# Office of Medicaid BOARD OF HEARINGS

#### **Appellant Name and Address:**



Appeal Decision: DENIED Appeal Number: 2505725

**Decision Date:** 5/29/2025 **Hearing Date:** 05/20/2025

Hearing Officer: Sharon Dehmand

Appearance for Appellant:

Pro se

#### Appearance for MassHealth:

Timothy Nolan, Manager, Clinical Pharmacy Maria Kassos, Clinical Pharmacist, Medicare Clinical Programs



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: Managed Care

Organization – Denial

of Internal Appeal

Decision Date: 5/29/2025 Hearing Date: 05/20/2025

MassHealth's Rep.: Timothy Nolan Appellant's Rep.: Pro se

Maria Kassos

Hearing Location: 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 February 28, 2025, Fallon Health (Fallon), a contracted accountable care organization (ACO) for MassHealth denied the appellant's Level 1 appeal from the denial of prior authorization (PA) request for the drug Wegovy because Fallon determined the drug was not covered. See 130 CMR 406.413 and Exhibit 1. The appellant filed this appeal in a timely manner on March 27, 2025. See 130 CMR 610.015(B) and Exhibit 2. A denial of a request for prior authorization by an ACO is valid grounds for appeal before the Board of Hearings. See 130 CMR 508.010(B); 130 CMR 610.032(B)(2).

## **Action Taken by ACO**

Fallon denied the appellant's prior authorization request for the drug Wegovy.

#### Issue

Whether Fallon was correct in denying the appellant's prior authorization request for Wegovy because it determined the drug was not covered by MassHealth. See 130 CMR 406.413(C); 130

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CMR 450.303.

# **Summary of Evidence**

The ACO's representatives and the appellant who verified his identity appeared telephonically. The following is a summary of the testimony and evidence provided at the hearing:

The ACO's representative who is a pharmacist testified that the appellant started using Wegovy in the Spring of 2024. The appellant's Body Mass Index (BMI) is currently 23.8 and he does not have a history of myocardial infarction, stroke, or peripheral arterial occlusive disease. On January 6, 2025<sup>1</sup>, MassHealth listed Wegovy as a non-covered agent and required members to switch to Zepbound. On January 13, 2025, the ACO denied a PA request, sent on behalf of the appellant for Wegovy. On February 3, 2025, the appellant filed a level 1 appeal of the denial. The ACO's reviewing physician conducted an independent desk review of the request and denied the PA because the drug is not covered and the documentation submitted did not establish any cardiovascular disease. On February 28, 2025, the ACO issued a written denial.

The appellant testified that he had tried Zepbound for two weeks, resulting in gastric problems due to his IBS and increased heart rate. He referred to two letters submitted in support of his contention that the use of Zepbound in combination with his other medications would result in an increased heart rate. He added that he has a family history of heart disease and stroke. The appellant expressed concern that, although he currently has a normal weight, he would start gaining weight without Wegovy.

The ACO's representative responded by stating that neither Wegovy's nor Zepbound's packet inserts list increased heart rate, and upon checking the drug interactions between Zepbound and the appellant's other medications, he did not find any.

The appellant responded by stating that the Drugs.com website lists an increased heart rate of 2-4 beats per minute as a drug interaction between Zepbound and Cyclobenzaprine, which is one of the medications he uses.

## **Findings of Fact**

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

- 1. The appellant is enrolled in Fallon Health, a MassHealth ACO. (Testimony).
- 2. The appellant is over the age of (Testimony and Exhibit 4).

<sup>1</sup> Contrary to the testimony, the correct date for MassHealth's policy change is January 1, 2025.

