Prior Authorization and Pharmacy Information Guide

Help your patients get started on Zepbound™ (tirzepatide) injection

Here's what to do:

Prescribe Zepbound › **Submit Prior Authorization (PA)** › **Explore Savings Eligibility*** › **Provide Start Information**

*For eligible and commercially insured patients on Zepbound. **Government beneficiaries excluded, terms and conditions apply.**

Requirements may vary by plan. In this guide are common types of information that may be requested.

Indication

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

Select Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound 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.

Zepbound 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 Zepbound 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 Zepbound.

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

Lilly

once weekly zepbound™ (tirzepatide) injection 0.5 mL

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

Help your patients get started on Zepbound

- Does your patient have coverage for Zepbound? If coverage status is unknown, advise patients to check with their pharmacy insurance provider to confirm that Zepbound is covered
- Formulary access alone may not guarantee patient coverage. A patient's employer may also need to opt in to coverage of Zepbound even if Zepbound is on formulary
- Patients enrolled in Medicare likely do not have coverage for anti-obesity medications

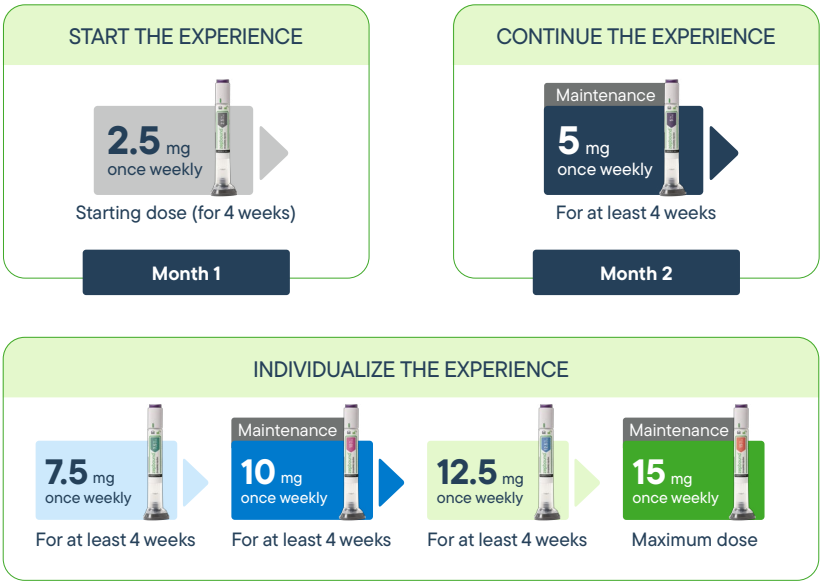
Prescribe Zepbound[1]

STARTING AND CONTINUING ZEPBOUND

A once-weekly, subcutaneous injection[1]

Recommended maintenance dosages are 5 mg, 10 mg, or 15 mg[1]:

- Initiate with the 2.5-mg dose
- After 4 weeks, increase to the 5-mg dose
- 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
- Consider treatment response and tolerability when selecting maintenance dosage. If not tolerated, consider a lower maintenance dosage



For adults with obesity (BMI of ≥30 kg/m^2) or with overweight (BMI of ≥27 kg/m^2) with at least 1 weight-related comorbidity.[1]
The 2.5-mg dosage is for treatment initiation and is not intended for chronic weight management.[1]

WRITING ZEPBOUND

℞ 2.5-mg dose

Zepbound
2.5 mg/0.5 mL
Inject 1 pen (0.5 mL) SC once weekly

Dispense 4 pens for a 28-day supply (2 mL)

℞ 5-mg dose

Zepbound
5 mg/0.5 mL
Inject 1 pen (0.5 mL) SC once weekly

Dispense 4 pens for a 28-day supply (2 mL)

BMI=body mass index; SC=subcutaneous.

Select important safety information

Zepbound 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 Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.

