omvoh™
(mirikizumab-mrkz)
300 mg/15 mL infusion | 100 mg/mL injection

EPIC® EHR SYSTEM

ELECTRONIC HEALTH RECORD (EHR) INSTRUCTIONS TO UPDATE ORDER SETS WITH OMVOH™

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INDICATION
Omvoh is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC).

SELECT IMPORTANT SAFETY INFORMATION
Contraindications: Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

Please see additional Important Safety Information on page 7, and click for Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.

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BACKGROUND, INSTRUCTIONS, AND LIMITATIONS

These instructions are created specifically to update order sets in the Epic EHR system and will not work in other EHR systems. These instructions are designed to be used with Omvoh™ for the aforementioned indication and should not be used for other conditions, treatments, or therapeutic areas.

The processes outlined in this resource are variable and not all steps will apply to every customer. Any steps or settings that are not part of a customer's standard process should be excluded or modified accordingly. Any questions should be directed to the appropriate service provider. The customer is solely responsible for implementing, testing, monitoring, and the ongoing operation of any EHR resource.

A customer may choose to modify existing EHR order sets with Omvoh. Order sets consolidate notes, referrals, imaging studies, laboratory orders and bundles, medications, patient education, coding and billing information, and other orderable items used to manage a condition or problem. Order sets can improve the user experience and help reduce practice variation and medication error. These instructions detail specifically how to add the induction and maintenance dosing of Omvoh to existing order sets.

Treatment selection is always a decision made by the health care provider, and order sets may be overridden to reflect a provider's treatment decision. An EHR newsletter or other communication medium may be considered to notify end users of the availability and contents of the updated order sets.

Dosing and administration

The IV formulation delivers the induction dose to increase the likelihood of reducing symptoms and disease severity, followed by a lower self-administered SC dose to maintain the response.[1]

Omvoh Infusions

INDUCTION VIA IV INFUSION

300 mg IV[a] at Weeks 0, 4, and 8

Week 0

Week 4

Week 8

IV infusions with Omvoh are administered every 4 weeks for 3 doses before transitioning to maintenance dosing at Week 12.

Omvoh for IV infusion, is supplied as a single-dose vial, with a strength of 300 mg/15 mL (20 mg/mL), packed in a carton of 1.

Omvoh Maintenance Dosing Through SC Injection

MAINTENANCE VIA SC INJECTION

200 mg SC via 2 × 100 mg consecutive injections every 4 weeks starting at Week 12

Week 12 and every 4 weeks thereafter

SC injections every 4 weeks for maintenance are available in a prefilled pen.

Omvoh is intended for use under the guidance and supervision of an HCP. Patients may self-inject after training in proper technique.

Omvoh, for SC use, is supplied as a single-dose prefilled pen, with a strength of 100 mg/mL, packed in a carton of 2 (for a total dispensing quantity of 2 mL).

IV=intravenous; SC=subcutaneous

[a]Over at least 30 minutes.

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EPIC INSTRUCTIONS

Updating existing SmartSets requires minimal time but must be implemented at the system level. First, identify the SmartGroups with the moderately to severely active UC medications listed. Once a SmartGroup has been modified, it may be used in SmartSets.

