Jemperli (dostarlimab-gxly) Injection 500 mg

ADDING JEMPERLI TO AN ONCOEMR® EHR REGIMEN

as Both Mono- and Combination Therapy

EHR=electronic health record.
OncoEMR is a registered trademark of Flatiron Health, Inc.

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).
- JEMPERLI, as a single agent, is indicated for the treatment of adult patients with mismatch repair deficient (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.

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 Important Safety Information on pages 8-10 and full Prescribing Information, including Medication Guide.

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ABOUT THIS GUIDE

Implementing JEMPERLI Regimens within the EHR

This guide provides health systems with technical instructions for creating regimens that include JEMPERLI based on its approved indications. For these patients, JEMPERLI may be considered either as monotherapy or in combination with carboplatin and paclitaxel.

NOTE: It is important to evaluate oncology regimens frequently as treatment options, such as JEMPERLI, become available.

When developing JEMPERLI regimens, several caveats can be considered

- This guide is for the OncoEMR® EHR system and is not appropriate for other conditions, treatments, or therapeutic areas or for other EHR systems.
- This guide does not constitute guidance for treatment or medical advice. It is the responsibility of the healthcare provider (HCP) to select a treatment based on their independent medical judgment and the needs of each individual patient.
- Not all process steps will apply to every organization; organizations should exclude or modify steps and settings to align with their standard process. When creating a combination regimen, additional elements may need to be considered or necessary based on the approved product labeling of each medication.
- All technical questions should be directed to the appropriate service provider. The organization is solely responsible for implementing, testing, and monitoring the ongoing operation of any EHR tools.
- The examples and instructions listed in this guide are based on the most recent version of OncoEMR. 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 health systems by their internal or external EHR 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 OncoEMR. GSK does not endorse or recommend any EHR system.

Suggested regimen content

Key clinical details from the JEMPERLI Prescribing Information are included on the following pages and may be incorporated as part of the treatment plans based on steps in the instructions section that follows. The Prescribing Information in this section is to be used as a reference, and it is strongly recommended that clinical and operational leadership align the treatment plan contents with the expectations and goals of the organization. The organization may add or edit any details as desired to align with governing EHR policies and standards. The same considerations should be given for other medications included in the combination regimen.

Overview of JEMPERLI Regimens

JEMPERLI may be incorporated into Regimens either as part of an initial combination regimen with carboplatin and paclitaxel or as a monotherapy, depending on the indication.[1]

Below are the recommended treatment dosing schedules for JEMPERLI in combination with carboplatin and paclitaxel and JEMPERLI as monotherapy[1]:

Recommended dosage

Recommended dosage	Duration/timing of treatment
Combination Therapy	
500 mg[a] JEMPERLI every 3 weeks for 6 cycles in combination with carboplatin and paclitaxel[b] followed by 1000 mg[a] JEMPERLI as monotherapy every 6 weeks for all cycles thereafter. Administer JEMPERLI prior to carboplatin and paclitaxel when given on the same day.	Until disease progression, unacceptable toxicity, or up to 3 years.
Monotherapy	
500 mg[a] JEMPERLI every 3 weeks for 4 cycles followed by 1000 mg[a] JEMPERLI every 6 weeks for all cycles thereafter.	Until disease progression or unacceptable toxicity.

[a]30-minute intravenous infusion.

[b]Refer to the Prescribing Information for the agents administered in combination with JEMPERLI, as appropriate..

NOTE: The examples in this guide are based on combination therapy. If monotherapy treatment regimens are needed, these steps can be repeated with JEMPERLI alone, following the JEMPERLI Prescribing Information. The steps described in this guide can be repeated and tailored as needed for the dosing regimen based on the approved indication. The specific components listed are for illustrative purposes only. Please refer to the full Prescribing Information for complete details and proper dosage of each indication of JEMPERLI and administration instructions.

EHR REGIMENS HELP STREAMLINE ONCOLOGY WORKFLOWS

Regimens are commonly used to help facilitate the care of patients. After the initial release of a regimen, updating regimens is a common process and provides an opportunity to incorporate treatment updates and guideline changes.

Regimens are usually updated at the health system level to help reduce variation. Typically, oncologists conduct a clinical review to approve a proposed regimen update. Various stakeholders may participate in reviewing regimen modification requests prior to approval.

As treatment options such as JEMPERLI become available, it may be necessary to create a new regimen or update an existing regimen based on new information about prescribing JEMPERLI for its approved indications. Updating relevant regimens to include JEMPERLI communicates to the care team that it is available for appropriate patients.

