Zepbound (tirzepatide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Initial: 32 weeks Continuation: 6 months

Medications	Quantity Limit
Zepbound (tirzepatide)	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Zepbound (tirzepatide) for adults may be approved if the following criteria are met:

I. Individual is 18 years of age or older and one of the following:
   A. Documentation* is provided that individual has a BMI of 30 kg/m^2 or greater (**documentation of BMI is required within 60 days of the request*); **OR**
   B. Documentation* is provided that individual has a BMI of greater than or equal to 27 kg/m^2 and at least one of the following weight-related comorbid conditions (**documentation of BMI is required within 60 days of the request*):
      1. Hypertension defined as treated hypertension or with systolic blood pressure (SBP) ≥130 mmHg or diastolic blood pressure ≥80 mmHg; **OR**
      2. Type II Diabetes Mellitus; **OR**
      3. Dyslipidemia defined as treated dyslipidemia or has low-density lipoprotein (LDL) ≥160 mg/dL (4.1 mmol/L) or triglycerides ≥150 mg/dL (1.7 mmol/L), or high-density lipoprotein (HDL) <40 mg/dL (1.0 mmol/L) for men or HDL <50 mg/dL (1.3 mmol/L) for women; **OR**
      4. Obstructive sleep apnea (as a result of having a BMI of 27 or greater); **OR**
      5. Cardiovascular disease (example includes ischemic cardiovascular disease, New York Heart Association (NYHA) Functional Class I-III heart failure);

AND

II. Individual has tried but was unsuccessful losing weight through a healthcare provider supervised comprehensive lifestyle program for at least 6 months (AHA/ACC/TOS 2013), prior to request for drug therapy, that included ALL the following:
   A. A calorie deficit of approximately 30% (i.e. 500 kcals relative to their estimated total energy expenditure) in calories per day has

been achieved by the individual for at least 6 months (AHA/ACC/TOS 2013); **AND**

B. An exercise goal of completing at least 150 minutes of exercise per week has been achieved for at least 6 months (AHA/ACC/TOS 2013); **OR**
    1. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk); **AND**

C. Individual was unable to achieve at least a 5% weight reduction with calorie deficit goals, exercise goals, and behavior therapy (AHA/ACC/TOS 2013); **AND**

III. Individual is currently maintained on a healthcare provider supervised lifestyle program that includes all of the following:
    A. An individualized calculated calorie deficit of approximately 30% (or 500 kcals relative to their estimated total energy expenditure) in calories per day (AHA/ACC/TOS 2013); **AND**
    B. Completing at least 150 minutes of exercise per week (AHA/ACC/TOS 2013); **OR**
        1. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk); **AND**

IV. Individual is NOT receiving two or more medications for weight loss at the same time; **AND**

V. Healthcare provider has consulted with individual regarding risks (including but not limited to adverse drug events), benefits, realistic expectations associated with the requested drug and the need for long-term follow-up and adherence to behavior modifications.

Continuation requests for Zepbound (tirzepatide) for adults may be approved if ALL of the following criteria are met:

I. Individual is 18 years of age or older and one of the following:
    A. Documentation is provided that at initiation of therapy, individual had a BMI of 30 kg/m^2 or greater; **OR**
    B. Documentation is provided that at initiation of therapy, individual had a BMI of greater than or equal to 27 kg/m^2 and at least one of the following weight-related comorbid conditions:
        1. Hypertension defined as treated hypertension or with systolic blood pressure (SBP) ≥130 mmHg or diastolic blood pressure ≥80 mmHg; **OR**
        2. Type II Diabetes Mellitus; **OR**
        3. Dyslipidemia defined as treated dyslipidemia or has low-density lipoprotein (LDL) ≥160 mg/dL (4.1 mmol/L) or triglycerides ≥150 mg/dL (1.7 mmol/L), or high-density lipoprotein (HDL) <40 mg/dL

(1.0 mmol/L) for men or HDL <50 mg/dL (1.3 mmol/L) for women; **OR**

4. Obstructive sleep apnea (as a result of having a BMI of 27 or greater); **OR**
5. Cardiovascular disease (example includes ischemic cardiovascular disease, New York Heart Association (NYHA) Functional Class I-III heart failure);

AND

II. Documentation^ is provided that individual has achieved/maintained an initial 5% weight loss while utilizing Zepbound (tirzepatide) therapy (^ *documentation showing the achieved/maintained 5% weight loss is required within 60 days of each continuation/subsequent request*); **AND**

