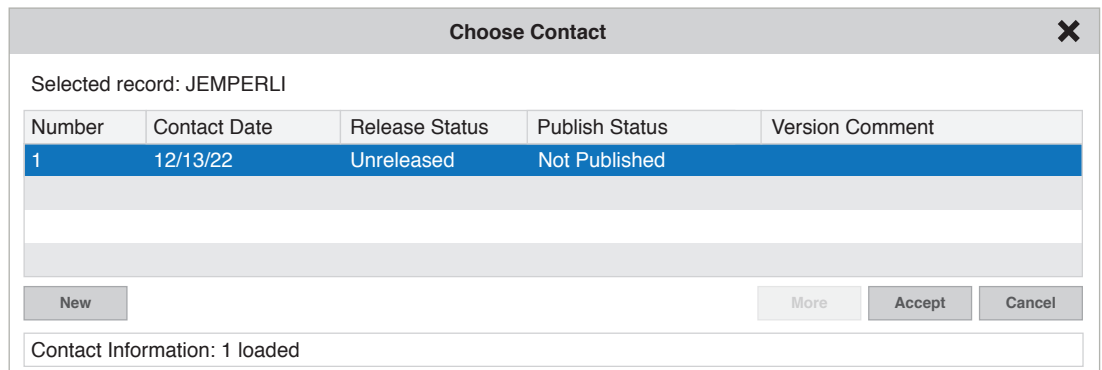
Creating a New Order Group and Adding Medications and Orders

1. Select the **Epic** button > **Admin** > **Beacon Admin** > **Order Group Builder** to open the Order Group Record.
2. Select the **Create** tab (image not shown).
3. Enter the **Name** of the **Order Group** to be set up. For example, JEMPERLI.



Example of Order Group Search

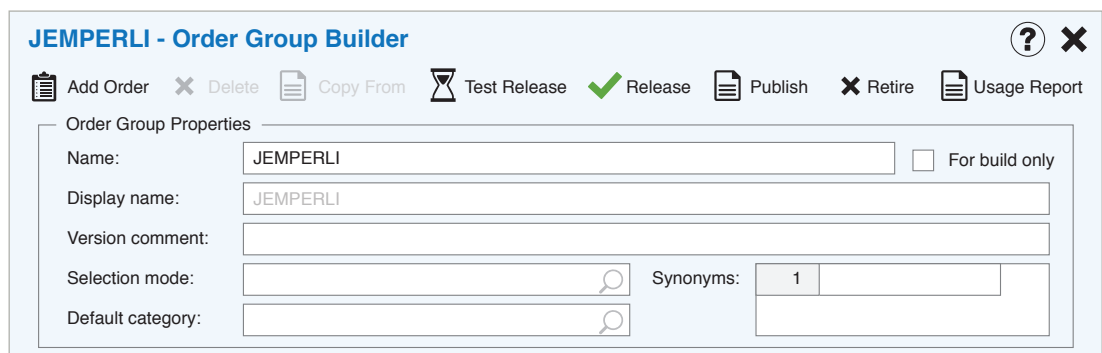
4. Select **Accept** on the initial contact date to open the **Order Group Builder**.



Number	Contact Date	Release Status	Publish Status	Version Comment
1	12/13/22	Unreleased	Not Published	

Example of Order Group Builder Contact Selection

5. Populate appropriate **Order Group Properties**. Enter a **Default Category**. Add **Synonyms** to help when searching for **Order Groups**.



Example of Order Group Builder

How to Set Up a New Order Group for JEMPERLI in Epic (cont.)

Creating a New Order Group and Adding Medications and Orders (cont.)