Step 1 – Update the SmartGroup

1. Open the management console **Tools > Management Console** (use of the management console typically requires appropriate user rights and privileges)
2. Select **SmartGroups** from the **Decision Support** menu to launch a new window
3. **Select** the desired SmartGroup (OSQ record) to be modified (one or more moderately to severely active UC medication SmartGroups may be available). If there are no existing SmartGroup records, consider creating a new SmartGroup.* If desired, other SmartGroups may be updated:
   - For the Patient Education Resources SmartGroup, you may add desired links to the Omvoh patient education resources
   - For the General – Provider and Nursing Notes SmartGroup (naming conventions and selections of the appropriate SmartGroup may vary; review which SmartGroup may be most relevant based on system naming conventions and guidelines), you may add desired links to the Omvoh recommended evaluations and immunizations prior to treatment initiation. Alternatively, this information can be added to the Omvoh Order Composer settings (see step 8 below)
4. Click the **Create** tab
5. Update the **Name**, **ID**, **Contact Date**, and **Record Type** of the SmartGroup if needed. Click Accept once done
6. Click **Configuration** from the menu
7. Click **Add Item** and select the **Item Type** (example: Medications)
8. Select the Omvoh 300 mg intravenous infusion dosing option and complete the dosing details (300 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8). In the Admin Instruction section, add that the 300 mg dosing is the induction dosing. Continue to add the Omvoh maintenance dosing options to the Medications section (200 mg subcutaneous injection, given as 2 consecutive injections of 100 mg each in different injection sites)
   - **Induction dosing:** The recommended induction dose for adult patients with UC for Omvoh is 300 mg administered by intravenous infusion over at least 30 minutes at Week 0, Week 4, and Week 8. Omvoh for IV infusion, is supplied as a single-dose vial, with a strength of 300 mg/15 mL (20 mg/mL), packed in a carton of 1

     In the sig field, enter: Induction dosing 300 mg administered by IV infusion over at least 30 minutes at Week 0, Week 4, and Week 8.

     Please complete the sig field as desired (structured or free text). A structured sig field may be recommended. When the standard drop-down options to complete the sig field don't contain all details needed to complete the sig, consider adding the information above to represent full details. The text may be abbreviated as desired

     Adjust the Order Composer for 300 mg Omvoh to indicate that this is an induction dosing for Week 0, Week 4, and Week 8

     Additional Order Composer settings can be adjusted per customer preference (e.g., consider the Omvoh recommended evaluations and immunizations prior to treatment initiation [see section 2.1. in the Prescribing Information])

     Information regarding preparation and administration of Omvoh for intravenous infusion can be found in section 2.3 of the Omvoh Prescribing Information and in the Appendix on page 5

*If creating a new SmartGroup, the system should consider what other medications may also warrant inclusion.

EPIC INSTRUCTIONS (CONT'D)

8. (CONT'D)
   - **Maintenance dosing:** The recommended maintenance dose for adult patients with UC for Omvoh is 200 mg administered by subcutaneous injection (given as 2 consecutive injections of 100 mg each in different injection sites) at Week 12 and every 4 weeks thereafter. Omvoh, for SC use, is supplied as a single-dose prefilled pen, with a strength of 100 mg/mL, packed in a carton of 2 (for a total dispensing quantity of 2 mL)

     In the sig field, enter: The recommended maintenance dose for adult patients with UC for Omvoh is 200 mg administered by subcutaneous injection (given as two consecutive injections of 100 mg each, for a total dispensing quantity of 2 mL) at Week 12, and every 4 weeks thereafter.

     Please complete the sig field as desired (structured or free text). A structured sig field may be recommended. When the standard drop-down options to complete the sig field don't contain all details needed to complete the sig, consider adding the information above to represent full details. The text may be abbreviated as desired

     Adjust the Order Composer for 200 mg Omvoh to indicate that this is a maintenance dosing for Week 12 and every 4 weeks thereafter

     Additional Order Composer settings can be adjusted per customer preference (for example, there are recommended evaluations and immunizations prior to initiating treatment with Omvoh [see section 2.1. in the Prescribing Information])

     Information regarding preparation and administration of Omvoh for subcutaneous injection can be found in section 2.4 of the Omvoh Prescribing Information and in the Appendix on page 5
9. Select **General Info** and set the record name, display name, and other information as desired
10. Release after satisfactory testing has been completed

Step 2 – Update All Applicable SmartSets

1. Identify all SmartSets that would benefit from the modified SmartGroup using search terms such as "moderately to severely active ulcerative colitis" or "ulcerative colitis"
2. Update the desired SmartSets with the modified SmartGroup record created in Step 1
3. Release after satisfactory testing has been completed

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APPENDIX

Section 2.3 from the Omvoh Prescribing Information: Preparation and Administration of OMVOH for Intravenous Infusion