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

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

Submit Prior Authorization (PA)

You will likely need to submit a PA request before your patient's insurance will cover Zepbound. It is important to accurately provide detailed information in the PA request to help your patients access Zepbound. You may contact a patient's pharmacy benefit manager (PBM) to better understand specific PA requirements, step therapy requirements, duration of approval, and other relevant information. Relevant information that an insurer may require for consideration of PA approval can be found on pages 3-7.

PRODUCT INFORMATION[1]

MEDICATION NAME

Zepbound™ (tirzepatide)

Indication

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

STRENGTHS

Available dosing strengths	NDC
2.5 mg/0.5 mL in a single-dose pen	0002-2506-80
5 mg/0.5 mL in a single-dose pen	0002-2495-80
7.5 mg/0.5 mL in a single-dose pen	0002-2484-80
10 mg/0.5 mL in a single-dose pen	0002-2471-80
12.5 mg/0.5 mL in a single-dose pen	0002-2460-80
15 mg/0.5 mL in a single-dose pen	0002-2457-80

Recommended maintenance dosages are 5 mg, 10 mg, or 15 mg[1]:

- Initiate with the 2.5-mg dose
- After 4 weeks, increase to the 5-mg dose
- 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
- Consider treatment response and tolerability when selecting maintenance dosage. If not tolerated, consider a lower maintenance dosage

For adult patients with obesity (BMI of ≥30 kg/m^2) or with overweight (BMI of ≥27 kg/m^2) with at least 1 weight-related comorbidity.[1]
The 2.5-mg dosage is for treatment initiation and is not intended for chronic weight management.[1]
NDC=National Drug Code.

Select Important Safety Information

Risk of Thyroid C-cell Tumors: Counsel patients regarding the potential risk for MTC with the use of Zepbound 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 Zepbound. 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.

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

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Submit PA (continued)

CLINICAL INFORMATION

DIAGNOSIS

HCPs should ensure the patient has documentation of an appropriate diagnosis and any weight-related comorbidities **(see ICD-10 codes on pages 5-7)**.

PRIOR ANTI-OBESITY OR WEIGHT LOSS MEDICATIONS

Examples include Alli® (orlistat), Contrave® (naltrexone/bupropion), Qsymia® (phentermine/topiramate), Saxenda® (liraglutide), Xenical® (orlistat), Wegovy® (semaglutide).

LIFESTYLE MODIFICATION

Consider including documentation of any current efforts the patient is making to lose weight and any prior attempts in the past 3, 6, or 12 months. Include specifics on any counseling, dietary, or exercise programs the patient has previously attempted or is currently following.

BMI

Calculation: weight (kg) / height $(m)^2$

PA criteria vary by payer. Completing accurate, detailed, and thorough information will help ensure payers receive everything they need in consideration of the PA approval or denial and that the PA is not denied solely due to insufficient information

ICD-10=International Classification of Diseases (10th revision).

Select Important Safety Information

Severe Gastrointestinal Disease: Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute Kidney Injury: Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

Acute Gallbladder Disease: Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1.0% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

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Submit PA (continued)

ICD-10 CODES[2]

Below are commonly identified ICD-10 codes related to Zepbound. Some less commonly used codes may be missing. For additional codes, please refer to a coding resource.*

COMMONLY REPORTED CODES

Code	Code description
E66.0	Obesity due to excess calories
- E66.01	– Morbid (severe) obesity due to excess calories
- E66.09	– Other obesity due to excess calories

OTHER OBESITY-RELATED CODES

Code	Code description
E66.1	Drug-induced obesity
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E66.3	Overweight
E66.8	Other obesity
E66.9	Obesity, unspecified (can be used once for initial visit only)

*The ICD-10-CM code list is not all-inclusive. Appropriate codes vary by patient, payer, and setting for care. Correct coding is the responsibility of the provider submitting the claim. Eli Lilly and Company does not make any representation or guarantee for reimbursement or coverage.