6. Select **Add Order**.
7. Search for and select appropriate **Category**.

Add Order

Order:

Category:

Example of the Add Order Search

dostarlimab-gxly (JEMPERLI) 500 mg soln

Product: **JEMPERLI (dostarlimab-gxly) 500 MG INTRAVENOUS SOLUTION**

Sig Method: **Specify Dose, Route, Frequency** | Taper/Ramp | Combination Dosage

Dose:

Route:

Frequency:

Duration:

Starting: Ending: First fill:

Dispense: mL Refill:

Total Supply:
 Dispense As Written

Mark long-term DOSTARLIMAB-GXLY

Patient Sig: **Administer infusion intravenously over 30 minutes**
[+ Add additional information to the patient sig.](#)

Report: **Common sizes:**
Vial: 10 mL

Class:

Note to Pharmacy: [+ Add Note to Pharmacy](#)

Indications:

Mismatch Repair Deficient or Microsatellite Instability-High Primary Advanced or Recurrent Endometrial Cancer

Mismatch Repair Deficient Recurrent or Advanced Solid Tumors

Mismatch Repair Deficient Recurrent or Advanced Endometrial Cancer

Taking:

Renewal Provider:

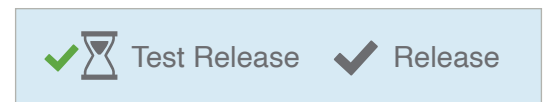
Exception Code:

Example of an Order Composer in Epic

How to Set Up a New Order Group for JEMPERLI in Epic (cont.)

Creating a New Order Group and Adding Medications and Orders (cont.)

8. Enter the medication in the **Order** field and select **Accept**.
9. Enter **Medication Details** as appropriate including dose, route, frequency, starting time, and any additional order instructions. Below dosing is for illustrative purposes. Please refer to the [Prescribing Information](#) for proper dosing based on the appropriate indication.
 - JEMPERLI injection, for intravenous use
 - Dose 1 through 4: 500 mg every 3 weeks
 - Subsequent dosing beginning 3 weeks after Dose 4 (Dose 5 onwards): 1,000 mg every 6 weeks
 - Administration: For Preparation and Administration, please refer to the [Prescribing Information](#)
10. Select **Accept**.
11. **Repeat** process to add associated orders such as patient education and labs as recommended in the [Prescribing Information](#) and per clinical discretion.
12. After all orders have been added, **Release** the **Order Group** to make the changes available and prevent other administrative users from making changes without creating a new contact.



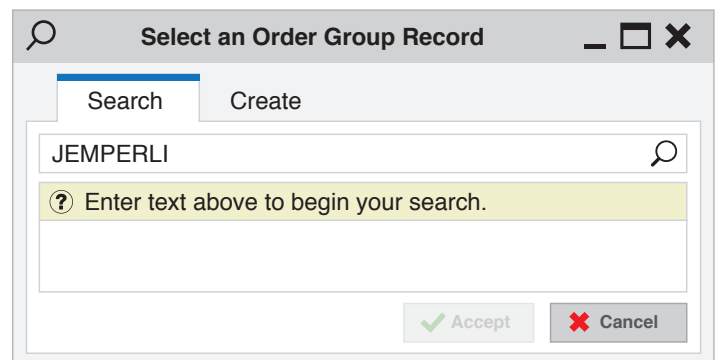
Example of Releasing the Order Group

How to Add JEMPERLI Order Group to a Protocol in Epic

After the JEMPERLI **Order Group** has been set up, it can be added to an appropriate Protocol.

1. Use **Epic** button > **Admin** > **Beacon Admin** > **Protocol Builder** to open the **Protocol Builder** search window.

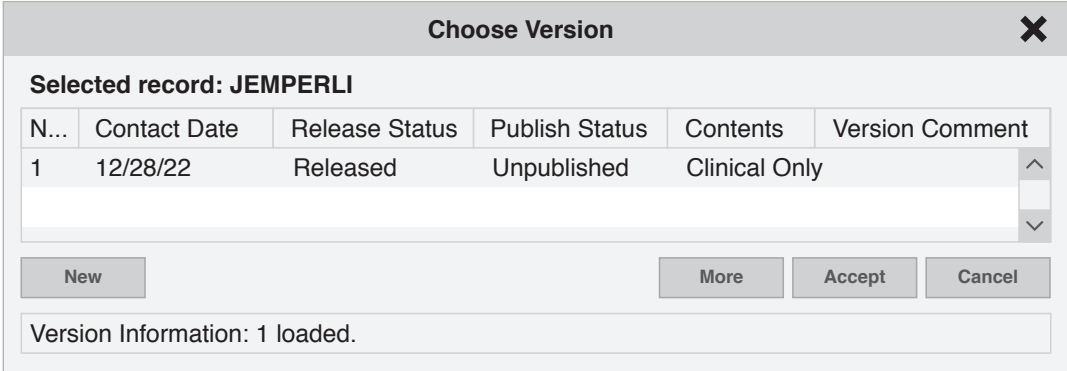
*Note: If a protocol does not exist, utilize the **Create** tab to create a new protocol.*



