

Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2178519
Decision Date:	01/14/2022	Hearing Date:	12/14/2021
Hearing Officer:	Casey Groff		

Appearance for Appellant:

Pro se

Appearance for MassHealth:

Kristen Danis, Pharm.D., R.Ph., Consultant
Pharmacist IV, Drug Utilization Program
(DUR); Meghan Serell, Pharm.D., R.Ph.
Consultant Pharmacist IV, DUR



*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:	Drug Utilization Review
Decision Date:	01/14/2022	Hearing Date:	12/14/2021
MassHealth's Rep.:	Kristen Danis, Pharm.D., R.Ph.; Meghan Serell, Pharm.D., R.Ph.	Appellant's Rep.:	<i>Pro se</i>
Hearing Location:	Telephonic	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 October 1, 2021, MassHealth denied the Appellant's prior authorization (PA) medication request for Saxenda 18 mg/3 ml pen-injector. See Exh. 2; see also Exh. 4, p. 7. Appellant filed this appeal in a timely manner on October 26, 2021. See 130 CMR 610.015(B) and Exhibit 1. Denial of a request for prior authorization is a valid basis for appeal. See 130 CMR 610.032.

Action Taken by MassHealth

MassHealth denied Appellant's PA request for Saxenda 18 mg/3 ml pen.

Issue

The appeal issue is whether MassHealth was correct in denying Appellant's PA request for Saxenda 18 mg/3 ml pen.

Summary of Evidence

A registered pharmacist from MassHealth's Drug Utilization Review (DUR) Program appeared at the hearing via telephone and testified as follows: Appellant is an adult MassHealth member under the age of 65. See Exhibit 4, p. 3. On October 1, 2021 MassHealth received a prior authorization (PA) request from Appellant's provider, sent on behalf of Appellant, seeking initial approval for Saxenda 18/mg/3ml pen-injectors. See Exh. 4, p. 3. According to the PA request, Appellant's provider, a specialist in obesity medicine, indicated that the primary diagnosis related to the medication request was "obesity, unspecified." Id. at 4. Appellant has a body mass index (BMI) of 38 and is enrolled in a diet and lifestyle modification program through Mass General Hospital (MGH). The PA request indicated that Appellant ended a previous therapy of Metformin as on June 10, 2021 due to gastrointestinal (GI) distress. Id. at 4. Appellant is unable to take stimulant weight loss medications due to hypertension. Id. at 5.

Through a notice dated October 1, 2021, MassHealth informed Appellant that it denied her PA request for Saxenda because "MassHealth does not pay for any drug used for the treatment of obesity." Id. at 7. Documentary submissions indicate that Saxenda is a glucagon-like peptide-1 (GLP-1) receptor agonist that has been FDA approved for the treatment of chronic weight management in adult patients who are "obese" (30 kg/m² or greater), or who are "overweight" (27 kg/m² or greater) in the presence of at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia). Id. at 17. The MassHealth representative explained that MassHealth regulations at 130 CMR 406.413(B) specifically exclude coverage for drugs intended for obesity management. Because this drug is FDA approved solely for chronic weight management, it is excluded from MassHealth coverage.

Appellant appeared by telephone and testified that her obesity has impeded her ability to maintain a normal life. Despite being capable of work, no one is willing to hire her because of her weight. Her mental health has suffered as a result. Appellant explained that the history of GLP-1 antagonist drugs was initially used to treat diabetes by reducing A1C levels, not weight loss. During treatment it was observed that the reduction of A1C also helped patients lose weight. Appellant previously did a trial of Saxenda and had extremely positive results and was able to lose weight. It has been the only medication she has been truly effective. She has tried many other weight loss medications in the past which did not work and/or she was unable to take. After she ended Saxenda, however, her A1C levels increased and she regained weight. She also suffers from diabetes and hypertension. Without this medication, she will remain unemployed, on food stamps, and will incur additional health problems – all of which will be more costly to the state than simply covering the drug. As a MassHealth recipient she should be entitled to this medically necessary medication which has proven to be effective. Appellant noted that the regulations have an exception that should entitle her to this drug.

In response, the MassHealth representative explained that she was aware that Saxenda is designed to reduce A1C levels, however it has only received FDA approval for the treatment of obesity and weight management. MassHealth will not pay for an off-label use of a drug. There are similar medications indicated for the treatment of diabetes, but Saxenda has not been approved in this regard.

