# Office of Medicaid
# BOARD OF HEARINGS

**Appellant Name and Address:**

[redacted]

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| **Appeal Decision:** | Approved | **Appeal Number:** | 2410692 |
| **Decision Date:** | 10/03/2024 | **Hearing Date:** | 09/10/2024 |
| **Hearing Officer:** | Alexandra Shube | | |

**Appearance for Appellant:**
*Via telephone*:
Pro se

**Appearance for ACO:**
*Via telephone for Mass General Brigham Health Plan*
Debbi Murphy, Mgr. Appeals & Grievances
Julie Balistreri, Sr. Mgr. Appeals & Grievances
David Lyczkowski, MD, Medical Dir.

Michaele Freeman, MCO Contract Mgr. for MassHealth

*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

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| **Appeal Decision:** | Approved | **Issue:** | ACO; Prior Authorization – Pharmacy, Zepbound |
| **Decision Date:** | 10/03/2024 | **Hearing Date:** | 09/10/2024 |
| **ACO's Rep.:** | Debbi Murphy, et al. | **Appellant's Rep.:** | Pro se |
| **Hearing Location:** | Charlestown MassHealth Enrollment Center - 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

Through a notice dated June 10, 2024, Mass General Brigham Health Plan (MGBHP), a MassHealth accountable care organization (ACO), informed the appellant that it had denied his internal appeal of a prior authorization request for the drug Zepbound because the medical evidence did not meet the medical necessity criteria (Exhibit 1). The appellant filed this appeal in a timely manner on July 9, 2024 (see 130 CMR 610.015(B) and Exhibit 2). An ACO's denial of a request for prior authorization is valid grounds for appeal to the Board of Hearings (130 CMR 610.032(B)(2)).[1]

## Action Taken by ACO

MGBHP denied the appellant's prior authorization request for the drug Zepbound.

[1] An accountable care organization is defined at 130 CMR 501.001 as an entity that enters into a population-based payment model contract with EOHHS as an accountable care organization, wherein the entity is held financially accountable for the cost and quality of care for an attributed or enrolled member population. ACOs include Accountable Care Partnership Plans, Primary Care ACOs, and MCO-Administered ACOs.

# Issue

The appeal issue is whether MassHealth's agent or designee, MGBHP, was correct in denying the appellant's internal appeal of a prior authorization request for the drug Zepbound because the appellant did not meet the prior authorization and medical necessity criteria for the requested drug.

# Summary of Evidence

The appellant, who is an adult between the ages 21 and 65, appeared at hearing via telephone. MGBHP also appeared at hearing via telephone and was represented by its manager of appeals and grievances, senior manager of appeals and grievances, and medical director. The MCO contract manager for MassHealth also appeared at hearing via telephone as an observer.

MGBHP testified as follows: on May 7, 2024, the appellant's provider submitted a request for prior authorization of Zepbound (tirzepatide) injectable 2.5mg. The drug is FDA approved for chronic weight management in adults with the following:

- obesity with a body mass index (BMI) of 30 or more; or
- overweight with a BMI of 27 or more with one of the following 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.

At the time of MGBHP's decision and at the time of this hearing, pursuant to the MassHealth Drug List (here in after the "Drug List"), before MassHealth or a MassHealth ACO can approve Zepbound, a member must have tried and had an inadequate response or adverse reaction to semaglutide (such as Wegovy or Ozempic).[2] Additionally, pursuant to the Drug List, if the member has not received semaglutide, the member must have had an inadequate or adverse reaction to liraglutide (such as Victoza or Saxenda) and either an inadequate response to semaglutide, adverse reaction to semaglutide, or contraindication to semaglutide. As the appellant had not tried a semaglutide or liraglutide, he did not meet the step therapy requirements in the Drug List. Thus, on May 7, 2024, MGBHP denied the appellant's prior authorization request for Zepbound because he did not meet the clinical requirements for the medication.

[2] As of the hearing date on September 10, 2024, the MassHealth Drug List prior authorization criteria for Zepbound and other anti-obesity agents had last been revised in May 2024. See Exhibit 5, page 81. At the time of writing this decision on October 2, 2024, the same Drug List had been revised as of October 2024. The prior authorization criteria for Zepbound no longer includes any requirement that a member trial and have an inadequate response or adverse reaction to semaglutide (Wegovy or Ozempic). See Exhibit 6.