Example of Protocol Builder Search

How to Add JEMPERLI Order Group to a Protocol in Epic (cont.)

2. Select the appropriate **Protocol** and select **Accept**.
3. On the **Version** window, create a **new contact** to make the protocol editable.



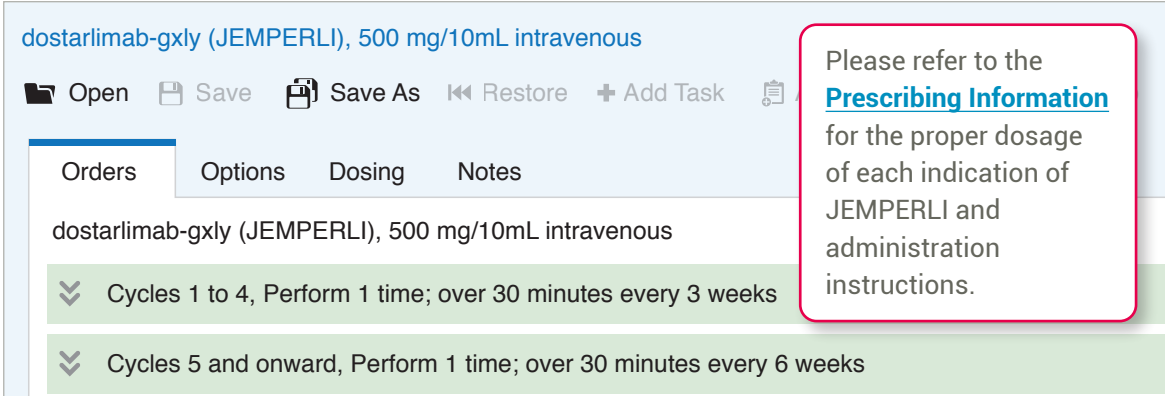
N...	Contact Date	Release Status	Publish Status	Contents	Version Comment
1	12/28/22	Released	Unpublished	Clinical Only	

Buttons: New, More, Accept, Cancel

Version Information: 1 loaded.

Example of Version Window

4. In the Protocol Builder, identify where the **Order Group** should be added. Identify the appropriate **Cycle** and **Days** within the Cycle to add the **Order Group**.



dostarlimab-gxly (JEMPERLI), 500 mg/10mL intravenous

Open Save Save As Restore Add Task

Orders Options Dosing Notes


dostarlimab-gxly (JEMPERLI), 500 mg/10mL intravenous

- ⌵ Cycles 1 to 4, Perform 1 time; over 30 minutes every 3 weeks
- ⌵ Cycles 5 and onward, Perform 1 time; over 30 minutes every 6 weeks

Please refer to the [Prescribing Information](#) for the proper dosage of each indication of JEMPERLI and administration instructions.

Example of Protocol Builder Cycle

How to Add JEMPERLI Order Group to a Protocol in Epic (cont.)



- Open the **Cycle** by selecting  before the cycle name and select the **Week**.
- Click on the order group under which the new order group should display. Select **Add Order Group**.
- In **Select Order Group**, search for and select the **newly created order group**, for example **JEMPERLI**.
- Add the **Order Group** to all **Cycles** and **Weeks** as appropriate.
- Similarly, lab orders, such as CMP or TSH, and patient education orders can be added to the appropriate cycle/days.
- After all orders have been added, release the Protocol to make the changes available and prevent other administrative users from making changes without creating a new contact.

