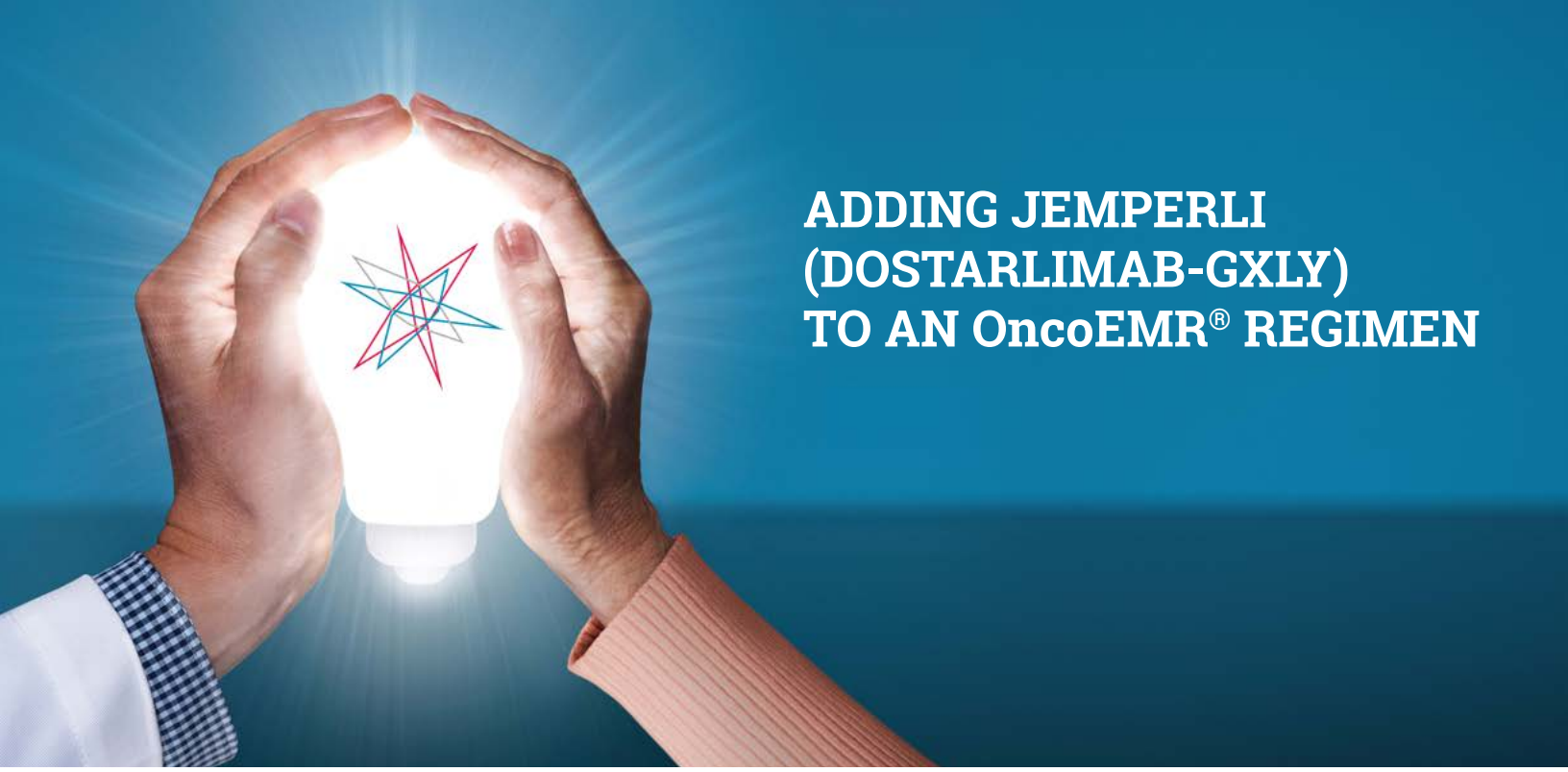


ADDING JEMPERLI (DOSTARLIMAB-GXLY) TO AN OncoEMR® REGIMEN

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 7-9 and full Prescribing Information.

dMMR = mismatch repair deficient.