- 3. The appellant started using Wegovy in the Spring of 2024. (Testimony and Exhibit 5).
- 4. On January 1, 2025, MassHealth listed Wegovy as a non-covered agent and required members to switch to Zepbound. (Testimony and www.mass.gov/druglist).
- 5. In order to qualify for an exception to this rule, documentation of the following in relevant part is required:
  - appropriate diagnosis; and
  - member is ≥ years of age; and
  - member weight (dated within the 90 days prior to initiation of pharmacotherapy for obesity); **and**
  - member BMI is ≥ 27 kg/m2 (dated within the 90 days prior to initiation of pharmacotherapy for obesity); and
  - medical records documenting a diagnosis of cardiovascular disease defined as at least one of the following:
    - o history of myocardial infarction (MI); or
    - history of stroke (ischemic or hemorrhagic stroke); or
    - symptomatic peripheral arterial disease.
- 6. The appellant does not have a history of myocardial infarction, stroke, or peripheral arterial occlusive disease. (Testimony and Exhibit 6).
- 7. The appellant's BMI is currently 23.8 kg/m2. (Testimony and Exhibit 5).
- 8. On January 13, 2025, the ACO denied a PA request sent on behalf of the appellant for Wegovy. (Exhibit and Exhibit 5).
- 9. On February 3, 2025, the appellant filed a level 1 appeal of the denial. (Testimony and Exhibit 5).
- 10. On February 28, 2025, the ACO denied the PA because the drug is not covered, and the documentation submitted did not establish any cardiovascular disease. (Testimony and Exhibit 1).
- 11. The appellant filed this appeal in a timely manner on March 27, 2025. (Exhibit 2).

# **Analysis and Conclusions of Law**

MassHealth members who are younger than years old, except those excluded under 130 CMR

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508.002, must enroll in a MassHealth Managed Care Organization (MCO)<sup>2</sup> available for their coverage type. See 130 CMR 450.117(A); 130 CMR 508.001(A). MassHealth managed care options include an accountable care organization (ACO)<sup>3</sup> for MassHealth CommonHealth members who also meet the requirements for eligibility set forth under 130 CMR 508.006. Members who participate in an ACO obtain all covered services through the ACO. See 130 CMR 508.007(A)(2).

Members enrolled in a managed care provider are entitled to a fair hearing under 130 CMR 610.000 to address adverse determinations by an ACO if the member has exhausted all remedies available through the contractor's internal appeal process. See 130 CMR 508.010(B).

Here, the appellant has exhausted all remedies available through the ACO's internal appeal process and has timely filed this appeal with the Board of Hearings. <u>Id.</u>; 130 CMR 610.018.

Generally, MassHealth and MCOs must cover any service that is deemed "medically necessary." The following is the regulatory definition of 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 priorauthorization 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.
- (B) Medically necessary services must be of a quality that meets professionally recognized standards of health care, and must be substantiated by records including

<sup>2</sup> Managed care organizations provide "management of medical care, including primary care, behavioral health services, and other medical services" for enrolled members. See 130 CMR 450.117(B).

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<sup>&</sup>lt;sup>3</sup> 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 enroll member population. ACOs include Accountable Care Partnership Plans, Primary Care ACOs, and MCO-Administered ACOs.

evidence of such medical necessity and quality. A provider must make those records, including medical records, available to the MassHealth agency upon request. (See 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)

- (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.

See 130 CMR 450.204.

As per 130 CMR 450.204(D), 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." The MassHealth Drug List is an alphabetical list of commonly prescribed drugs and therapeutic class tables. The List specifies which drugs need prior authorization (PA) when prescribed for MassHealth members. The PA requirements specified in the Drug List reflect MassHealth's policy described in the pharmacy regulations and other communications from MassHealth, as well as MassHealth's and the Drug Utilization Review (DUR) Board's review of drugs within certain therapeutic classes. See

https://mhdl.pharmacy.services.conduent.com/MHDL/pubintro.do?category=Introduction+to+MassHealth+Drug+List.

Pursuant to 130 CMR 406.413(C), MassHealth covers drugs that are not explicitly excluded under 130 CMR 406.413(B). The limitations and exclusions in 130 CMR 406.413(B) do not apply to medically necessary drug therapy for MassHealth Standard and CommonHealth enrollees younger than years old. The MassHealth Drug List specifies those drugs that are payable under MassHealth. Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 406.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. See 130 CMR 450.303: Prior Authorization. Fallon Health's Member Handbook echoes the same restrictions. (Exhibit 7, Fallon Health Member Handbook, p. 31).