JEMPERLI - View Only - Protocol Builder

Open Save Save As Restore Add Task Add Blank

Orders Options Dosing Notes

JEMPERLI

- ^ Cycles 1 to 4 – Perform: 1 time. Length: over 30 minutes every 3 weeks
 - ^  Day 1 – Perform 1 time on day 1 of the cycle Day length: 1 day.
 - ^ dostarlimab-gxly (JEMPERLI) IV Injection 500mg/10mL
- ^ Cycles 5 and onward – Perform 1 time; over 30 minutes every 6 weeks
 - ^  Day 1 – Perform 1 time on day 1 of the cycle. Day length: 1 day.
 - ^ dostarlimab-gxly (JEMPERLI) IV Injection 500mg/10mL

Insert relevant labs, prescriptions, and communication orders as determined appropriate by your institution.

Below dosing is for illustrative purposes. Please refer to the [Prescribing Information](#) for proper dosing based on the appropriate indication.

- Dose 1 through Dose 4: 500 mg every 3 weeks
- Subsequent dosing beginning 3 weeks after Dose 4 (Dose 5 onwards): 1,000 mg every 6 weeks

The above template shows a hypothetical example of a Protocol Builder for Cycles to help demonstrate what you will see in the Epic system.

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Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions, which can be severe or fatal, can occur in any organ system or tissue and can occur at any time during or after treatment with a PD-1/PD-L1–blocking antibody, including JEMPERLI.
- Monitor closely for signs and symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function tests at baseline and periodically during treatment. For suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Severe and Fatal Immune-Mediated Adverse Reactions (cont.)

- Based on the severity of the adverse reaction, withhold or permanently discontinue JEMPERLI. In general, if JEMPERLI requires interruption or discontinuation, administer systemic corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) until improvement to ≤Grade 1. Upon improvement to ≤Grade 1, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids.

Immune-Mediated Pneumonitis

- JEMPERLI can cause immune-mediated pneumonitis, which can be fatal. In patients treated with other PD-1/PD-L1–blocking antibodies, the incidence of pneumonitis is higher in patients who have received prior thoracic radiation. Pneumonitis occurred in 2.3% (14/605) of patients, including Grade 2 (1.3%), Grade 3 (0.8%), and Grade 4 (0.2%) pneumonitis.

Immune-Mediated Colitis

- Colitis occurred in 1.3% (8/605) of patients, including Grade 2 (0.7%) and Grade 3 (0.7%) adverse reactions. Cytomegalovirus infection/reactivation have occurred in patients with corticosteroid-refractory immune-mediated colitis. In such cases, consider repeating infectious workup to exclude alternative etiologies.

Immune-Mediated Hepatitis

- JEMPERLI can cause immune-mediated hepatitis, which can be fatal. Grade 3 hepatitis occurred in 0.5% (3/605) of patients.

Immune-Mediated Endocrinopathies

- Adrenal Insufficiency
 - Adrenal insufficiency occurred in 1.2% (7/605) of patients, including Grade 2 (0.5%) and Grade 3 (0.7%). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment per institutional guidelines, including hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

IMPORTANT SAFETY INFORMATION (cont.)

Immune-Mediated Endocrinopathies (cont.)

- Hypophysitis
 - JEMPERLI can cause immune-mediated hypophysitis. Grade 3 hypophysitis occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypophysitis occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Thyroid Disorders
 - Grade 2 thyroiditis occurred in 0.5% (3/605) of patients. Grade 2 hypothyroidism occurred in 12% (28/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 2 hypothyroidism occurred in 8% (46/605) of patients receiving JEMPERLI as a single agent. Hyperthyroidism occurred in 3.3% (8/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel, including Grade 2 (2.9%) and Grade 3 (0.4%). Hyperthyroidism occurred in 2.3% (14/605) of patients receiving JEMPERLI as a single agent, including Grade 2 (2.1%) and Grade 3 (0.2%). Initiate thyroid hormone replacement or medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.
- Type 1 Diabetes Mellitus, Which Can Present with Diabetic Ketoacidosis
 - JEMPERLI can cause type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Grade 3 type 1 diabetes mellitus occurred in 0.4% (1/241) of patients receiving JEMPERLI in combination with carboplatin and paclitaxel. Grade 3 type 1 diabetes mellitus occurred in 0.2% (1/605) of patients receiving JEMPERLI as a single agent. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold or permanently discontinue JEMPERLI depending on severity.