DEVELOPING A REGIMEN

Upon request and approval from the clinical team, the EHR support team creates regimens that include the necessary orders for a given course of treatment. When there are existing regimens, it may be easier to edit and adapt what is already in the EHR. However, a new regimen can also be created if needed.

When a healthcare professional assigns a regimen to a patient, it becomes the patient's plan for treatment. Once the healthcare professional has created a regimen specific to the patient, OncoEMR® enables users to save it as a preferred regimen. Regimens can be saved in a HCP's individual library—and can optionally be shared publicly with others in the practice or in the entire health system.

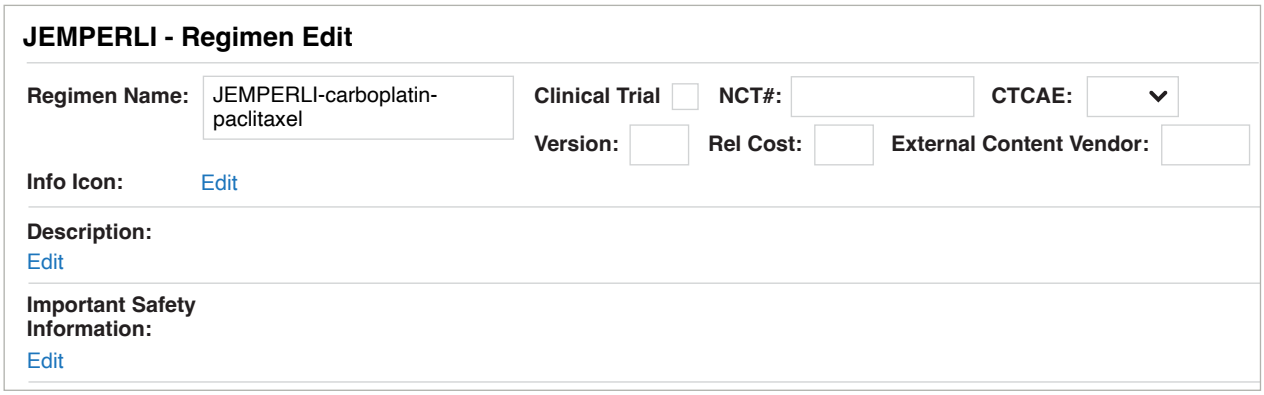
NOTE: If JEMPERLI is not available for selection in OncoEMR, the practice may need to run a drug database update. As a backup option, the practice EHR support team may be able to manually add JEMPERLI, subject to the practice's business rules for drug database maintenance. Users can create new regimens; however, creating or editing custom regimen templates requires full permissions.

Creating a Regimen for JEMPERLI

Regimens facilitate care by organizing clinical actions for the administration and monitoring of infusion medications across multiple encounters within a defined time frame. If a regimen does not already exist, a new regimen can be created and populated with the appropriate clinical components to support consistent and streamlined care delivery. Alternatively, users may create a new regimen by copying an existing template and updating appropriately. These steps can be repeated and tailored as needed for the dosing regimen based on the approved indication. The specific components listed below are for illustrative purposes only. Please refer to the full **Prescribing Information** for complete details and proper dosage of each indication of JEMPERLI and administration instructions.

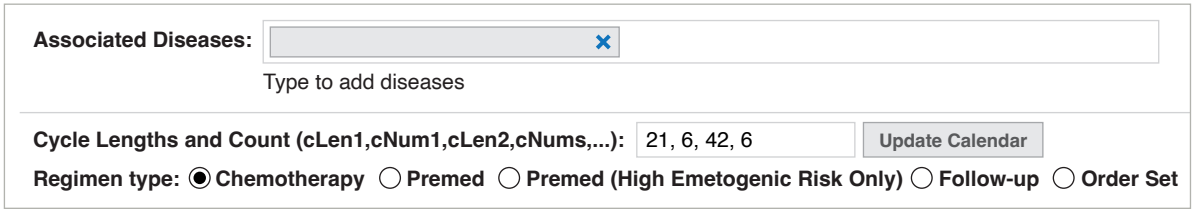
1. Navigate to the **Customize** page and choose **Regimen List**.
2. Select **New Regimen** to display a blank template.
3. Enter a name for the regimen, according to the practice conventions; for example, JEMPERLI-carboplatin-paclitaxel.
4. In the Important Safety Information field, select **Edit** to include JEMPERLI indication per product label. Please refer to the **Prescribing Information** for full details.

Example of the Regimen Edit options



5. In the **Associated Disease(s)** field, enter applicable diseases.
6. Set **Cycle Lengths and Counts**; for example, Cycles 1-6 Perform 1 time. Length: 21 days.
7. Select **Update Calendar**.

