Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision: Denied **Appeal Number:** 2300517

Decision Date: 3/13/2023 **Hearing Date:** 02/22/2023

Hearing Officer: Paul C. Moore

Appellant Representative:

Pro se (by telephone)

MassHealth Representative:

Phuong Luc, Pharm.D., MassHealth Drug Utilization Review Program (by telephone)



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: 3/13/2023 **Hearing Date:** 02/22/2023

MassHealth Rep.: Dr. Luc Appellant Rep.: Pro se

Hearing Location: Board of Hearings

(remote)

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 October 15, 2022, MassHealth denied the appellant's prior authorization (PA) request for prescription medication Saxenda, 18 mg./3 ml. pen, because MassHealth does not pay for any drug used for the treatment of obesity (Exh. 1). The appellant filed this appeal with the Board of Hearings (BOH) in a timely manner on January 20, 2023 (130 CMR 610.015(B)(1); Exh. 2). Denial of PA is a valid ground for appeal (130 CMR 610.032).

Action Taken by MassHealth

MassHealth denied the appellant's PA request for prescription medication Saxenda 18 mg./3 ml. pen.

¹ MassHealth Eligibility Operations Memo 20-09, "MassHealth Response to Coronavirus Disease 2019 (COVID-19)," issued April 7, 2020, states in relevant part: "In response to the current Coronavirus Disease 2019 (COVID-19) national emergency, MassHealth is implementing the following protocols to support the public health efforts to expedite medical care and maintain care for both new MassHealth applicants and existing members. Regarding Fair Hearings during the COVID-19 outbreak national emergency, and through the end of the month in which such national emergency period ends: All appeal hearings will be telephonic; and Individuals will have up to 120 days, instead of the standard 30 days, to request a fair hearing for member eligibility—related concerns."

Page 1 of Appeal No.: 2300517

Issue

The appeal issue is whether MassHealth was correct, pursuant to 130 CMR 406.413(B)(4) and 130 CMR 450.204, in denying the appellant's PA request for Saxenda 18 mg./3 ml. pen.

Summary of Evidence

The MassHealth representative, a doctor of pharmacy and licensed pharmacist, testified by telephone that on October 14, 2022, the appellant's prescriber, Adam Laird, N.P. ("the prescriber"), submitted a drug PA request to the MassHealth Drug Utilization Review Program ("DUR") on behalf of the appellant for the prescribed drug Saxenda 18 mg./3 ml. pen (Exh. 3). The MassHealth representative testified that Saxenda, also called liraglutide, is a glucagon-like peptide-1 receptor agonist used as an adjunct to a reduced-calorie diet and increased physical activity for weight management. The MassHealth representative noted that under 130 CMR 406.413(B)(4), drugs used for the treatment of obesity are excluded from MassHealth coverage (Testimony). Therefore, on October 15, 2022, MassHealth sent the appellant and the prescriber a denial notice (Exh. 1).

The MassHealth representative testified that the prescriber indicated on the PA request form submitted to MassHealth that Saxenda was requested for treatment of the appellant's obesity (Exh. 4, p. 3). In support of this request, the prescriber attached copies of medical office notes. He documented that the appellant has a baseline body mass index ("BMI") of 37.51, and that she does not have comorbid risk factors such as dyslipidemia, hypertension, type two diabetes, or sleep apnea (*Id.*, p. 5). Further, the prescriber indicated that the appellant would use one pen of the drug once a day for thirty days, and that the dosage would be tapered after the first month of therapy (*Id.*). The prescriber also documented that the appellant has been unsuccessful losing weight through diet modification and exercise (*Id.*, p. 8). The prescriber also documented that the appellant has chronic obstructive pulmonary disease (COPD), and is a smoker (*Id.*, p. 10).

With this PA request, the prescriber provided a list of the appellant's current medications, which includes metoprolol succinate 50 mg. extended-release tablet, one by mouth once per day (*Id.*, p. 12). The MassHealth representative stated that this drug is used to treat hypertension (Testimony).

The appellant, who is under age 65, testified by telephone that she has been on a diet for a long time, is 5'3", and currently weighs 190 lbs. She stated that she has hypertension, and recently was scheduled for dental work, which was canceled because her blood pressure was so high at the appointment. She also is prescribed Simvastatin for hyperlipidemia. She was recently referred to a cardiologist. Members of her family have suffered strokes. Her dosage of antihypertensive medication, metoprolol, was recently doubled from 50 mg. per day to 100 mg. per day. She also has recently been diagnosed with a hole in one of her eardrums, and a sinus infection (Testimony).

She underwent total hip replacement surgery about two years ago. She walks outdoors with her granddaughter at times (Testimony).

Page 2 of Appeal No.: 2300517

The MassHealth representative testified that the prescriber previously submitted a PA request for Ozempic, a different prescribed drug, also for the appellant's weight loss, on October 31, 2022. This drug is also used for the treatment of Type 2 diabetes, according to the MassHealth representative. MassHealth DUR did not approve this drug for the appellant, as the indication for use was for weight loss (Testimony).