On May 13, 2024, MGBHP received an internal appeal from the appellant which was reviewed by one of its medical directors. The appellant has a BMI of 29 (based on his weight from a May 1, 2024 visit summary) and one of the comorbidities (obstructive sleep apnea), but he has not tried semaglutide or liraglutide. Thus, on June 10, 2024, MGBHP notified the appellant that his internal appeal was denied. This is the notice under appeal. It states that "Zepbound can be approved if you have a BMI above 27 with sleep apnea AND you have tried semaglutide (Wegovy or Ozempic) for at least 3 months without weight loss, or you are medically unable to take semaglutide. The documentation received does not indicate that you meet this requirement."

The appellant testified that he has sleep apnea and would like to sleep without being connected to his CPAP machine. In addition to not having to sleep with a hose strapped to his face every night, being approved for Zepbound would also save his insurance plan the cost of CPAP supplies. MassHealth wants him to trial Ozempic first which is specifically for those with diabetes and he has heard people have trouble coming off it. He has lost weight in the past and it did not fix his sleep apnea. Zepbound is not a semaglutide like Ozempic and he stated there is a study showing that people on Zepbound with severe sleep apnea have shown a reduction in apnea episodes of over 65%. He does not want to take Ozempic and he does not want to have to trial and fail a drug in order to be approved for the drug his doctor prescribed.

Dr. Lyczkowski from MGBHP responded that it carefully considered the appellant's reasoning. He explained that neither MassHealth nor the FDA has approved Zepbound for the treatment of obstructive sleep apnea. The study referenced by the appellant was only one single trial comparing Zepbound to a placebo. It was not a large study. Notably, the study focused on people with obesity (a BMI over 30) and sleep apnea. The appellant is overweight with a BMI of 29, not obese, and does not fit into the study population. Even if the FDA approved Zepbound in the future for the treatment of sleep apnea, it would be for people who meet those criteria, and currently, the appellant does not. But, as of now, there is no FDA approval for Zepbound to treat sleep apnea. Additionally, he noted that Zepbound is a drug in the same family as Wegovy and several other of the newer weight loss drugs. The mechanism of action by which it's suspected that Zepbound is effective in reducing sleep apnea is that it reduces weight. It is known that weight loss is very effective in improving sleep apnea symptoms and often weight loss alone can resolve sleep apnea. There is not enough evidence that Zepbound is unique among the drugs in this class in helping sleep apnea. It is very likely that Wegovy or Ozempic (because it causes weight loss) would also benefit people with sleep apnea, but there just hasn't been a study yet. Even if the FDA does grant an indication for Zepbound to treat sleep apnea, MassHealth could still have a step therapy requirement and require a member to trial Wegovy and have an inadequate response to Wegovy before approving Zepbound. In addition to the FDA not approving Zepbound for the treatment of sleep apnea, and most relevant here, MassHealth has not approved it for that indication. As a MassHealth ACO, MGBHP is obligated to adhere to MassHealth regulations, rules, and Drug List.

With the October 2024 update in the Drug List, this hearing officer reached out to MGPH's manager and senior manager of appeals and grievances. The manager of appeals and grievances responded that she reviewed the appellant's clinical documentation against the updated MassHealth criteria. Based on his documented medical history, weight, and BMI, he meets the MassHealth criteria for coverage of Zepbound.

# Findings of Fact

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

1. The appellant is an adult between the ages of 21 and 65 (Exhibit 4 and Testimony).

2. The appellant is enrolled in the Mass General Brigham Health Plan, a MassHealth accountable care organization (Testimony and Exhibit 5).

3. On May 7, 2024, the appellant's provider submitted a request for prior authorization of Zepbound (tirzepatide) injectable 2.5mg (Testimony and Exhibit 5).

4. On May 7, 2024, MGBHP denied the appellant's prior authorization request for Zepbound because he did not meet the clinical requirements for the medication (Testimony and Exhibit 5).

5. On May 13, 2024, the appellant filed an internal appeal with MGBHP (Testimony and Exhibit 5).

6. After a review of all documentation, on June 10, 2024, MGBHP notified that appellant that his internal appeal was denied because "Zepbound can be approved if you have a BMI above 27 with sleep apnea AND you have tried semaglutide (Wegovy or Ozempic) for at least 3 months without weight loss, or you are medically unable to take semaglutide. The documentation received does not indicate that you meet this requirement." (Testimony and Exhibit 5).