Example of updating the Regimen Calendar



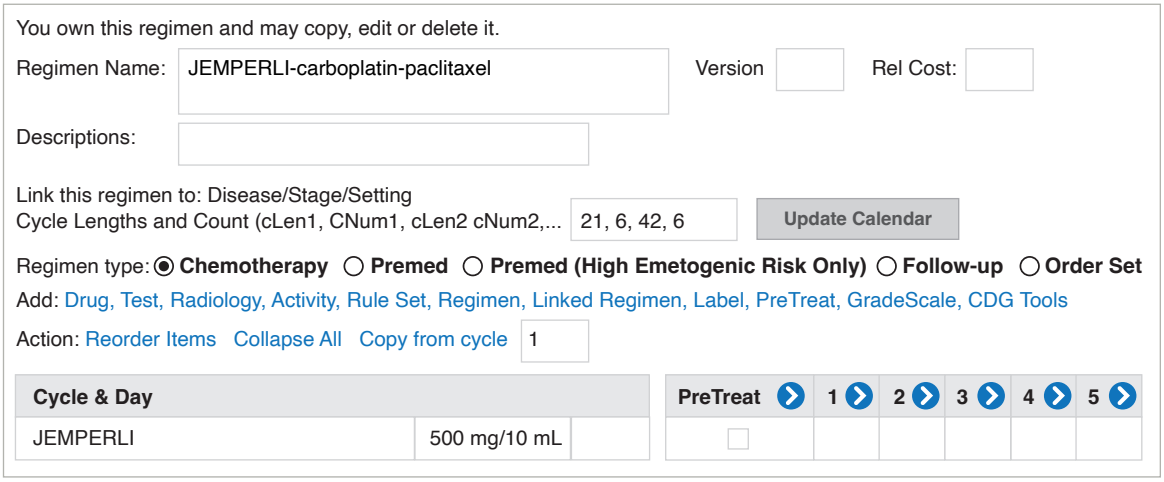
Creating a Regimen for JEMPERLI (cont.)

8. In the **Calendar**, add orders to the regimen. From the **Add**: options, select **Drug**.

9. Search for and select dostarlimab-gxly (JEMPERLI) 500 mg/10 mL to add to the regimen.

10. In the regimen build sheet, set appropriate days for the infusions to be ordered; for example, **6 cycles of 21 days each, then 6 cycles of 42 days each**:
    - Build Cycle 1 and save. Copy from Cycle 1 to create Cycles 2-6.
    - Build Cycle 7 and save. Copy from Cycle 7 to create Cycles 8-12.

Example of JEMPERLI added to the regimen



11. Select **Save**.

Additional combination regimen considerations

Since Combination Regimens involve multiple medications, additional orders may be needed to fulfill safety requirements. It is important for the organization to review the prescribing information of each medication with careful consideration given to safety requirements provided in the approved labeling. This process will most likely be similar to what organizations have done in the past with other combination regimens.

As a reminder, this guide is only intended to provide technical guidance. Decisions regarding the inclusion or exclusion of additional orders are the responsibility of the organization and its decision-makers.

To create a regimen for JEMPERLI based on other indications, the previous steps can be followed and adjusted as needed.

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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.
- 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.
- 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.

Please see additional Important Safety Information on pages 8-10 and full Prescribing Information, including Medication Guide.

Important Safety Information (cont.)

Immune-Mediated Endocrinopathies (cont.)

- Thyroid Disorders
  - Grade 2 thyroiditis occurred in 0.5% (3/605) of patients. Grade 2 hypothyroidism occurred in 12% (30/241) 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
  - *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

Please see additional Important Safety Information on pages 8-10 and full Prescribing Information, including Medication Guide.

Important Safety Information (cont.)

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 (≥20%), including laboratory abnormalities, in patients with EC who received JEMPERLI in combination with carboplatin and paclitaxel were decreased hemoglobin, increased creatinine, peripheral neuropathy, decreased white blood cell count, fatigue, nausea, alopecia, decreased platelets, increased glucose, decreased lymphocytes, decreased magnesium, decreased neutrophils, increased AST, arthralgia, rash, constipation, diarrhea, increased ALT, decreased potassium, decreased albumin, decreased sodium, increased alkaline phosphatase, abdominal pain, dyspnea, decreased appetite, increased amylase, decreased phosphate, urinary tract infection, and vomiting.

The most common adverse reactions (≥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.

Please see full Prescribing Information, including Medication Guide, for JEMPERLI.

Reference: 1. JEMPERLI. Prescribing information. GSK; 2025.