Immune-Mediated Nephritis with Renal Dysfunction

- JEMPERLI can cause immune-mediated nephritis, which can be fatal. Grade 2 nephritis, including tubulointerstitial nephritis, occurred in 0.5% (3/605) of patients.

Immune-Mediated Dermatologic Adverse Reactions

- JEMPERLI can cause immune-mediated rash or dermatitis. Bullous and exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS), have occurred with PD-1/PD-L1–blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes. Withhold or permanently discontinue JEMPERLI depending on severity.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred in <1% of the 605 patients treated with JEMPERLI or were reported with the use of other PD-1/PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions.
 - *Nervous System:* Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy
 - *Cardiac/Vascular:* Myocarditis, pericarditis, vasculitis
 - *Ocular:* Uveitis, iritis, other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various grades of visual impairment to include blindness can occur
 - *Gastrointestinal:* Pancreatitis, including increases in serum amylase and lipase levels, gastritis, duodenitis
 - *Musculoskeletal and Connective Tissue:* Myositis/polymyositis, rhabdomyolysis and associated sequelae including renal failure, arthritis, polymyalgia rheumatica
 - *Endocrine:* Hypoparathyroidism

IMPORTANT SAFETY INFORMATION (cont.)

Other Immune-Mediated Adverse Reactions (cont.)

- *Other (Hematologic/Immune):* Autoimmune hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection

Infusion-Related Reactions

- Severe or life-threatening infusion-related reactions have been reported with PD-1/PD-L1–blocking antibodies. Severe infusion-related reactions (Grade 3) occurred in 0.2% (1/605) of patients receiving JEMPERLI. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion or permanently discontinue JEMPERLI based on severity of reaction.

Complications of Allogeneic HSCT

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after treatment with a PD-1/PD-L1–blocking antibody, which may occur despite intervening therapy. Monitor patients closely for transplant-related complications and intervene promptly.

Embryo-Fetal Toxicity and Lactation

- Based on its mechanism of action, JEMPERLI can cause fetal harm. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with JEMPERLI and for 4 months after their last dose. Because of the potential for serious adverse reactions from JEMPERLI in a breastfed child, advise women not to breastfeed during treatment with JEMPERLI and for 4 months after their last dose.

Common Adverse Reactions

The most common adverse reactions ($\geq 20\%$) in patients with dMMR/MSI-H EC who received JEMPERLI in combination with carboplatin and paclitaxel were rash, diarrhea, hypothyroidism, and hypertension. The most common Grade 3 or 4 laboratory abnormalities ($\geq 10\%$) were decreased neutrophils, decreased hemoglobin, decreased white blood cell count, decreased lymphocytes, increased glucose, decreased sodium, and decreased platelets.

The most common adverse reactions ($\geq 20\%$) in patients with dMMR EC who received JEMPERLI as a single agent were fatigue/asthenia, anemia, nausea, diarrhea, constipation, vomiting, and rash. The most common Grade 3 or 4 laboratory abnormalities ($> 2\%$) were decreased lymphocytes, decreased sodium, increased alanine aminotransferase, increased creatinine, decreased neutrophils, decreased albumin, and increased alkaline phosphatase.

The most common adverse reactions ($\geq 20\%$) in patients with dMMR solid tumors who received JEMPERLI as a single agent were fatigue/asthenia, anemia, diarrhea, and nausea. The most common Grade 3 or 4 laboratory abnormalities ($\geq 2\%$) were decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin.

Please see full [Prescribing Information](#).

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DSTBROC240004 March 2024
Produced in USA.

File name: EMR Guide Epic