1. OMVOH for intravenous use is intended for administration by a healthcare provider using aseptic technique. Each vial is for single use only.
2. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be a clear to opalescent, colorless to slightly yellow to slightly brown solution, and free of visible particles. Do not use OMVOH if it is cloudy or there are visible particles.
3. Using an 18 to 21 gauge needle withdraw 15 mL of OMVOH solution from the vial and transfer to an infusion bag ranging in size from 50 mL to 250 mL of 0.9% Sodium Chloride Injection or 5% Dextrose Injection. Do not mix with other drugs. Do not dilute or infuse through the same intravenous line with solutions other than 0.9% Sodium Chloride or 5% Dextrose Injection.
4. Gently invert the infusion bag to mix the contents. Do not shake the prepared infusion bag.
5. Connect the intravenous administration set (infusion line) to the prepared infusion bag and prime the line.
6. Administer the infusion over at least 30 minutes.
7. At the end of the infusion, flush the line with 0.9% Sodium Chloride Injection or 5% Dextrose Injection.
   - Administer the flush at the same infusion rate as used for OMVOH administration.
   - The time required to flush OMVOH solution from the infusion line is in addition to the minimum 30-minute infusion time.

Storage of Diluted Solution

- Start the infusion immediately after preparation. If not used immediately, store the diluted infusion solution in the refrigerator at 2°C to 8°C (36°F to 46°F). Use the diluted infusion solution within 48 total hours, of which not more than 5 hours are permitted at non-refrigerated temperatures not to exceed 25°C (77°F), starting from the time of vial puncture.
- Keep drug product away from direct heat or light. Do not freeze the diluted solution in the prepared infusion bag.

Section 2.4 from the Omvoh Prescribing Information: Preparation and Administration of OMVOH for Subcutaneous Injection

- A full maintenance dose will require 2 prefilled pens.
- OMVOH is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject OMVOH after training in subcutaneous injection technique. Provide proper training to patients and/or caregivers on the subcutaneous injection technique of OMVOH according to the "Instructions for Use", included with the packaged product.
- Before injection, remove OMVOH prefilled pen from the refrigerator and leave at room temperature for 30 minutes. Do not shake the prefilled pens.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. The solution should be a clear to opalescent, colorless to slightly yellow to slightly brown solution, and free of visible particles. Do not use OMVOH if it is cloudy or there are visible particles.
- Sites for injection include the abdomen, thigh, and back of the upper arm. Instruct patients to inject in a different location every time. For example, if the first injection was in the abdomen, administer the second injection (to complete a full dose) in another area of the abdomen, or upper arm, or thigh.
- Do not inject into areas where the skin is tender, bruised, erythematous, or indurated.
- OMVOH does not contain preservatives; therefore, discard any unused product. Do not reuse.
- If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing every 4 weeks.

Please see Important Safety Information on page 7, and click for Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.

NOTES

- The Customers (i.e., physician, medical group, integrated delivery network) shall be solely responsible for implementation, testing, and monitoring of the instructions to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and set-up (customization) for each EHR system may vary. Lilly shall not be responsible for revising the implementation instructions it provides to any customer if the Customer modifies or changes its software, or the configuration of its EHR system, after such time as the implementation instructions have been initially provided by Lilly
- While Lilly tests its implementation instructions on multiple EHR systems, the instructions are not guaranteed to work for all available EHR systems and Lilly shall have no liability thereto
- The instructions have not been designed to and are not resources and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
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WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritus, were reported during induction. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

Infections

Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment. In clinical trials, subjects were excluded if they had evidence of active TB, a history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity

Drug-induced liver injury in conjunction with pruritus was reported in a clinical trial patient following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline. Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management. Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Avoid use of live vaccines in patients treated with Omvoh. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS

Most common adverse reactions (≥2%) associated with Omvoh treatment are upper respiratory tract infections and arthralgia during induction, and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during maintenance.

MR HCP ISI UC APP

Please click for Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the device.

Reference: Omvoh (mirikizumab-mrkz). Prescribing Information. Lilly USA, LLC.