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 Regimens that include JEMPERLI (dostarlimab-gxly) or want to add JEMPERLI to an existing Regimen. Regimens group together 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 treatment plans 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 HCP 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 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 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 OncoEMR. GSK does not endorse or recommend any EMR system.

EMR REGIMENS HELP SIMPLIFY ONCOLOGY WORKFLOWS

Regimens are commonly used to help facilitate patient care. After the initial release of a new treatment guideline by a medical society, the OncoEMR system may benefit from a clinical update. The optimization of treatment Regimens is a common process and provides an opportunity to incorporate treatment updates. Regimens are typically modified at the health system level to help reduce treatment variation. Typically, an oncology practice will conduct a clinical review process to confirm and approve a suggested Regimen optimization. Various stakeholders may participate in reviewing Regimen modification requests prior to the approval.

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

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 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 practice IT Team creates Regimens that include the necessary orders for a given course of treatment. When an HCP assigns a specific course of treatment to a patient, it becomes the patient's Regimen.

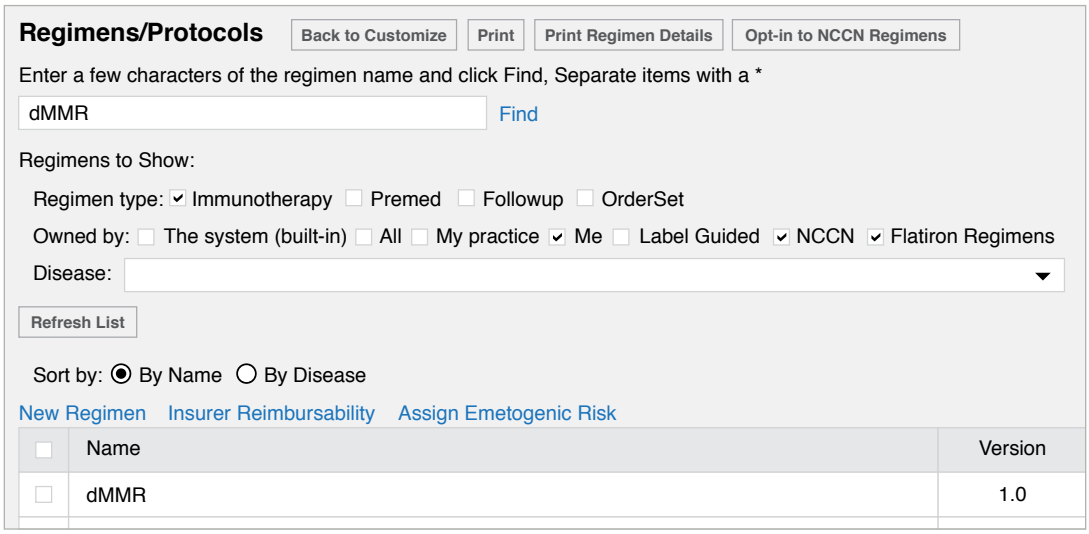
EDITING AN EXISTING REGIMEN

As new tests, treatments, and protocols evolve, it may be appropriate to adjust patients' existing treatment plans and monitoring. With appropriate permissions, users can modify existing Regimens for ease in adding orders to an existing treatment plan.

Adding JEMPERLI to the Regimen

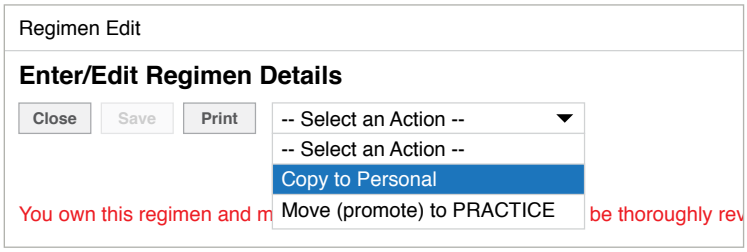
Custom Regimen templates can be created only with full permissions. However, a Regimen template can be created using a copy of an existing Regimen. Copying a Regimen template is the method described in this guide.