ICD-10-CM=International Classification of Diseases (10th revision) Clinical Modification.

Indication

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m^2 or greater (obesity) or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

Select Important Safety Information

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 tirzepatide. In clinical trials of tirzepatide for a different indication, 14 events of acute pancreatitis were confirmed by adjudication in 13 tirzepatide-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). In Zepbound clinical trials, 0.2% of Zepbound-treated patients had acute pancreatitis confirmed by adjudication (0.14 patients per 100 years of exposure) versus 0.2% of placebo-treated patients (0.15 patients per 100 years of exposure). Zepbound 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 Zepbound. Observe patients for signs and symptoms of pancreatitis, including persistent severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by vomiting. If pancreatitis is suspected, discontinue Zepbound and initiate appropriate management. If the diagnosis of pancreatitis is confirmed, Zepbound should not be restarted.

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Submit PA (continued)

ICD-10 CODES[2]

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BMI REPORTING FOR ADULT BMI ≥27 kg/m²

Code	Code description	Code	Code description
Z68.27	BMI 27.0-27.9	Z68.36	BMI 36.0-36.9
Z68.28	BMI 28.0-28.9	Z68.37	BMI 37.0-37.9
Z68.29	BMI 29.0-29.9	Z68.38	BMI 38.0-38.9
Z68.30	BMI 30.0-30.9	Z68.39	BMI 39.0-39.9
Z68.31	BMI 31.0-31.9	Z68.41	BMI 40.0-44.9
Z68.32	BMI 32.0-32.9	Z68.42	BMI 45.0-49.9
Z68.33	BMI 33.0-33.9	Z68.43	BMI 50.0-59.9
Z68.34	BMI 34.0-34.9	Z68.44	BMI 60.0-69.9
Z68.35	BMI 35.0-35.9	Z68.45	BMI ≥70

*The ICD-10-CM code list is not all-inclusive. Appropriate codes vary by patient, payer, and setting for care. Correct coding is the responsibility of the provider submitting the claim. Eli Lilly and Company does not make any representation or guarantee for reimbursement or coverage.

Indication

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- 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

Limitations of Use:

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- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

Select Important Safety Information

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) in patients treated with tirzepatide. In Zepbound clinical trials, 0.1% of Zepbound treated patients had severe hypersensitivity reactions compared to no placebo treated patients. If hypersensitivity reactions occur, advise patients to promptly seek medical attention and discontinue use of Zepbound. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Zepbound. 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 Zepbound.

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Submit PA (continued)

ICD-10 CODES[2]

Below are commonly identified ICD-10 codes related to Zepbound. Some less commonly used codes may be missing. For additional codes, please refer to a coding resource.*

CODES FOR SELECT WEIGHT-RELATED COMORBIDITIES

Zepbound is not indicated for treatment of these conditions.

Code	Code description
I10	Essential (primary) hypertension
E78.5	Hyperlipidemia, unspecified
E11	Type 2 diabetes mellitus
G47.33	Obstructive sleep apnea (adult) (pediatric)
I51.9	Heart disease, unspecified

*The ICD-10-CM code list is not all-inclusive. Appropriate codes vary by patient, payer, and setting for care. Correct coding is the responsibility of the provider submitting the claim. Eli Lilly and Company does not make any representation or guarantee for reimbursement or coverage.

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- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

Select Important Safety Information

Hypoglycemia: Zepbound lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m^2, hypoglycemia (plasma glucose <54mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo treated patients. In this trial, patients taking Zepbound in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Zepbound-treated patients not taking a sulfonylurea (2.1%). Hypoglycemia has also been associated with ZEPBOUND and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. There is also increased risk of hypoglycemia in patients treated with tirzepatide in combination with insulin. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Zepbound and during Zepbound treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

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

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

Explore Savings Eligibility

For eligible and commercially insured patients on Zepbound. Government beneficiaries excluded, terms and conditions apply.

