

Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2412410
Decision Date:	10/28/2024	Hearing Date:	9/11/2024
Hearing Officer:	Patrick Grogan	Record Open to:	N/A

Appearance for Appellant:



Appearance for MassHealth:

Phuong Luc, DUR

Interpreter:

N/A



*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, DUR, Zepbound
Decision Date:	10/28/2024	Hearing Date:	9/11/2024
MassHealth's Rep.:	Phuong Luc, DUR	Appellant's Rep.:	
Hearing Location:	Remote (Tel)	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

Through a notice dated August 2, 2024, MassHealth notified the Appellant that it denied the prior authorization (PA) request for the prescription medication Zepbound (130 CMR 406.413; Exhibit 1). The Appellant filed this appeal in a timely manner August 9, 2024 (130 CMR 610.015(B); Exhibit 2). Denial of assistance is valid grounds for appeal (130 CMR 610.032).

Action Taken by MassHealth

MassHealth notified the Appellant that it denied the PA request for the prescription medication Zepbound.

Issue

The appeal issue is whether MassHealth correctly denied the PA request for the prescription medication Zepbound.

Summary of Evidence

The Appellant is a MassHealth member over the age of 65. (Testimony, Exhibit 4). The Appellant seeks prior authorization for Zepbound 2.5mg/.05 ML Pen. (Testimony, Exhibit 6) On August 2, 2024, the Appellant's request for prior authorization for Zepbound was denied for the reason:

Your prior authorization request for ZEPBOUND 2.5MG/.05 ML PEN is denied. Information provided did not contain sufficient information to determine medical necessity. For additional information, please refer to the Therapeutic Class Tables at www.mass.gov/druglist. (Exhibit 1, pg. 1)

At Hearing, MassHealth was represented by a licensed pharmacist with MassHealth's Drug Utilization Review Program (DUR). MassHealth testified that MassHealth received a PA request on behalf of the Appellant for Zepbound, 2.5 mg/0.5 ml pen to treat obesity. To approve a request for this medication, MassHealth requires an appropriate diagnosis, appropriate dose and frequency, as well as other criteria. (See, Exhibit 6, p. 30-31; the MassHealth Drug List, Table 81 (www.mass.gov/druglist)). Specific prerequisites to any approval of Zepbound include trial of a semaglutide (such as Wegovy), or documentation of an intolerance to a semaglutide. If a semaglutide trial is not undertaken, a trial of a liraglutide or documentation of an intolerance to a liraglutide is required. (See, Exhibit. 6, p. 30-31; the MassHealth Drug List, Table 81 (www.mass.gov/druglist)).

MassHealth highlighted specific portions of the submitted request for prior authorization requirements for Zepbound. (Testimony). On page 3 of the prior authorization request, the Appellant's treating physician stated "Wegovy is fine too, whichever can get covered/is in stock." (Exhibit 6, pg. 5) Within the submitted medical records, the summary of an office visit is included that occurred on [REDACTED] 2024. (Exhibit 6, pg. 8-20). It is specifically noted within that summary, "discussed diet and exercise Reviewed wegovy and zepbound. These are great options but medicare won't cover them" (Exhibit 6, pg. 15) MassHealth explained that a letter, dated September 3, 2024, was sent to the Appellant explaining what was required before MassHealth could consider an approval of Zepbound. (Testimony, Exhibit 6, pgs. 24-26) MassHealth stated that no additional information was received and that MassHealth stood by the denial. (Testimony)

The Appellant testified regarding her physical conditions and the impact weight has on her health. (Testimony). The Appellant conceded that she has tried neither a semaglutide nor a liraglutide. (Testimony) The Appellant testified that she had concerns regarding trying a semaglutide, because of potential side effects, specifically side effects she has read about through news articles she read on her phone and reports she watched. (Testimony) The Appellant explained she knows people who have vision issues and believes that it is caused by side effects from Wegovy as well as other medications. (Testimony) The Appellant explained she is already prescribed medications that may affect her vision and has concerns regarding her risks. (Testimony) The Appellant stated the medicine she requested is less costly than Wegovy. (Testimony) The Appellant stated she was concerned that without losing weight, she wouldn't be

around much longer. (Testimony)