7. On July 9, 2024, the appellant timely appealed the denial (Exhibit 2).

8. Pursuant to medical records dated May 1, 2024, the appellant has a BMI of 29 and obstructive sleep apnea, but has not tried Wegovy or other semaglutides or liraglutides (Testimony and Exhibit 5).

9. At the time of MGBHP's determination and hearing, the MassHealth Drug List had last been revised in May 2024 and required that a member trial and have an inadequate response or adverse reaction to semaglutide (such as Wegovy or Ozempic). If the member has not

received semaglutide, the member must have had an inadequate or adverse reaction to liraglutide (such as Victoza or Saxenda) and either an inadequate response to semaglutide, adverse reaction to semaglutide, or contraindication to semaglutide. (Testimony and Exhibit 5 at 80-81).

10. The MassHealth Drug List revised the prior authorization criteria for Zepbound and other anti-obesity agents in October 2024. The Zepbound criteria no longer requires a trial and inadequate response or adverse reaction to semaglutide or liraglutide. (Exhibit 6).

11. The updated prior authorization for Zepbound requires in relevant part:
    - 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 90 days prior to treatment initiation); **or**
        - member BMI is ≥30 kg/m2 (dated within the 90 days prior to treatment initiation).

    (Exhibit 6).

12. Based on the appellant's documented medical history, weight, and BMI, he meets the MassHealth criteria for coverage of Zepbound (Testimony and Exhibit 7).

# Analysis and Conclusions of Law

MassHealth members who are younger than 65 years old must enroll in a MassHealth managed care provider available for their coverage type. Members described in 130 CMR 508.001(B) or who are excluded from participation in a MassHealth managed care provider pursuant to 130 CMR 508.002(A) are not required to enroll with a MassHealth managed care provider. 130 CMR 508.001(A).

Pursuant to 130 CMR 508.010(B), members are entitled to a fair hearing under 130 CMR 610.000: *MassHealth: Fair Hearing Rules* to appeal:

(B) a determination by the MassHealth behavioral health contractor, by one of the MCOs, Accountable Care Partnership Plans, or SCOs as further described in 130 CMR 610.032(B), if the member has exhausted all remedies available through the contractor's internal appeals process…

The appellant exhausted the internal appeal process offered through his ACO, and thus is entitled to a fair hearing pursuant to the above regulations. As MassHealth's agent, MGBHP is required to follow MassHealth rules and regulations pertaining to a member's care. By regulation, MassHealth will not pay for services that are not medically necessary. 130 CMR 450.204 states the following regarding 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.***

(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; see also 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."[3] Further, the criteria reflect MassHealth's policy as described in its pharmacy regulations and the reviews conducted by the agency and the Drug Utilization Review (DUR) board. See Id.

As published in its Drug List, MassHealth has imposed the following prior authorization criteria for coverage of Zepbound (tirzepatide):

- 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 treatment initiation); **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:
        - 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 90 days prior to treatment initiation); **or**
        - member BMI is ≥30 kg/m2 (dated within the 90 days prior to treatment initiation).
- For recertification for obesity/overweight, documentation of the following is required:
    - member weight (dated within the last 90 days); **and**
    - one of the following:
        - weight loss of ≥ 5% from baseline body weight; **or**
        - both of the following:
            - improvement in secondary measures; **and**
            - clinical rationale for continuation of therapy.

[3] See https://mhdl.pharmacy.services.conduent.com/MHDL/ last visited on October 2, 2024.

The Drug List prior authorization criteria for Zepbound was revised as of October 2024 and no longer requires that a member trial and have an inadequate response or adverse reaction to Wegovy (or other semaglutide or liraglutide). Based on records available, the appellant has a BMI of 29 (as of the most recent medical records provided, from a visit dated May 1, 2024) and obstructive sleep apnea. While MGBHP's original determination was correct based on the regulations and Drug List criteria at the time of its initial decision and internal appeal, the appellant now meets the Drug List criteria for approval of Zepbound.

For these reasons, the appeal is approved.

## Order for ACO

Approve the appellant's prior authorization request for Zepbound injectable 2.5mg.

## Implementation of this Decision

If the ACO fails to comply with the above order, you should report this in writing to the Director of the Board of Hearings, at the address on the first page of this decision.

Alexandra Shube
Hearing Officer
Board of Hearings

MassHealth Representative: Mass General Brigham Health Plan, Attn: Julie Balistreri, 399 Revolution Drive, Suite 810, Somerville, MA 02145