Pay as little as

$25 **for a 1-month, 2-month, or 3-month prescription if eligible and commercially insured with coverage for Zepbound**

Governmental beneficiaries excluded, terms and conditions apply.
One month is defined as 28 days and 4 pens. Two months is defined as 56 days and 8 pens. Three months is defined as 84 days and up to 12 pens.

Prior to receiving specific ID and RxBIN numbers, patients will need to enroll by visiting the Zepbound™ Savings Card website or using the QR code below.

For eligible and commercially insured patients on Zepbound. Government beneficiaries excluded, terms and conditions apply.

HAVE PATIENTS SCAN THE CODE FOR
ZEPBOUND SAVINGS INFORMATION

TERMS AND CONDITIONS

Subject to Lilly USA, LLC's (Lilly's) right to terminate, rescind, revoke or amend the Zepbound Savings Card Program ("Card" or "Program") eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, the Card expires and savings end on 12/31/2024. **Card savings are not available to patients without commercial drug insurance or who are enrolled in any state, federal, or government funded healthcare program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medicare Advantage, Medigap, DoD, VA, TRICARE®/CHAMPUS, or any state prescription drug assistance program.**

MONTHLY AND ANNUAL MAXIMUM SAVINGS: For patients with commercial drug insurance coverage for Zepbound: You must have commercial drug insurance that covers Zepbound™ (tirzepatide) and a prescription consistent with FDA-approved product labeling to pay as little as $25 for a 1-month, 2-month, or 3-month prescription fill of Zepbound. Month is defined as 28-days and up to 4 pens. Card savings are subject to a maximum monthly savings of up to $150 per 1-month prescription, $300 per 2-month prescription, or $450 per 3-month prescription fill and separate maximum annual savings of up to $1,800 per calendar year. Subject to Lilly USA, LLC's ("Lilly") right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2024.

For patients with commercial drug insurance who do not have coverage for Zepbound: You must have commercial drug insurance that does not cover Zepbound and a prescription consistent with FDA-approved product labeling to obtain savings of up to $563 off your 1-month prescription fill of Zepbound. Month is defined as 28-days and up to 4 pens. Card savings are subject to a maximum monthly savings of up to $563 and a separate maximum annual savings of up to $7,319 per calendar year. Subject to Lilly's right to terminate, rescind, revoke, or amend Card eligibility criteria and/or Card terms and conditions which may occur at Lilly's sole discretion, without notice, and for any reason, Card expires and savings end on 12/31/2024.

ADDITIONAL TERMS AND CONDITIONS:

You are responsible for any applicable taxes, fees and any amount that exceeds the monthly or annual maximum benefits. Card may be used for a maximum of up to 13 prescription fills per calendar year. Savings card activation is required. Participation in the Program requires a valid patient HIPAA authorization. This Card may be terminated, rescinded, revoked, or amended by Lilly at any time without notice and for any reason. Subject to additional terms and conditions. Eligibility criteria and terms and conditions for the Zepbound Savings Card Program may change from time to time at Lilly's sole discretion and for any reason; the most current version can be found at https://zepbound.lilly.com/coverage-savings. Card benefits void where prohibited by law.

Select Important Safety Information

Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide 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.

