once weekly

mounjaro®

(tirzepatide) injection 0.5 mL

2.5 mg | 5 mg | 7.5 mg | 10 mg | 12.5 mg | 15 mg

Mounjaro Prior Authorization Process Tips

Indication and Select Safety Information

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.

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 Important Safety Information on last page and click to access the full Prescribing Information and Medication Guide, including Boxed Warning.

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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[1]

Example Diagnosis Codes for Type 2 Diabetes (required to include at least 1)	
E11.65	Type 2 diabetes mellitus with hyperglycemia
E11.8	Type 2 diabetes mellitus with unspecified complications
E11.9	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

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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
• Inadequate treatment response, intolerance, or contraindication to **metformin** • Inadequate response or contraindication to **at least 1 of the following oral antihyperglycemic agents:** – Sulfonylureas – Thiazolidinedione – DPP-4 inhibitors – SGLT-2 inhibitors – Combination of the above therapies	• Duration and dates of treatment • Documented contraindication(s) (if applicable) • Documented adverse events of treatment intolerance
Details of Patient's Medical History	**Supporting Documentation From Patient Chart**
• Recent A1C level(s) • Documentation of additional comorbidities • Presence of family or personal history of certain conditions	• Clinical notes for detailed diagnosis • Additional laboratory results

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

CoverMyMeds can offer support services and online submission capabilities to help you quickly submit PAs. For assistance in the PA process, visit **CoverMyMeds.com**.

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

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Important Safety Information

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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.

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.

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.

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.

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