MassHealth responded that side effects are potential, and it is unknown whether a particular person will experience side effects from medication. (Testimony). MassHealth explained that Zepbound falls under the same classification as the drugs in Table 81, and similar drugs under the same classification present a risk of similar side effects. (Testimony) MassHealth explained that without documentation of a trial of a semaglutide, a trial of a liraglutide, or information of intolerance to them, MassHealth cannot approve a prior authorization request for Zepbound at this time. (Testimony) MassHealth explained that the Appellant's doctor may submit information, including citations to peer reviewed articles, to explain the Appellant's concerns with the trial of specific medications for the Appellant which are a prerequisite for the prior approval process for Zepbound. (Testimony)

Findings of Fact

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

1. The Appellant is a MassHealth member over the age of 65. (Exhibit 4)
2. The Appellant seeks prior authorization for Zepbound 2.5mg/.05 ML Pen. (Testimony, Exhibit 6)
3. On August 2, 2024, the Appellant's request for prior authorization for Zepbound was denied for the reason that information provided did not contain sufficient information to determine medical necessity. (Exhibit 1)
4. Specific prerequisites to any approval of Zepbound include trial of a semaglutide (such as Wegovy), or documentation of an intolerance to a semaglutide. If a semaglutide trial is not undertaken, a trial of a liraglutide or documentation of an intolerance to a liraglutide is required. (See, Exhibit. 6, p. 30-31; the MassHealth Drug List, Table 81 (www.mass.gov/druglist)).
5. On page 3 of the prior authorization request, the Appellant's treating physician stated "Wegovy is fine too, whichever can get covered/is in stock." (Exhibit 6, pg. 5)
6. Within the submitted medical records, the summary of an office visit is included. (Exhibit 6, pg. 8-20). It is specifically noted within that summary, "discussed diet and exercise Reviewed wegovy and zepbound. These are great options but medicare won't cover them" (Exhibit 6, pg. 15)

Analysis and Conclusions of Law

MassHealth does not cover a medical service unless it is “medically necessary.” The threshold considerations for determining whether a service is medically necessary are set forth under 130 CMR 450.204, which states, in full:

450.204: Medical Necessity

(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, or 517.007.

(B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including evidence of such medical necessity and quality. ...

(C) A provider's opinion or clinical determination that a service is not medically necessary does not constitute an action by the MassHealth agency.

(D) Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines. (130 CMR 450.204) (Emphasis added).

As subsection (D) indicates, MassHealth establishes additional medical necessity criteria throughout its regulations and publications governing specific health-related service-types. For coverage of prescription drugs, MassHealth publishes and routinely updates a “Drug List” - a formulary that identifies whether a covered drug is subject to prior approval and the specific criteria required to establish medical necessity for the drug (See, 130 CMR 406.422; 130 CMR 450.303). The criteria used to determine medical necessity is “based upon generally accepted standards of practice, review of the medical literature, federal and state policies, as well as laws applicable to the Massachusetts Medicaid Program.”¹ Further, the criteria set forth reflects MassHealth’s policy as described in its pharmacy regulations and the reviews conducted by the agency and the DUR board. *Id.*

¹ See <https://mhdh.pharmacy.services.conduent.com/MHDL/>

As published in its Drug List, MassHealth has imposed the following PA criteria for coverage of Zepbound:

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 last 90 days prior to treatment initiation); **and**
 - member has been counseled to continue reduced-calorie diet and increased physical activity; **and**
 - requested quantity is \leq four pens/28 days; **and**
 - requested agent will not be used in combination with another GLP-1 receptor agonist; **and**
 - one of the following:
 - both of the following:
 - 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**
 - systemic osteoarthritis; **or**
 - type 2 diabetes mellitus; **and**
 - member BMI is ≥ 27 kg/m² (dated within the last 90 days prior to treatment initiation); **or**
 - member BMI is ≥ 30 kg/m² (dated within the last 90 days prior to treatment initiation); **and**
 - one of the following:
 - if member has received semaglutide, one of the following:
 - inadequate response to Wegovy as defined by all of the following:
 - member is adherent to Wegovy*; **and**

