

Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2407528
Decision Date:	08/22/2024	Hearing Date:	06/17/2024
Hearing Officer:	Christine Therrien	Record Open to:	07/11/2024

Appearance for Appellant:



Appearance for MassHealth:

Phuong Luc, Pharm.D., 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 (DUR)
Decision Date:	08/22/2024	Hearing Date:	06/17/2024
MassHealth's Rep.:	Phuong Luc	Appellant's Rep.:	Pro se, with mother
Hearing Location:	Quincy Harbor South - Telephonic		

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 4/23/24, MassHealth denied the appellant's request for prior authorization (PA) for [REDACTED] Extended-Release (ER) 8-90 mg. [REDACTED] because MassHealth does not pay for legend drugs that are manufactured by companies that have not signed rebate agreements with the U.S. Secretary of Health and Human Services (HHS). (130 CMR 406.412; and Exhibit 1). The appellant filed this appeal with the Board of Hearings on 5/9/24. (130 CMR 610.015(B); Exhibit 2.) Denial of PA is a valid ground for appeal. (130 CMR 610.032.)

Action Taken by MassHealth

MassHealth denied the appellant's request for PA of [REDACTED]

Issue

The appeal issue is whether MassHealth was correct, pursuant to 130 CMR 406.412, in denying the appellant's PA request for [REDACTED]

Summary of Evidence

A MassHealth representative from the UMass Drug Utilization Review Program (DUR) submitted into evidence a copy of a PA request for the prescription drug [REDACTED] ER 8-90 mg. tablet. (Exhibit 5). The PA request, dated 4/22/24, states the [REDACTED] was prescribed to treat the appellant's obesity. (Exhibit 5, p. 4). The MassHealth representative testified that this PA request was denied on 4/23/23 because MassHealth does not pay for legend drugs that are manufactured by companies that have not signed rebate agreements with the HHS. (Exhibit 1).

The MassHealth representative testified that the information submitted by the appellant was insufficient to determine medical necessity. MassHealth sent a letter to the appellant detailing the information missing from the appellant's PA request. Specifically, MassHealth requested that the appellant's provider submit information on trials of alternative agents whose manufacturers take part in the federal rebate program, as well as the clinical rationale for using an agent whose manufacturer does not take part in the federal rebate program. (Exhibit 5). Under 130 CMR 406.412(A)(1), MassHealth will pay for prescription drugs that have been approved by the U.S. Food and Drug Administration (FDA) and are manufactured by companies that have rebate agreements with the HHS. The manufacturer of [REDACTED] has not signed a rebate agreement with HHS. (Exhibit 5, p. 12). The appellant's provider did not submit additional information.

The MassHealth representative explained that there are 12 other drugs to treat the appellant's condition that do have rebate agreements with HHS. For MassHealth to consider [REDACTED] for the appellant, the appellant's provider can document why the appellant has an acute contraindication to the other medications available.

The appellant was represented by his mother who appeared telephonically and testified that the appellant has had adverse reactions to injectables. (Exhibit 6, p.11). The appellant's representative testified that she has heard there are shortages of other medications, which makes [REDACTED] the only medication available for the appellant. The appellant's representative testified that the appellant takes several other medications, and some of the medications on the approved list are contraindicated.

The MassHealth representative testified that there are drugs on the list that are not injectables. The MassHealth representative testified that the burden is on the provider to show MassHealth that every drug on the list is contraindicated.

The record was left open until 7/11/24 to give the appellant the opportunity to submit additional information from his provider for the DUR to review.

The appellant did not submit any additional information.

Findings of Fact

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

1. On 4/22/24, a PA request for the prescription drug [REDACTED] ER 8-90 mg. tablet, prescribed to treat the appellant's obesity, was submitted to MassHealth.
2. On 4/23/23, the PA request was denied because MassHealth does not pay for legend drugs that are manufactured by companies that have not signed rebate agreements with the HHS.
3. The information submitted by the appellant was insufficient to determine medical necessity.
4. MassHealth sent a letter to the appellant requesting that the appellant's provider submit information on trials of alternative agents whose manufacturers take part in the federal rebate program, as well as the clinical rationale for using an agent whose manufacturer does not take part in the federal rebate program.
5. Under 130 CMR 406.412(A)(1), MassHealth will pay for prescription drugs that have been approved by the FDA and are manufactured by companies that have rebate agreements with the HHS. The manufacturer of [REDACTED] has not signed a rebate agreement with HHS.
6. The appellant's provider did not submit additional information.
7. There are 12 other drugs to treat the appellant's condition whose manufacturers have signed rebate agreements with HHS, several of which are non-injectables.
8. For MassHealth to consider [REDACTED] for the appellant, the appellant's provider can document why the appellant has an acute contraindication to the other medications available.
9. The appellant has had adverse reactions to injectables.
10. The record was left open until 7/11/24 to allow the appellant to submit additional information from his provider for the DUR to review.
11. The appellant did not submit any additional information.

Analysis and Conclusions of Law

Pursuant to MassHealth regulation 130 CMR 450.204:

The MassHealth agency will not pay a provider for services that are not medically necessary and may impose sanctions on a provider for providing or prescribing a service or for admitting a member to an inpatient facility where such service or admission is not medically necessary.

(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....

Additionally,

[i]n certain instances, the MassHealth agency requires providers to obtain prior authorization to provide medical services. These instances are identified in the billing instructions, program regulations, associated lists of service codes and service descriptions, provider bulletins, and other written issuances from the MassHealth agency.

(130 CMR 450.303)

MassHealth's specific service limitations include coverage of prescription drugs. The pertinent regulations related to prescription drug requests are set forth in the Pharmacy Manual regulations found at 130 CMR 406.000. "Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303." (130 CMR 406.422(A)). "The MassHealth agency pays only for prescription drugs that are approved by the

U.S. Food and Drug Administration 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)).

The appellant requested PA for [REDACTED] which is a drug whose manufacturer does not have a rebate agreement with HHS. MassHealth indicated that it may be able to determine medical necessity for the product if the appellant’s provider submits information on trials of alternative agents whose manufacturers take part in the federal rebate program, and on the clinical rationale for using an agent whose manufacturer does not take part in the federal rebate program. None of this information was provided to MassHealth either before the hearing, at the hearing, or during a record open period following the hearing.

The appellant’s representative stated the appellant has not trialed all of the drugs for his condition which HHS will rebate because the appellant has had adverse reactions to injectables. The regulations are clear in the requirement that a prescription drug must be approved by the FDA¹ and be manufactured by a company that has a rebate agreement with HHS in order to be eligible for coverage by MassHealth. The appellant has had adverse reactions to injectables, but he has not tried the various other oral medications whose manufacturers have rebate agreements with HHS. It is not clear which drugs may be effective for the appellant because there was no evidence presented to show that he had tried all of the alternative medications that are covered by MassHealth.

Accordingly, the appeal is denied.

Order for MassHealth

None.

Notification of Your Right to Appeal to Court

¹ There is no dispute that [REDACTED] has been approved by the FDA.

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.

Christine Therrien
Hearing Officer
Board of Hearings

MassHealth Representative: Drug Utilization Review Program, ForHealth Consulting at UMass Chan Medical School