As published in MassHealth's Drug List, effective January 1, 2025, Wegovy will no longer be covered for MassHealth members for the treatment of overweight or obesity for adults. MassHealth members over years of age receiving Wegovy for the treatment of overweight or obesity will be required to switch to Zepbound. See <a href="www.mass.gov/druglist">www.mass.gov/druglist</a>. In order to qualify for an exception, documentation of the following is required for risk reduction of major adverse cardiovascular events in members with established cardiovascular disease and obesity or overweight:

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- appropriate diagnosis; and
- member is ≥ years of age; 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 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
- medical records documenting a diagnosis of cardiovascular disease defined as at least one of the following:
- o history of myocardial infarction (MI); or
- history of stroke (ischemic or hemorrhagic stroke); or
- symptomatic peripheral arterial disease (e.g., intermittent claudication with ankle-brachial index <0.85, peripheral arterial revascularization procedure, or amputation due to atherosclerotic disease); and
- o attestation that the member does not have any of the following:
  - o type 1 diabetes mellitus; or
  - o type 2 diabetes mellitus; or
  - o New York Heart Association class IV heart failure; and
- member has been counseled to continue reduced-calorie diet and increased physical activity; and
- requested agent will not be used in combination with another GLP-1 receptor agonist; and
- o requested quantity is ≤ four pens/28 days.

#### See <u>id.</u>

A fair hearing decision must be based upon "evidence, testimony, materials, and legal rules, presented at hearing, including the MassHealth agency's interpretation of its rules, policies and regulations." See 130 CMR 610.082(A). Based on the regulations and Drug List criteria, Fallon Health correctly denied the appellant's prior authorization request for Wegovy for at least two reasons.

First, medical records submitted by both the appellant and Fallon Health are devoid of a history of myocardial infarction or stroke or symptomatic peripheral arterial disease. See generally Exhibits 5 and 6. Since, the appellant's medical records contain no evidence of cardiovascular disease or stroke in the appellant's medical history, and MassHealth's criteria do not recognize family history alone as a basis for an exception. See Exhibit 5, pp. 21-22; <u>id</u>. Therefore, the appellant's assertion regarding his family history of heart disease and stroke is irrelevant to this analysis.

Second, MassHealth's listed exception criteria do not include an increased heart rate as a qualifying condition. See <a href="www.mass.gov/druglist">www.mass.gov/druglist</a>. The appellant referenced two letters from his healthcare providers, dated February 3, 2025, and March 10, 2025, to support his claim that there

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may be a potential increased heart rate as a result of an interaction between Zepbound and Cyclobenzaprine. However, this argument is unpersuasive, as MassHealth does not include increased heart rate among its listed exceptions. Furthermore, a comparison of the package inserts for Zepbound and Wegovyy reveals that their reported "adverse reactions" and "drug interactions" are nearly identical, further weakening the appellant's claim. See Exhibit 6, pp. 9, 12; Exhibit 8. Regardless of the aforementioned, since MassHealth does not list an increase in heart rate as a qualifying condition, this argument is wholly irrelevant to the analysis of the case.

An appellant bears the burden of proof at fair hearings "to demonstrate the invalidity of the administrative determination." See <u>Andrews v. Division of Medical Assistance</u>, 68 Mass. App. Ct. 228, 231 (2007); see also <u>Craven v. State Ethics Comm'n</u>, 390 Mass. 191, 200 (1983)("[p]roof by a preponderance of the evidence is the standard generally applicable to administrative proceedings"). Based on the evidence, testimony, and medical records in this case, the appellant did not establish, by a preponderance of the evidence, that ACO erred in denying his PA request for Wegovy.

Based on the foregoing reasons, this appeal is DENIED.

## **Order for ACO**

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.

Sharon Dehmand, Esq. Hearing Officer Board of Hearings

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<sup>&</sup>lt;sup>4</sup> The packet inserts for both drugs note an increase in heart rate of 1 to 4 beats per minute. See Exhibit 8, pp. 3, 24.

MassHealth Representative: Fallon Health, Member Appeals and Grievances, 10 Chestnut Street, Worcester, MA 01608