Findings of Fact

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

1. Appellant is an adult MassHealth member under the age of 65.
2. On October 1, 2021 MassHealth received a PA request from Appellant's provider, sent on behalf of Appellant, seeking initial approval for Saxenda 18/mg/3ml pen-injectors.
3. According to the PA request, Appellant's provider, a specialist in obesity medicine, indicated that the primary diagnosis related to the medication request was "obesity, unspecified."
4. Appellant has a BMI of 38 and is enrolled in a diet and lifestyle modification program through MGH.
5. Through a notice dated October 1, 2021, MassHealth informed Appellant that it denied her PA request for Saxenda because "MassHealth does not pay for any drug used for the treatment of obesity."
6. Saxenda is a GLP-1 receptor agonist that has been FDA approved for the treatment of chronic weight management in adult patients who are clinically "obese" or who are clinically "overweight" with at least one weight-related comorbid condition (e.g. hypertension, type 2 diabetes mellitus, or dyslipidemia).

Analysis and Conclusions of Law

MassHealth covers the cost of prescription drugs for eligible MassHealth members, subject to restrictions and limitations described in its regulations. See 130 CMR 406.403. Generally, MassHealth does not pay for any drug prescribed for other than the FDA-approved indications as listed in the package insert. See 130 CMR 406.413(C)(3). Through its published "Drug List" MassHealth identifies the commonly prescribed medications/drugs that are payable under MassHealth and whether coverage for such drugs must be requested through MassHealth's prior authorization (PA) process. See 130 CMR 406.412; see also 130 CMR 406.402. Coverage for drugs that do not appear on the MassHealth Drug List, may be requested through the prior authorization process, "*[e]xcept for the [excluded] drugs and drug therapies described in 130 CMR 406.413(B).*" 130 CMR 406.402; see 130 CMR 406.413(C). MassHealth provides the following regarding drugs that are excluded from coverage:

(B) **Drug Exclusions**. 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 the mentally retarded (ICF/MR).

(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 drug when used for the treatment of male or female sexual dysfunction. (130 CMR 406.413(B)).

130 CMR 406.413(B)

Appellant, through her provider, sought MassHealth approval for Saxenda – a drug that is FDA approved and used for the treatment of obesity and weight management. In the PA request, Appellant’s provider identified Appellant’s diagnosis of “obesity, unspecified” as the basis for the requested treatment. See Exh. 4. At hearing, Appellant testified that her issue with weight negatively affects her other conditions, including diabetes, her mental health, and inability to get hired for a job. By denying coverage - Appellant argues – the State will incur greater costs on unemployment, food stamps, and additional medical expenses. Despite Appellant’s testimony, the MassHealth regulations are unambiguous on this issue. MassHealth explicitly excludes from coverage any drug “***used for the treatment of obesity.***” 130 CMR 406.413(B)(4). Because Saxenda is specifically indicated for this purpose, it is not covered by MassHealth. While MassHealth may pay for medications used to treat “related” conditions (diabetes, depression), it has nonetheless implemented a regulatory prohibition on coverage of drugs used for obesity management. Id.

Furthermore, the sole regulatory exception to 130 CMR 406.413(B) applies to enrollees *under the age of 21*, who may seek coverage of an excluded drug through a showing of medical necessity. See 130 CMR 406.413(C). This exception is not applicable in the instant case as Appellant is over the age of 21. While MassHealth carved out an avenue for providers to request drugs that are otherwise *limited* in coverage, (i.e. more-costly brand name drug when there is a

less-costly generic available),¹ it does not extend to *excluded* drugs described in 130 CMR 406.413(B), above. See 130 CMR 406.422; see also 130 CMR 406.413(A), (C).

Based on the foregoing, MassHealth did not err in denying Appellant's PA request for Saxenda. The appeal is DENIED.

Any argument made by Appellant about the fairness or sufficiency of the controlling regulations cannot be addressed here. If Appellant wishes to seek judicial review of the legality or sufficiency of any MassHealth regulations, she must do so in accordance with 130 CMR 610.092.²

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.

Casey Groff
Hearing Officer
Board of Hearings

cc:

MassHealth Representative: UMMS Drug Utilization Review, Commonwealth Medicine, 333 South Street, Shrewsbury, MA 01545

¹ Under this avenue, the prescriber may submit a medical necessity narrative in cases where the limitations on covered drugs under 406.313(A) and (C) would result in inadequate treatment for a diagnosed medical condition. See 130 CMR 406.422. Notably, this provision omits reference to excluded drugs described in subsection 406.413(B). Id.

² 130 CMR 610.082 (C) ("Basis of Fair Hearing Decisions") states in pertinent part:(2) Notwithstanding 130 CMR 610.082(C)(1), the hearing officer shall not render a decision regarding the legality of federal or state law including, but not limited to, MassHealth's regulations. If the legality of such law or regulations is raised by the appellant, the hearing officer shall render a decision based on the applicable law or regulation as interpreted by MassHealth. Such decision shall include a statement that the hearing officer cannot rule on the legality of such law or regulation and shall be subject to judicial review in accordance with 130 CMR 610.092.