Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision: Denied Appeal Number: 2504819

Decision Date: 06/06/2025 **Hearing Date:** 4/30/2025

Hearing Officer: Cynthia Kopka

Appearance for Appellant:

Appearance for MassHealth: Phuong Luc, Pharm.D., R.Ph.



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
Board of Hearings
100 Hancock Street, Quincy, Massachusetts 02171

APPEAL DECISION

Appeal Decision: Denied Issue: Prior Authorization -

Drug Utilization

Review

Decision Date: 06/06/2025 **Hearing Date:** 4/30/2025

MassHealth's Rep.: Phuong Luc Appellant's Rep.:

Hearing Location: Quincy (remote) Aid Pending: No

Authority

This hearing was conducted pursuant to Massachusetts General Laws Chapter 118E, Chapter 30A, and the rules and regulations promulgated thereunder.

Jurisdiction

By notice dated March 11, 2025, MassHealth Drug Utilization Review (DUR) denied Appellant's request for prior authorization. Exhibit 1. Appellant filed this appeal in a timely manner on March 25, 2025. Exhibit 2, 130 CMR 610.015(B). Denial of a request for prior authorization is a valid basis for appeal. 130 CMR 610.032.

Action Taken by MassHealth

MassHealth/DUR denied Appellant's request for prior authorization.

Issue

The appeal issue is whether MassHealth/DUR was correct in denying Appellant's request for prior authorization.

Summary of Evidence

Page 1 of Appeal No.: 2504819

A doctor of pharmacy from MassHealth's Drug Utilization Review Program (DUR) appeared by phone and offered documents in support. Exhibit 4. Appellant appeared by phone. A summary of testimony and documents follows.

On March 11, 2025, Appellant's provider submitted a prior authorization request for approval of Zepbound on Appellant's behalf with medical records in support. Exhibit 4 at 3-15. Zepbound is an injectable medication for treating obesity. Zepbound belongs to a class called glucagon-like peptide-1 (GLP-1) receptor agonists. MassHealth will approve coverage of Zepbound for individuals whose body mass index (BMI) is \geq 30 kg/m2 recorded within 90 days to the start of treatment and who have had an adequate trial of phentermine, a less-costly alternative medication. An adequate trial would be at least 90 days unless there was an adverse reaction or a contraindication to phentermine.

Appellant's provider requested coverage of Zepbound at a dose of 2.5mg/0.5mL once weekly indicated for obesity. *Id.* at 4. Appellant's provider documented that on February 24, 2025, Appellant's current (and baseline) BMI was 40.15 kg/m2. *Id.* Appellant also has been diagnosed with obstructive sleep apnea. *Id.* at 5. The prior authorization request form was incomplete regarding a prior trial with phentermine. *Id.* However, attached medical records dated February 24, 2025 indicated that Appellant has trialed phentermine with some success, but was requesting to switch to a GLP-1 medication. *Id.* at 10.

The MassHealth representative testified that based on the form and medical record submitted, it was unclear if an adequate trial with phentermine was attempted. To be considered an adequate trial, Appellant would have had to have tried phentermine for 90 days with a less than 5% reduction in body weight or no weight loss despite adherence at the next tolerated dose. To assess this, the physician would have to document Appellant's weight before and after the phentermine trial. Alternatively, there was no documentation that Appellant had an adverse reaction or contraindication to phentermine. On March 11, 2025, MassHealth denied Appellant's prior authorization request, as the information provided did not contain sufficient information to determine medical necessity. *Id.* at 17. The denial letter notified the prescriber that a new request could be submitted with additional clinical documentation of previous drug trials with dates, durations, and outcomes. *Id.*

On April 16, 2025, in advance of hearing, MassHealth sent Appellant a letter identifying the information that would need to be provided for approval of Zepbound:

Documentation that you have had an adequate trial with phentermine, or you are not a candidate for phentermine (satisfaction of criteria 1, 2, or 3 would be sufficient):

1) You have tried phentermine (with or without topiramate) and it did not work. Trial failure is defined as current BMI is \geq 27 kg/m2 (dated within the 90 days prior to treatment initiation of requested agent) despite adherence to phentermine at

Page 2 of Appeal No.: 2504819

the maximally tolerated dose for at least 90 days out of 120 days (pharmacy claims will be evaluated as applicable) and ONE of the following:

- You had insufficient clinical response defined as < 5% reduction in bodyweight from baseline despite initial trial of ≥ 3 months of treatment
- You had plateaued clinical response defined as no weight loss for at least ≥ 3 months of treatment
- 2) Copies of your **medical records** documenting you had unacceptable side effects to phentermine that are allergic in nature or cannot be expected or managed as part of weight loss therapy
- 3) Copies of your **medical records** documenting you have a contraindication that prevents the use of phentermine

Id. at 19.

Appellant testified that she only had a 30-day trial of phentermine, unaware that it had to be 90 days. Appellant testified that she gained weight while using phentermine despite adherence. Appellant testified that she tried losing weight with a keto diet, which was successful, but it caused her diverticulitis to flare up. Appellant gained significant weight after having to stop the keto diet. Appellant's weight is affecting her ability to breathe and work and causing stress on her herniated discs, resulting in numbness and tingling in her legs. Appellant has been consulting with a dietician and exercising regularly with no results. Appellant testified that she had difficulties getting an appointment with her doctor to resume phentermine to complete the trial. Appellant testified that in addition to weight gain, she experienced lethargy while taking phentermine, which also affected her job as a server.

The MassHealth representative testified that the weight gain itself would not be an adverse reaction, but would be a rationale to approve Zepbound after a full 90-day trial. There would not be sufficient time to see a clinical response to the medication after 30 days. Weight gain after 90 days would be considered an inadequate response. Examples of an adverse reaction would be palpitations or anxiety. The MassHealth representative testified that lethargy is not a typical side effect of phentermine.