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

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

TO THE PHARMACIST

- This Card must be accompanied by a valid prescription for Zepbound and can only be used by one Patient. By accepting this offer, you certify that you understand and agree to comply with the offer terms set forth herein.
- If you are required to do so under the terms of your third-party payer contracts or as otherwise required by law, you should notify the affected third-party payer of your redemption of this offer.
- This offer is valid for commercially insured Patients only. **Offer is not valid for Patients who are eligible to have their prescriptions reimbursed in whole or part by any governmental program.**
- Please return Card to Patient after claim is processed.
- Transmit claim online to RxBIN 018844. Processor requires valid Prescriber ID #, PCN, Patient Name, and DOB for claim adjudication.
- Card expires and savings end on 12/31/2024.
- For Insured/Covered Patients – Submit the co-pay authorized by the Patient's primary insurance as a secondary claim to Eversana using BIN 018844 and using the Coordination of Benefits fields with Coverage Code type 08. This will reduce the eligible Patient's out-of-pocket costs to as little as $25, subject to a maximum monthly savings of $150 and a separate maximum annual savings of $1,800 for the Program. Card may be used for a maximum of up to 13 prescription fills per calendar year.
- For Insured/Not Covered Patients – If Zepbound is Not Covered by the Patient's insurance, continue to process the Card along with the Patient's insurance card using the Coordination of Benefits fields with Coverage Code type 03. This will reduce the eligible Patient's out-of-pocket costs by up to $563 off their monthly fill for 4 pens of Zepbound, subject to a maximum monthly savings of up to $563 and a separate maximum annual savings of up to $7,319. Card may be used for a maximum of up to 13 prescription fills per calendar year.
- Pharmacy must submit claim within 90 days from date of service to be reimbursed.
- Pharmacists with questions, please call the Pharmacy Benefit Manager 1-855-282-4888.

Eligible patients can pay as little as $25 for a 1-month, 2-month, or 3-month prescription if commercially insured with coverage for Zepbound.
For eligible patients with commercial insurance without coverage, save up to $563 for a 1-month supply of Zepbound*

*One month is defined as 28 days and 4 pens. Two months is defined as 56 days and 8 pens. Three months is defined as 84 days and up to 12 pens.

Governmental beneficiaries excluded, terms and conditions apply.

Select Important Safety Information

Suicidal Behavior and Ideation: Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Zepbound for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Zepbound in patients who experience suicidal thoughts or behaviors. Avoid Zepbound in patients with a history of suicidal attempts or active suicidal ideation.

The most common adverse reactions, reported in ≥5% of patients treated with Zepbound are: nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, and gastroesophageal reflux disease.

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Provide Start Information

In adult patients with obesity (BMI ≥30 kg/m^2) or overweight (BMI ≥27 kg/m^2) with at least 1 weight-related comorbidity

HELPFUL TIPS[3]

REMIND patients that Zepbound is administered using a single-dose pen. There is no need to see or handle the needle[3]*

ADVISE patients to read the Instructions for Use[4]

ALLOW patients to practice the injection using the demonstration device

CONSIDER having patients administer the first dose in the office

DISCUSS SAFETY profile and that Zepbound may cause some side effects†

For example, patients may experience nausea, diarrhea, or vomiting.[1]

In order to mitigate these gastrointestinal side effects, they may find it helpful to[5-7]:

- Eat smaller meals—suggest that they split 3 daily meals into 4 or more smaller meals
- Stop eating when they feel full
- Avoid fatty foods
- Try eating bland foods

Encourage patients to continue to drink plenty of water and eat healthy meals to ensure they meet their needs for protein, micronutrients, fiber, and fluids

RECOMMEND that patients who are using oral hormonal contraceptives switch to a non-oral contraceptive method, or add a barrier method of contraception, for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation. Zepbound delays gastric emptying, so it may make oral contraceptives less effective.[1]

*If a dose is missed, instruct patients to administer Zepbound as soon as possible within 4 days after the missed dose. If more than 4 days have passed, skip the missed dose and administer the next dose on the regularly scheduled day.

†Side effects may vary and should be evaluated by the healthcare provider for appropriate management.

SHARE THE PATIENT INJECTION VIDEO

This video, available **here**, can help your patients learn about self-injecting Zepbound

Select Important Safety Information

Drug Interactions: Zepbound lowers blood glucose. When initiating Zepbound, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia. Zepbound delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Zepbound. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Zepbound.

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Important Safety Information

WARNING: RISK OF THYROID C-CELL TUMORS

In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound 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.

Zepbound 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 Zepbound 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 Zepbound.

Zepbound 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 Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.