1. Navigate to the **Customize** page and choose **Regimen List**. Search for an appropriate Regimen, such as dMMR.



Example of the Regimens/Protocols Selection Screen in OncoEMR

2. Select the Regimen to access the Edit process.
3. From the **Select an Action** dropdown, choose **Copy to Personal**, and update the title.



Regimen Action Options

Adding JEMPERLI to the Regimen (cont.)

4. From the **Add** options, select **Drug**.
5. Search for and select JEMPERLI to add to the Regimen.
6. Select **Save**.
7. In the Regimen build sheet, set appropriate weeks for the injections to be ordered. 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**

Add: Drug, Test, Radiology, Activity, RuleSet, Regimen, Linked Regimen, Label, GradeScale, CDG Tools
Action: Reorder Items Collapse All Copy from cycle 1

Cycle			PreTreat	1	2	3	4	5
dostarlimab-gxly (JEMPERLI)	500 mg/10 mL	All Insurers		1	1	1	1	1

Example of JEMPERLI 500 mg/10 mL Added to the Regimen

Add: Drug, Test, Radiology, Activity, RuleSet, Regimen, Linked Regimen, Label, GradeScale, CDG Tools
Action: Reorder Items Collapse All Copy from cycle 1

Cycle & Day			PreTreat	1											
				1	2	3	4	5	6	7	8	9	10	11	1
dostarlimab-gxly (JEMPERLI)	500 mg/10mL	All Insurers													

Example of the Build Sheet With Time Frames Expanded for Selection

OncoEMR®-Regimen Test

Enter/Edit a Regimen Test

Don't Save | Save | Delete

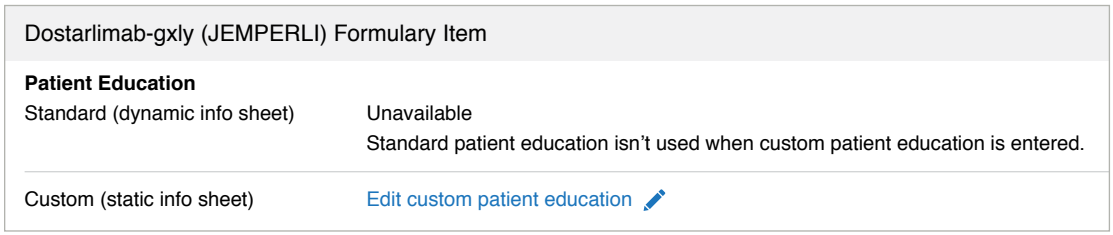
*Test: CMP
Non-Billable:
Specimen Type: Blood
Frequency: Other
cc: Providers:
Sig: CPT 80053
CPT® Code (Procedure): 80053 Procedure Qty: 1
LOINC Code:
Insurer Group:
*=Required Field

8. From the **Add** options, select **Test**. Search for and select desired lab order.
9. Select **Save**.

Example of Adding a Lab to the Regimen

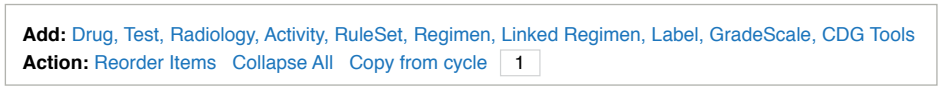
Adding JEMPERLI to the Regimen (cont.)

10. Patient education is part of the Formulary Item and is available and customizable from the information icon.



Create Custom Patient Education From Formulary

11. To indicate when specific information should be provided to the patient, select **Label** from the **Add** options. Enter appropriate caregiver instructions to provide patient education, then **Save**.



Options for Adding to a Regimen

12. Add labs and patient education to the appropriate days in the Regimen build.
13. When edits are completed, from the **Select an Action** dropdown, choose **Move (promote) to PRACTICE**.

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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.

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

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%) 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 (≥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 (≥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 (≥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 (≥2%) were decreased lymphocytes, decreased sodium, increased alkaline phosphatase, and decreased albumin.

Please see full Prescribing Information.

File name: EMR Guide OncoEMR