



# Mounjaro

## Prior Authorization

### Process Tips

#### Indication and Select Safety Information

**Indication:** Mounjaro (tirzepatide) is indicated as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus.

**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.

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# PA Submission Process Tips When Prescribing Mounjaro for Type 2 Diabetes

Sometimes the patient's health plan may require a prior authorization (PA) before covering Mounjaro.

It is important to provide the correct information to ensure there are no delays in treatment. While payer and health plan requirements can vary, these PA submission forms often include ICD-10-CM diagnosis codes and requests for information regarding the patient's treatment and medical history.

## Example ICD-10-CM diagnosis codes<sup>1</sup>

Example Diagnosis Codes for Type 2 Diabetes (required to include at least 1)	
<b>E11.65</b>	Type 2 diabetes mellitus with hyperglycemia
<b>E11.8</b>	Type 2 diabetes mellitus with unspecified complications
<b>E11.9</b>	Type 2 diabetes mellitus without complications



**These diagnosis codes are for informational use only and are not intended to guarantee reimbursement. It is the provider's responsibility to review the payer's guidance to ensure appropriate codes are selected based on the patient's medical record.**

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## Examples of additional information that may be seen on PA forms

Patient treatment history and medical history help document the need to be treated with Mounjaro for type 2 diabetes. It is important to review individual payer guidance prior to submitting and consult with the payer for other required documentation.

Details of Current and Previous Therapies	Supporting Documentation From Patient Chart
<ul style="list-style-type: none"> <li>• Inadequate treatment response, intolerance, or contraindication to <b>metformin</b></li> <li>• Inadequate response or contraindication to <b>at least 1 of the following oral antihyperglycemic agents:</b> <ul style="list-style-type: none"> <li>– Sulfonylureas</li> <li>– Thiazolidinedione</li> <li>– DPP-4 inhibitors</li> <li>– SGLT-2 inhibitors</li> <li>– Combination of the above therapies</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Duration and dates of treatment</li> <li>• Documented contraindication(s) (if applicable)</li> <li>• Documented adverse events of treatment intolerance</li> </ul>
Details of Patient's Medical History	Supporting Documentation From Patient Chart
<ul style="list-style-type: none"> <li>• Recent A1C level(s)</li> <li>• Documentation of additional comorbidities</li> <li>• Presence of family or personal history of certain conditions</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical notes for detailed diagnosis</li> <li>• Additional laboratory results</li> </ul>

DPP-4=dipeptidyl peptidase-4; SGLT-2=sodium-glucose co-transporter 2.

Reference: 1. 2019 International Classification of Diseases, 10th Revision CM Codes, Centers for Medicare & Medicaid Services.

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# EMPOWER YOUR PATIENTS WITH INFORMATION IF YOU USE COVERMYMEDS<sup>®</sup> FOR PAs

Many patients appreciate insights into their healthcare journey, including the status of their prior authorizations. CoverMyMeds now offers providers the ability to notify patients of their PA outcome in real time via text or email.

## No more back-and-forth phone calls. Here's how it works:

- 1** Start a PA request at [covermymeds.com](https://covermymeds.com) or open a pharmacy-initiated request.
- 2** With patient consent, **select option** on PA page **to inform patient** of PA outcome.
- 3** Enter the **patient contact** information.
- 4** **Submit the PA** to the plan; once plan determination is received, the patient and provider's office are notified.

### HAVE QUESTIONS FOR COVERMYMEDS?

Live Chat: [covermymeds.com](https://covermymeds.com) | Phone **1-866-452-5017**  
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## Important Safety Information for Mounjaro<sup>®</sup> (tirzepatide)

### **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.

**Contraindications:** Mounjaro is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Mounjaro. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with Mounjaro.

**Risk of Thyroid C-cell Tumors:** 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. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

**Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, or Mounjaro. Observe patients for signs and symptoms, including persistent or severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by nausea or vomiting. If pancreatitis is suspected, discontinue Mounjaro and initiate appropriate management.

**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 and 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 tirzepatide or any of the excipients in 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.

**Acute Kidney Injury Due to Volume Depletion:** There have been postmarketing reports of acute kidney injury, in some cases requiring hemodialysis, in patients treated with GLP-1 receptor agonists, or Mounjaro. The majority of reported events occurred in patients who experienced gastrointestinal adverse reactions leading to dehydration such as nausea, vomiting, or diarrhea. Monitor renal function in patients reporting adverse reactions to Mounjaro that could lead to volume depletion, especially during dosage initiation and escalation of Mounjaro.

**Severe Gastrointestinal Adverse Reactions:** Use of Mounjaro has been associated with gastrointestinal adverse reactions, sometimes severe. In the pool of placebo-controlled trials in adults, severe gastrointestinal adverse reactions occurred more frequently among patients receiving Mounjaro (5 mg 1.3%, 10 mg 0.4%, 15 mg 1.2%) than placebo (0.9%). Severe gastrointestinal adverse reactions have also been reported postmarketing with GLP-1 receptor agonists. Mounjaro is not recommended in patients with severe gastroparesis.

**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 placebo-controlled clinical trials in adults, 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.

**Pulmonary Aspiration During General Anesthesia or Deep Sedation:** Mounjaro delays gastric emptying. There have been rare postmarketing reports of pulmonary aspiration in patients receiving GLP-1 receptor agonists undergoing elective surgeries or procedures requiring general anesthesia or deep sedation who had residual gastric contents despite reported adherence to preoperative fasting recommendations. Instruct patients to inform healthcare providers prior to any planned surgeries or procedures if they are taking Mounjaro.

**Adverse Reactions in Adults:** 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:** In a single-dose clinical lactation study, the concentration of tirzepatide in breast milk was found to be either undetectable or low compared to the maternal administered dose. There are no available data on the effects of tirzepatide on the breastfed infant or 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:** Adverse reactions reported in pediatric patients 10 years of age and older treated with Mounjaro were similar to those reported in adults with the exception of a higher incidence of vomiting, abdominal pain, and hypoglycemia. The safety and effectiveness of Mounjaro have not been established and use is not recommended in patients less than 10 years of age.

**Dosage Forms and Strengths:** Mounjaro is available as a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL subcutaneous injection in a prefilled single-dose pen.

Please click to access [Prescribing Information](#), including **Boxed Warning about possible thyroid tumors, including thyroid cancer, and Medication Guide**.

Please see [Instructions for Use](#) included with the pen.

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