The MassHealth representative testified that another medication, Victoza, has the same active ingredient as Saxenda, and does not require a PA request to be submitted to MassHealth for approval (Testimony).

Findings of Fact

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

- 1. On October 14, 2022, the appellant's prescriber, Adam Laird, N.P., submitted a PA drug request to the MassHealth DUR on behalf of the appellant for the prescribed drug Saxenda 18 mg./3 ml. pen (Exh. 3).
- 2. The appellant's prescriber documented that Saxenda is requested for "obesity, unspecified" (Exh. 3, p. 3).
- 3. MassHealth denied the PA request by notice dated October 15, 2022, on the basis that MassHealth does not pay for any drug used for the treatment of obesity (Exh. 1).
- 4. The appellant timely appealed the denial notice with the BOH (Exh. 2).
- 5. Saxenda, also called liraglutide, is a glucagon-like peptide-1 receptor agonist used as an adjunct to a reduced-calorie diet and increased physical activity for weight management (Testimony, Exh. 3).
- 6. The appellant is also diagnosed with COPD, hypertension and hyperlipidemia (Testimony, Exh. 3).
- 7. The prescriber also documented that the appellant has been unsuccessful losing weight through diet modification and exercise (Exh. 3, p. 8).
- 8. The appellant is 5'3" and weighs approximately 190 lbs. (Testimony).
- 9. The appellant has a baseline BMI of 37.51 (Testimony, Exh. 3).
- 10. The appellant's dosage of her antihypertensive medication was recently increased (Testimony).

11. The appellant does not have sleep apnea, nor has she been diagnosed with Type 2 diabetes (Testimony).

Analysis and Conclusions of Law

Generally, MassHealth will not pay for any services or prescriptions that are not medically necessary (130 CMR 450.204). 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.

130 CMR 450.204(A).

Specifically, regarding pharmaceuticals, MassHealth publishes a Drug List that specifies the drugs that are payable by MassHealth, and these drugs must be "approved by the U.S. Food and Drug Administration ["FDA"] and manufactured by companies that have signed rebate agreements with the U.S. Secretary of Health and Human Services pursuant to 42 U.S.C. 1396r-8" (130 CMR 406.412(A)(1)).

Saxenda does not appear on the MassHealth Drug List.

MassHealth regulation 130 CMR 406.413(C)(1) states in pertinent part:

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 21 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.

(Emphasis added)

Next, turning to MassHealth regulation 130 CMR 406.413(B), "Drug Exclusions:"

Page 4 of Appeal No.: 2300517

The MassHealth agency does not pay for the following types of prescription or over-the-counter drugs or drug therapy.

- (1) Cosmetic. The MassHealth agency does not pay for any drug when used for cosmetic purposes or for hair growth.
- (2) Cough and Cold. The MassHealth agency does not pay for any drug used solely for the symptomatic relief of coughs and colds, including, but not limited to, those that contain an antitussive or expectorant as a major ingredient, unless dispensed to a member who is a resident in a nursing facility or an intermediate care facility for individuals with intellectual disabilities (ICF/IID).
- (3) Fertility. The MassHealth agency does not pay for any drug used to promote male or female fertility.

(4) Obesity Management. The MassHealth agency does not pay for any drug used for the treatment of obesity.

- (5) Less-than-effective Drugs. The MassHealth agency does not pay for any drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
- (6) Experimental and Investigational Drugs. The MassHealth agency does not pay for any drug that is experimental, medically unproven, or investigational in nature.
- (7) Drugs for Sexual Dysfunction. The MassHealth agency does not pay for any drugs when used for the treatment of male or female sexual dysfunction.

(Emphasis added)

Finally, MassHealth regulation 130 CMR 406.422(A) states in relevant part:

Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303: Prior Authorization. If the limitations on covered drugs 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 the MassHealth agency for prior authorization for an otherwise noncovered drug.²

(Emphasis added)

the appellant's "obesity – unspecified." As set forth above at 130 CMR 406.413(B)(4), MassHealth does not pay for *any* drug used for the treatment of obesity. Some exceptions exist for types of drugs

In the instant matter, the appellant's prescriber requested Saxenda 18 mg./3 ml. pen specifically for

² MassHealth limitations set forth on coverage of drugs in 130 CMR 406.412(A) and 406.413(A) and (C) relate to interchangeable drug products, immunizing biologicals and tubercular (TB) drugs, and any drug prescribed for other than the FDA-approved indications as listed in the package insert, among other exclusions not relevant to this appeal.

typically not covered by MassHealth, as listed at 130 CMR 406.412(A) and 406.413(A) and (C). However, exceptions do *not* exist for drugs used to treat obesity, as set forth at 130 CMR 406.413(B).

MassHealth's decision to deny the PA request for Saxenda for treatment of the appellant's obesity was correct.

For these reasons, the appeal must be 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.

Paul C. Moore Hearing Officer Board of Hearings

cc: MassHealth Drug Utilization Review Program

Page 6 of Appeal No.: 2300517