Risk of Thyroid C-cell Tumors: Counsel patients regarding the potential risk for MTC with the use of Zepbound 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 Zepbound. 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.

Severe Gastrointestinal Disease: Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

Acute Kidney Injury: Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

Acute Gallbladder Disease: Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1.0% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

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 tirzepatide. In clinical trials of tirzepatide for a different indication, 14 events of acute pancreatitis were confirmed by adjudication in 13 tirzepatide-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). In Zepbound clinical trials, 0.2% of Zepbound-treated patients had acute pancreatitis confirmed by adjudication (0.14 patients per 100 years of exposure) versus 0.2% of placebo-treated patients (0.15 patients per 100 years of exposure). Zepbound 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 Zepbound. 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 Zepbound and initiate appropriate management. If the diagnosis of pancreatitis is confirmed, Zepbound should not be restarted.

Hypersensitivity Reactions: There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) in patients treated with tirzepatide. In Zepbound clinical trials, 0.1% of Zepbound-treated patients had severe hypersensitivity reactions compared to no placebo-treated patients. If hypersensitivity reactions occur, advise patients to promptly seek medical attention and discontinue use of Zepbound. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Zepbound. 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 Zepbound.

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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Important Safety Information (continued)

Hypoglycemia: Zepbound lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m^2, hypoglycemia (plasma glucose <54mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo-treated patients. In this trial, patients taking Zepbound in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Zepbound-treated patients not taking a sulfonylurea (2.1%). Hypoglycemia has also been associated with Zepbound and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. There is also increased risk of hypoglycemia in patients treated with tirzepatide in combination with insulin. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Zepbound and during Zepbound treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus: Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide 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.

Suicidal Behavior and Ideation: Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Zepbound for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Zepbound in patients who experience suicidal thoughts or behaviors. Avoid Zepbound in patients with a history of suicidal attempts or active suicidal ideation.

The most common adverse reactions, reported in ≥5% of patients treated with Zepbound are: nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, and gastroesophageal reflux disease.

Drug Interactions: Zepbound lowers blood glucose. When initiating Zepbound, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia. Zepbound delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Zepbound. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Zepbound.

Pregnancy: Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue Zepbound when a pregnancy is recognized. Available data with tirzepatide in pregnant patients are insufficient to evaluate for a drug-related risk of 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 during pregnancy. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Zepbound (tirzepatide) during pregnancy. Pregnant patients exposed to Zepbound and healthcare providers are encouraged to contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

Lactation: There are no data on the presence of tirzepatide or its metabolites in animal or 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 Zepbound and any potential adverse effects on the breastfed infant from Zepbound or from the underlying maternal condition.

Females and Males of Reproductive Potential: Use of Zepbound may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception, for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation.

Pediatric Use: The safety and effectiveness of Zepbound have not been established in pediatric patients less than 18 years of age.

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

Please see Instructions for Use included with the pen.

ZP HCP ISI 08NOV2023

References: 1. Zepbound. Prescribing Information. Lilly USA, LLC. **2.** CDC. ICD-10 tabular list of diseases and injuries. Accessed June 17, 2023. https://ftp.cdc.gov/pub/health_statistics/nchs/publications/ICD10CM/2022/icd10cm-tabular-2022-April-1.pdf **3.** Zepbound. Instructions for Use. Lilly USA, LLC. **4.** Zepbound. Medication Guide. Lilly USA, LLC. **5.** Maceira E, Lesar TS, Smith H. Medication related nausea and vomiting in palliative medicine. *Ann Palliat Med*. 2012;1(2):161-176. **6.** Kruger DF, Bode B, Spollett GR. Understanding GLP-1 analogs and enhancing patients success. *Diabetes Educ*. 2010;36(suppl 3):44S-72S. **7.** Reid TS. Practical use of glucagon-like peptide-1 receptor agonist therapy in primary care. *Clin Diabetes*. 2013;31(4):148-157.

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