Findings of Fact

Based on a preponderance of the evidence, I find the following:

- 1. On March 11, 2025, Appellant's provider submitted a prior authorization request to MassHealth for approval of Zepbound on Appellant's behalf with medical records in support. Exhibit 4 at 3-15.
- 2. Appellant's provider requested coverage of Zepbound at a dose of 2.5mg/0.5mL once

Page 3 of Appeal No.: 2504819

weekly indicated for obesity. Appellant's provider documented that on February 24, 2025, Appellant's current (and baseline) BMI was 40.15 kg/m2. Appellant also has been diagnosed with obstructive sleep apnea. *Id.* at 4-5.

- 3. On March 11, 2025, MassHealth denied Appellant's prior authorization request, as Information provided did not contain sufficient information to determine medical necessity. Exhibit 1, Exhibit 4 at 17.
- 4. Appellant filed a timely appeal on March 25, 2025. Exhibit 2.
- 5. Appellant has not trialed phentermine for at least 90 days.
- 6. Documentation submitted by the appellant did not include that Appellant has had an adverse reaction or has a contraindication to phentermine.

Analysis and Conclusions of Law

Under 130 CMR 406.422, prescribers must obtain prior authorization from MassHealth for drugs identified by MassHealth in accordance with 130 CMR 450.303. If the limitations on payment specified in 130 CMR 406.412(A) and 406.413(A) and (C) would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to MassHealth for prior authorization for an otherwise non-covered drug. 130 CMR 406.422(A).

The regulatory definition of medical necessity is set forth at 130 CMR 450.204, which states in relevant part as follows:

- (A) A service is "medically necessary" if:
 - (1) it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity; and
 - (2) there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency. Services that are less costly to the MassHealth agency include, but are not limited to, health care reasonably known by the provider, or identified by the MassHealth agency pursuant to a prior-authorization request, to be available to the member through sources described in 130 CMR 450.317(C), 503.007: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits*.

Page 4 of Appeal No.: 2504819

•••

(D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.

MassHealth publishes a drug list, which specifies which drugs are payable under MassHealth and/or which drugs require prior authorization. 130 CMR 406.402. According to the Drug List, effective April 1, 2025, Zepbound (tirzepatide) requires prior authorization. Exhibit 4 at 21. In addition to the requirements for all anti-obesity agents, the Drug List sets forth the following evaluation criteria for approval for Zepbound:

Documentation of the following is required:

- appropriate diagnosis; and
- member is ≥ 18 years of age; and
- appropriate dosing; and
- member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); and
- member has been counseled to continue reduced-calorie diet and increased physical activity; and
- requested quantity is ≤ four pens/28 days; and
- requested agent will not be used in combination with another GLP-1 receptor agonist; and
- one of the following*:
 - inadequate response to phentermine with or without topiramate defined as all of the following:
 - member is adherent to phentermine (defined as ≥ 90 out of the last 120 days)**; and
 - one of the following:
 - insufficient clinical response defined as < 5% reduction in body weight from baseline despite initial trial of ≥ three months of treatment with the maximally tolerated dose of phentermine; or
 - plateaued clinical response defined as no weight loss for at least ≥ three months of treatment with the maximally tolerated dose of phentermine; and
 - member's current BMI is ≥ 27 kg/m2 (dated within the 90 days prior to treatment initiation of requested agent); or
 - medical records documenting adverse reaction to phentermine that is allergic in nature or cannot be expected or managed as part of weight loss therapy; or

Page 5 of Appeal No.: 2504819

- medical records documenting contraindication to phentermine; and
- one of the following:
 - member BMI is ≥ 30 kg/m2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]);
 and
 - both of the following:
 - member BMI is ≥ 27 kg/m2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity [does not have to be the requested agent]); and
 - one of the following weight-related comorbid conditions:
 - coronary heart disease or other atherosclerotic disease; or
 - dyslipidemia; or
 - hypertension; or
 - non-alcoholic steatohepatitis (NASH); or
 - obstructive sleep apnea; or
 - polycystic ovarian syndrome; or
 - prediabetes; **or**
 - systemic osteoarthritis; or
 - type 2 diabetes mellitus.

Id. at 27-28. Additionally, the MassHealth Drug List provides:

The following are acceptable contraindications to phentermine:

- Allergy to phentermine or any of the excipients
- Arrhythmia
- Bipolar disorder with mania
- Concomitant use of stimulants
- Congestive heart failure
- Coronary artery disease
- Glaucoma
- History of psychosis
- History of stroke
- Hyperthyroidism
- Substance use disorder (SUD)
- Uncontrolled anxiety despite pharmacotherapy
- Uncontrolled hypertension defined as average blood pressure of ≥ 140/90 mm Hg despite pharmacotherapy

Id. at 21.

Here, MassHealth denied Appellant's request for Zepbound because medical documentation did

Page 6 of Appeal No.: 2504819

not establish that Appellant had an inadequate response to phentermine after a 90-day trial, an adverse reaction to phentermine, or contraindication to phentermine. Appellant did not dispute these facts. Accordingly, this appeal is denied.

Order for MassHealth

None.

Notification of Your Right to Appeal to Court

If you disagree with this decision, you have the right to appeal to court in accordance with Chapter 30A of the Massachusetts General Laws. To appeal, you must file a complaint with the Superior Court for the county where you reside, or Suffolk County Superior Court, within 30 days of your receipt of this decision.

Cynthia Kopka Hearing Officer Board of Hearings

MassHealth Representative: Drug Utilization Review Program, ForHealth Consulting at UMass Chan Medical School, P.O. Box 2586, Worcester, MA 01613-2586, 508-722-3269

Page 7 of Appeal No.: 2504819