Electronic Health Record (EHR) instructions to update order sets with **Mounjaro®** in the Epic® EHR system

Indication

Mounjaro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- Mounjaro has not been studied in patients with a history of pancreatitis.
- Mounjaro is not indicated for use in patients with type 1 diabetes mellitus.

Select Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

In both male and female rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Mounjaro causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.

Mounjaro is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Mounjaro and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Mounjaro.

Please see additional Important Safety Information contained on pages 7-8, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and click to access **Full Prescribing Information** and **Medication Guide.**

once weekly
mounjaro®
(tirzepatide) injection 0.5 mL
2.5 mg | 5 mg | 7.5 mg | 10 mg | 12.5 mg | 15 mg

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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 Mounjaro in the treatment of type 2 diabetes and should not be used for other conditions, treatments, or therapeutic areas.

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

A health system may choose to optimize existing EHR order sets with Mounjaro. Order sets consolidate notes, referrals, imaging studies, lab 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. These instructions detail specifically how to add the induction and maintenance dosing of Mounjaro to existing order sets.

The recommended starting dose for adult patients taking Mounjaro is 2.5 mg injected subcutaneously once weekly for 4 weeks. Titrate to 5 mg Mounjaro after 4 weeks. Additional dose escalation will be at the physician's discretion. The following instructions outline the optimization process of order sets to reflect this recommended dosing. Treatment selection is always a decision made by the health care provider, and order sets may be overridden to reflect this. An EHR newsletter or other communication medium may be considered to notify end users of the availability and contents of the updated order sets.

Start Mounjaro[1]:

- Initiate with the 2.5-mg dose (once weekly)*
- After 4 weeks on the 2.5-mg dose, increase to the 5-mg dose (once weekly)

If additional glycemic control is needed, you can continue to increase the dose by 2.5-mg increments after at least 4 weeks on the current dose. The maximum dose is 15 mg once weekly.

*The 2.5 mg dose is not intended for glycemic control.

START

Starting dose (for 4 weeks) | For at least 4 weeks

IF ADDICTIONAL GLYCEMIC CONTROL IS NEEDED

For at least 4 weeks | For at least 4 weeks | For at least 4 weeks | Maximum dose

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Updating existing SmartSets requires minimal time but must be implemented at the system level. First, identify the SmartGroups with the type 2 diabetes medications listed. Once a SmartGroup has been optimized, 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 type 2 diabetes 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 patient Education Resources SmartGroup, you may add desired links to the Mounjaro patient education resources
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 Mounjaro 2.5 mg dosing option and complete the dosing details (4 weeks, once-weekly subcutaneous injection dosing). In the Admin Instruction section, add that the 2.5 mg dosing is the induction dosing. Continue to add all Mounjaro maintenance dosing options to the Medications section (5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg)
   a. **Induction dosing:** The recommended starting dose for adult patients for Mounjaro is 2.5 mg Mounjaro, once-weekly subcutaneous injection for 4 weeks. In the free text-sig, enter: Induction dosing for 4 weeks. Titrate to 5 mg Mounjaro after 4 weeks. Adjust the ***Order Composer*** for 2.5 mg Mounjaro to indicate it is an induction dosing for 4 weeks. Additional ***Order Composer*** settings can be adjusted per health system preference
   b. **Maintenance dosing:** The lowest dose of Mounjaro intended for glycemic control is 5 mg weekly; if additional glycemic control is needed, the dose can be increased in 2.5-mg increments. In the free text-sig, enter: 5 mg Mounjaro for at least 4 weeks after completing starting dose of 2.5 mg Mounjaro. Adjust the ***Order Composer*** for 5 mg Mounjaro to indicate it is a maintenance dosing for 4 weeks, after successfully completing the induction dosing. Additional ***Order Composer*** settings can be adjusted per health system preference
9. Select ***General Info*** and set the record name, display name, and other information as desired
10. Release after satisfactory testing has been completed