III. Individual continues to be engaged in a comprehensive lifestyle program which includes:
   A. Individual is currently maintained on an individualized calculated calorie deficit of approximately 30% (or 500 kcals relative to their estimated total energy expenditure) in calories per day (AHA/ACC/TOS 2013); **AND**
   B. Individual is currently maintaining 150 minutes of exercise per week (AHA/ACC/TOS 2013); **OR**
      i. Exercise requirements cannot be met due to clinical limitations (including but not limited to cardiovascular conditions, physical limitations, fall risk); **AND**

IV. Individual is able to tolerate a maintenance dosage of either 5 mg, 10 mg, or 15 mg once weekly (Label); **AND**

V. Individual is NOT receiving two or more medications for weight loss at the same time; **AND**

VI. Healthcare provider has consulted with individual regarding risks (including but not limited to adverse drug events), benefits, realistic expectations associated with the requested drug and the need for long-term follow-up and adherence to behavior modifications.

Requests for Zepbound (tirzepatide) may not be approved for any of the following:

I. Individual has a BMI of less than 18.5 kg/m^2 (CDC 2024); **OR**

II. Individual is using for treatment of type 2 diabetes mellitus; **OR**

III. Individual is using in combination with another tirzepatide-containing product or any GLP-1 receptor agonist; **OR**

IV. Individual has a personal or family history of medullary thyroid carcinoma (MTC); **OR**

V. Individual has been diagnosed with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2); **OR**

VI. Individual has a history of pancreatitis; **OR**

VII. Individual has severe gastrointestinal disease (including but not limited to gastroparesis); **OR**

VIII. Individual has a history of suicide attempts or has active suicidal ideation.

Key References:

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2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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5. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. *J Clin Sleep Med*. 2017;13(3):479-504. Published 2017 Mar 15. doi:10.5664/jcsm.6506.
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10. ElSayed NA, Aleppo G, Aroda VR, et al. 8. Obesity and Weight Management for the Prevention and Treatment of Type 2 Diabetes: Standards of Care in Diabetes-2023. *Diabetes Care*. 2023;46(Suppl 1):S128-S139. doi:10.2337/dc23-S008.
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12. Grunvald, E., Shah, R., Hernaez, R., Chandar, A. K., Pickett-Blakely, O., Teigen, L. M., Harindhanavudhi, T., Sultan, S., Singh, S., Davitkov, P., & AGA Clinical Guidelines Committee (2022). AGA Clinical Practice Guideline on Pharmacological Interventions for Adults With Obesity. *Gastroenterology*, *163*(5), 1198–1225. https://doi.org/10.1053/j.gastro.2022.08.045
13. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society [published correction appears in Circulation. 2014 Jun 24;129(25 Suppl 2):S139-40]. *Circulation*. 2014;129(25 Suppl 2):S102-S138. doi:10.1161/01.cir.0000437739.71477.ee.
14. Vivus LLC. A Phase IV Safety and Efficacy Study of VI-0521 in Obese Adolescents. Clinical Trials Identifier: NCT03922945. Last update March 3, 2022. Available at https://clinicaltrials.gov/ct2/show/NCT03922945.
15.

International Obesity Task Force BMI Cut-offs for Obesity by Sex and Age for Pediatric Patients Aged 12 Years and Older (Cole Criteria); *from Saxenda Package Insert (2020)*

Age (years)	Body Mass Index 30 kg/m^2	
	Males	Females
12	26.02	26.67
12.5	26.43	27.24
13	26.84	27.76
13.5	27.25	28.20
14	27.63	28.57
14.5	27.98	28.87
15	28.30	29.11

15.5	28.60	29.29
16	28.88	29.43
16.5	29.14	29.56
17	29.41	29.69
17.5	29.70	29.84

BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 years and Older; *from Qsymia Package Insert (2022) and Wegovy Package Insert (2023)*

Age (years)	95th Percentile BMI Value	
	Male	Female
12	24.2	25.3
12.5	24.7	25.8
13	25.2	26.3
13.5	25.6	26.8
14	26.0	27.3
14.5	26.5	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.6	28.9
16.5	27.9	29.3
17	28.3	29.6
17.5	28.6	30.0

BMI Percentiles by Age and Sex for Pediatric Patients Aged 12 years and Older; *from Wegovy Package Insert (2023)*

Age (years)	95th Percentile BMI Value	
	Male	Female
12	24.2	25.2
12.5	24.7	25.7
13	25.1	26.3
13.5	25.6	26.8
14	26.0	27.2
14.5	26.4	27.7
15	26.8	28.1
15.5	27.2	28.5
16	27.5	28.9
16.5	27.9	29.3
17	28.2	29.6
17.5	28.6	30.0

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.