COVERAGE AUTHORIZATION REQUESTS AND APPEALS GUIDE

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

Composing A Letter Of Medical Necessity

The following information is presented as a guide for informational purposes only and is not intended to provide reimbursement or legal advice. Laws, regulations, and policies concerning reimbursement are complex and are updated frequently. Eli Lilly and Company, with the use of the information contained herein, does not guarantee success in obtaining insurance payments. While we have made an effort to be current as of the issue date of this document, the information may not be as current or comprehensive when you view it. Providers are encouraged to contact third-party payers for specific information on their coverage policies. For more information, please call Mounjaro Answers Center at 1-800-LillyRX 1-800-545-5979.

Many health plans require a Letter of Medical Necessity when appealing a coverage determination or prior authorization for a patient's plan.* The purpose of a Letter of Medical Necessity is to explain the prescribing healthcare provider's (HCP's) rationale and clinical decision-making when choosing a treatment.

This resource, **Composing a Letter of Medical Necessity**, provides information on the process of drafting a Letter of Medical Necessity. Included on the following page is a list of considerations that can be followed when creating a Letter of Medical Necessity. In addition, 2 sample letters are attached to this document and include information that plans often require. Note that some plans have specific Coverage Authorization Forms that must be used to document a Letter of Medical Necessity.

Follow the patient's plan requirements when requesting Mounjaro; otherwise, treatment may be delayed.

*For Medicare beneficiaries, specific requirements must be met for the HCP to be considered a legal representative of the patient in an appeal. For additional information, please visit https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf.

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.

SELECT IMPORTANT SAFETY INFORMATION

WARNING: RISK OF THYROID C-CELL TUMORS

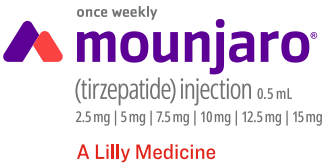
In both male and female rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Mounjaro causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced 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.

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.

Please see Important Safety Information including Boxed Warning about possible thyroid tumors, along with thyroid cancer, on pages 5-6 and click for Prescribing Information and Medication Guide for Mounjaro.

Lilly
A MEDICINE COMPANY



Composing A Letter Of Medical Necessity

Letter of Medical Necessity Considerations

1. If required and following patient's consent, include the patient's full name, date of birth, plan identification number, and case identification number if a decision has already been rendered.
2. Add the prescribing HCP's National Provider Identifier (NPI) number and specialty.
3. Provide a copy of the patient's records with the following details: patient's history (including relevant clinical and progress notes), diagnosis with specific International Classification of Diseases (ICD) code, and condition.
4. Note the severity of the patient's condition.
5. Document prior treatments, the duration of each, and the rationale for discontinuation. It may be beneficial to include Common Procedural Terminology (CPT)-4 and/or J-codes to define prior services/treatments, so that the health plan can conduct research and make a timely determination.
6. Attach clinical documentation that supports your recommendation; this information may be found in the Mounjaro Prescribing Information and/or clinical peer-reviewed literature. Disclaimer: may not be all-encompassing.

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

Sample Letter of Medical Necessity

HCPs can follow this format **FOR PATIENTS WHO ARE NOT CURRENTLY RECEIVING TREATMENT** with Mounjaro (tirzepatide).

[Date]
[Medical director]
[Name of health plan]
[Mailing address]

Re: **[Patient's name]**
[Plan identification number]
[Date of birth]
[Case identification number]

To Whom It May Concern:

We have reviewed and recognize your guidelines for the responsible management of medications within this class. We are requesting that you reassess your recent denial of Mounjaro coverage. We understand that the reason for your denial is **[copy reason verbatim from the plan's denial letter]**. However, we believe that Mounjaro **[dose, frequency]** is the appropriate treatment for the patient. In support of our recommendation for Mounjaro treatment, we have provided an overview of the patient's relevant clinical history below.

Patient's history, diagnosis, condition, and symptoms:

Patient must have a diagnosis for an indication of Mounjaro. Mounjaro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

[Please include relevant patient's medical records and supporting documentation in this area.]

Past Treatment(s)	Start/Stop Dates	Reason(s) for Discontinuation
[Drug name, strength, dosage]		
[Drug name, strength, dosage]		

[Please detail all that apply and add additional lines as needed.]

[Provide clinical rationale for this treatment; this information may be found in the Mounjaro Prescribing Information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Mounjaro.]

Please feel free to contact me, **[HCP's name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]
Encl: Medical records
Clinical trial information

Please see Important Safety Information including Boxed Warning about possible thyroid tumors, along with thyroid cancer, on pages 5-6 and click for Prescribing Information and Medication Guide for Mounjaro.

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

Sample Letter of Medical Necessity

HCPs can follow this format **FOR PATIENTS WHO HAVE BEEN TREATED** with Mounjaro (tirzepatide) and have had treatment interruption.

[Date]
[Medical director]
[Name of health plan]
[Mailing address]

[Patient's name]
[Plan identification number]
[Date of birth]
[Case identification number]

To Whom It May Concern:

I am writing to provide additional information to support my claim for **[patient's name]**'s treatment of type 2 diabetes **[ICD code]** with Mounjaro. In brief, continued treatment with Mounjaro **[dose, frequency]**, is medically appropriate and necessary for this patient. This letter includes the patient's medical history, previous treatments, and disease severity **[if applicable]** that support my recommendation for treatment with Mounjaro.

Patient's history, diagnosis, condition, and symptoms:

Patient must have a diagnosis for an indication of Mounjaro. Mounjaro is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

[Please include relevant patient's medical records and supporting documentation in this area.]

Past Treatment(s)	Start/Stop Dates	Reason(s) for Discontinuation
[Drug name, strength, dosage]		
[Drug name, strength, dosage]		

[Please detail all that apply and add additional lines as needed.]

[Provide clinical rationale for this treatment; this information may be found in the Mounjaro Prescribing Information and/or clinical peer-reviewed literature.]

[Insert your recommendation summary here, including your professional opinion of the patient's likely prognosis or disease progression without treatment with Mounjaro.]

Please feel free to contact me, **[HCP's name]**, at **[office phone number]** for any additional information you may require. We look forward to receiving your timely response and approval of this claim.

Sincerely,

[Physician's name and signature]
[Physician's medical specialty]
[Physician's NPI #]
[Physician's practice name]
[Phone #]
[Fax #]

[Patient's name and signature]
Encl: Medical records
Clinical trial information

Please see Important Safety Information including Boxed Warning about possible thyroid tumors, along with thyroid cancer, on pages 5-6 and click for Prescribing Information and Medication Guide for Mounjaro.

Important Safety Information for Mounjaro® (tirzepatide)

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

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.

 Please click for Prescribing Information and Medication Guide for Mounjaro.

Important Safety Information for Mounjaro® (tirzepatide) (cont.)

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

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.

TR HCP ISI 19DEC2025

Lilly
A MEDICINE COMPANY