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Step 2 Update All Applicable SmartSets

1. Identify all SmartSets that would benefit from the optimized SmartGroup using search terms such as "type 2 diabetes"
2. Update the desired SmartSets with the optimized SmartGroup record created in Step 1
3. Release after satisfactory testing has been completed

If desired, other SmartGroups may be updated:

- For patient Education Resources SmartGroup, you may add desired links to the Mounjaro patient education resources

Select Important Safety Information

Pancreatitis: Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists. Pancreatitis has been reported in Mounjaro clinical trials. Mounjaro has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Mounjaro. Observe patients for signs and symptoms including persistent severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by vomiting. If pancreatitis is suspected, discontinue Mounjaro and initiate appropriate management.

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- The Customers (ie, 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 change 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
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment, treatment and referral, the decision and action should ultimately be decided by a provider in consultation with the patient, after a review of the patient's records to determine eligibility, and Lilly shall have no liability thereto
- The instructions have not been designed to and are not tools and/or solutions for meeting Advancing Care Information and/or any other quality/accreditation requirement
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Hypoglycemia with Concomitant Use of Insulin Secretagogues or Insulin: Concomitant use with an insulin secretagogue (e.g., sulfonylurea) or insulin may increase the risk of hypoglycemia, including severe hypoglycemia. The risk of hypoglycemia may be lowered by reducing the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin. Inform patients using these concomitant medications of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

Hypersensitivity Reactions: Serious hypersensitivity reactions (e.g., anaphylaxis, angioedema), have been reported in patients treated with Mounjaro. If hypersensitivity reactions occur, discontinue use of Mounjaro; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous serious hypersensitivity to Mounjaro. Use caution in patients with a history of angioedema or anaphylaxis with a GLP-1 receptor agonist because it is unknown if such patients will be predisposed to these reactions with Mounjaro.

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Acute Kidney Injury: Mounjaro has been associated with gastrointestinal adverse reactions, which include nausea, vomiting, and diarrhea. These events may lead to dehydration, which if severe could cause acute kidney injury. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, sometimes requiring hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Mounjaro in patients with renal impairment reporting severe adverse gastrointestinal reactions.

Severe Gastrointestinal Disease: Use of Mounjaro has been associated with gastrointestinal adverse reactions, sometimes severe. Mounjaro has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Diabetic Retinopathy Complications in Patients with a History of Diabetic Retinopathy: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Mounjaro has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

Acute Gallbladder Disease: In clinical trials, acute gallbladder disease was reported by 0.6% of Mounjaro-treated patients and 0% of placebo-treated patients. If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

The most common adverse reactions reported in ≥5% of Mounjaro-treated patients in placebo-controlled trials were nausea, diarrhea, decreased appetite, vomiting, constipation, dyspepsia, and abdominal pain.

Drug Interactions: When initiating Mounjaro, consider reducing the dose of concomitantly administered insulin secretagogues (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia. Mounjaro delays gastric emptying, and thereby has the potential to impact the absorption of concomitantly administered oral medications, so caution should be exercised.

Pregnancy: Limited data on Mounjaro use in pregnant women are available to inform on drug-associated risk for major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide. Use only if potential benefit justifies the potential risk to the fetus.

Lactation: There are no data on the presence of tirzepatide in human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Mounjaro and any potential adverse effects on the breastfed infant from Mounjaro or from the underlying maternal condition.

Females of Reproductive Potential: Advise females using oral hormonal contraceptives to switch to a non-oral contraceptive method, or add a barrier method of contraception for 4 weeks after initiation and for 4 weeks after each dose escalation.

Pediatric Use: Safety and effectiveness of Mounjaro have not been established and use is not recommended in patients less than 18 years of age.

Please see accompanying Prescribing Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

TR HCP ISI 23MAY2023

Reference: 1. Mounjaro. Prescribing Information. Lilly USA, LLC.