- no weight loss over at least three months at the highest FDA-approved dose for Wegovy for obesity (semaglutide 2.4 mg weekly); **and**
 - member's current BMI is ≥ 27 kg/m² (dated within the 90 days prior to treatment initiation of Zepbound); **or**
- adverse reaction to semaglutide that cannot be managed or expected as part of GLP-1 receptor agonist therapy (e.g., nausea, vomiting, abdominal pain, etc.); **or**
- if member has not received semaglutide, both of the following:
 - one of the following:
 - inadequate response to liraglutide defined as all of the following:
 - member is adherent to liraglutide*; **and**
 - no weight loss over at least three months at the highest FDA-approved dose for liraglutide for obesity (liraglutide 3 mg daily); **and**
 - member's current BMI is ≥ 27 kg/m² (dated within the 90 days prior to treatment initiation of Zepbound); **or**
 - adverse reaction to liraglutide that cannot be managed or expected as part of GLP-1 receptor agonist therapy (e.g., nausea, vomiting, abdominal pain, etc.); **or**
 - contraindication to liraglutide; **and**
 - one of the following:
 - inadequate response to Wegovy defined as all of the following:
 - member is adherent to Wegovy*; **and**
 - no weight loss over at least three months at the highest FDA-approved dose for Wegovy for obesity (semaglutide 2.4 mg weekly); **and**
 - member's current BMI is ≥ 27 kg/m² (dated within the 90 days prior to treatment initiation of Zepbound); **or**

- adverse reaction to semaglutide that cannot be managed or expected as part of GLP-1 receptor agonist therapy (e.g., nausea, vomiting, abdominal pain, etc.); **or**
- contraindication to semaglutide. (See, Exhibit. 6, p. 30-31; the MassHealth Drug List, Table 81 (www.mass.gov/druglist)).

At issue in this case is MassHealth's denial of a PA request for the injectable prescription medication Zepbound 2.5 mg/0.5 ml pen. MassHealth denied the request because the information provided did not contain sufficient information to determine medical necessity. (Exhibit 1, pg. 1) The Appellant concedes that she has tried neither a semaglutide nor a liraglutide, rather the Appellant explained her concerns with attempting the medications based upon her independent research. (Testimony) The Appellant has the burden "to demonstrate the invalidity of the administrative determination." Andrews v. Division of Medical Assistance, 68 Mass. App. Ct. 228. See also Fisch v. Board of Registration in Med., 437 Mass. 128, 131 (2002); Faith Assembly of God of S. Dennis & Hyannis, Inc. v. State Bldg. Code Commn., 11 Mass. App. Ct. 333, 334 (1981); Haverhill Mun. Hosp. v. Commissioner of the Div. of Med. Assistance, 45 Mass. App. Ct. 386, 390 (1998). Based upon the evidence presented, the Appellant has not met this burden.

MassHealth did not err in denying the Appellant's prior authorization request. Here, the Appellant has not undergone a trial of a semaglutide, a trial of a liraglutide, nor furnished information of intolerance to them as required before prior authorization can occur. (See, Exhibit. 6, p. 30-31; the MassHealth Drug List, Table 81 (www.mass.gov/druglist)). Additionally, the Appellant testified regarding the concerns with trying the other medications. However, no information from the Appellant's physician, with citations to peer reviewed articles, was submitted in this Administrative Record to support her concerns with complying with the prior authorization criteria. To the contrary, evidence that the Appellant's physician supports the Appellant receiving Wegovy appears multiple times in this Administrative Record. (Exhibit 6, pgs. 5, 15) Accordingly, I find that the Appellant has not demonstrated, by a preponderance of the evidence, the invalidity of MassHealth's administrative determination to deny prior authorization for Zepbound at this time. Accordingly, based upon this Administrative Record, this appeal is DENIED.²

Order for MassHealth

None.

² This denial does not preclude the Appellant's medical provider from submitting a new prior authorization request to DUR, including all supporting documentation for review.

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.

Patrick M. Grogan
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, 774-455-3200