Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2418319
Decision Date:	01/14/2025	**Hearing Date:**	01/03/2025
Hearing Officer:	Amy B. Kullar, Esq.		

Appearance for Appellant:

[redacted]

Appearance for MassHealth:

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

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; Mounjaro
Decision Date:	01/14/2025	**Hearing Date:**	01/03/2025
MassHealth's Rep.:	Phuong Luc	**Appellant's Rep.:**	Pro se
Hearing Location:	Quincy Harbor South 7 (Telephone)	**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 23, 2024, MassHealth notified the appellant that it denied the prior authorization (PA) request for the prescription medication Mounjaro. *See* 130 CMR 406.413 and Exhibit 1. The appellant filed this appeal in a timely manner on November 29, 2024. *See* 130 CMR 610.015(B) and Exhibit 2. Denial of assistance is valid grounds for appeal. *See* 130 CMR 610.032.

Action Taken by MassHealth

MassHealth notified the appellant that it denied the PA request for the prescription medication Mounjaro.

Issue

The appeal issue is whether MassHealth correctly denied the PA request for the prescription medication Mounjaro.

Summary of Evidence

The appellant is an adult under the age of 65 who appeared telephonically and verified their identity. MassHealth was represented by a licensed pharmacist with MassHealth's Drug Utilization Review Program (DUR), who also appeared by telephone. The following is a summary of the testimony and evidence presented at hearing.

On October 23, 2024, MassHealth received a PA request on behalf of the appellant for Mounjaro, 12.5 mg./0.5 ml. pen to treat type 2 diabetes mellitus. Mounjaro, an injectable prescription medication, is a glucose-dependent insulinotropic polypeptide (GIP) receptor and a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. To approve a request for this medication for type 2 diabetes, MassHealth requires an appropriate diagnosis, appropriate dose and frequency, and trials of less-costly alternatives, such as Byetta, Trulicity, or Victoza for at least 90 days of therapy within a 120-day time period (Exhibit 5, pp. 41-43).

The DUR representative reviewed the PA request submitted on the appellant's behalf. The appellant's provider requested Mounjaro (tirzepatide) 12.5 mg./0.5 ml. pen to treat the appellant's type 2 diabetes mellitus (Exhibit 5, p. 4). The appellant's provider noted that the appellant's most recent A1C level is 5.8, as of July 2, 2024 (Exhibit 5, p. 5). The appellant's provider did not indicate that the appellant is currently prescribed any other antidiabetic medication. *Id*.

In response to the Additional Comments section of the PA request, the appellant's provider responded "No" to the questions "Has the patient had a failure, contraindication, or intolerance to metformin therapy?" and "Has the patient had a failure, contraindication, or intolerance to a GLP-1 receptor agonist?" (Exhibit 5, p. 11).

The DUR representative testified that there was no documentation submitted by the appellant's provider indicating that the appellant has tried metformin used in combination with Byette, Trulicity, or Victoza (*See* Exhibit 5, p. 5). Thus, the appellant's PA request was denied and MassHealth sent a denial notification to the appellant's provider; the following comment was included:

> Your prior authorization request for MOUNJARO 12.5 MG./0.5 ML. PEN is denied. MassHealth has concluded that there are more cost-effective alternatives. Please consider the use of metformin in combination with a GLP-1 agonist available without prior authorization. For additional information, please refer to the Therapeutic Class Tables at www.mass.gov/druglist.

(Exhibit 5 at 24).

The DUR representative stated that a letter was sent to the appellant on December 17, 2024, including the rationale for the denial and what the appellant's provider would need to submit as additional documentation for DUR to consider for approving the PA request (Exhibit 5, pp. 26-27). To date, DUR has not received any additional documentation from the appellant's provider.

The appellant testified that they had seen their primary care provider the day before the hearing, and that there seems to be a lot of confusion for their doctor as to why the appellant is not being approved for Mounjaro by MassHealth. The appellant does not understand why they cannot use Mounjaro when it is working for them. The appellant stated that the reason they did not do a trial of metformin was because the appellant is at risk of liver disease. When questioned, the appellant acknowledged that this diagnosis and risk was not documented in the PA request or noted in their list of diagnoses.

Findings of Fact

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

1. The appellant is an adult MassHealth CarePlus member. Exhibit 4.

2. On October 23, 2024, the appellant's provider submitted a prior authorization request seeking coverage for the prescription medication Mounjaro (tirzepatide), 12.5 mg./0.5 ml. pen, to treat the appellant's type 2 diabetes.

3. On October 23, 2024, MassHealth denied the appellant's request. Testimony and Exhibit 1.

4. The appellant timely appealed the denial to the Board of Hearings on November 29, 2024. Exhibit 2.

5. Mounjaro is an injectable medication indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

6. Mounjaro belongs to a class known as a glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) agonist.

7. For those with a diagnosis of type 2 diabetes, MassHealth will approve a request for Mounjaro with documentation of appropriate dose and frequency, trials of less-costly alternatives, and documentation that it will not be used in combination with another GLP-1 agonist.

8. The appellant has a documented diagnosis of type 2 diabetes.

9. The appellant's medical provider did not include any specifics about trials with Byette,

Trulicity, or Victoza including dates, duration, and/or whether these medications were taken separately or together.

10. The appellant's medical provider did not submit any documentation indicating that said trials took place in combination therapy.

Analysis and Conclusions of Law

MassHealth does not cover a medical service unless it is "medically necessary." The threshold considerations for determining whether a service is medically necessary are set forth under 130 CMR 450.204, which states, in full:

450.204: 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.

(130 CMR 450.204) (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; 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."[1] Further, the criteria set forth reflects MassHealth's policy as described in its pharmacy regulations and the reviews conducted by the agency and the DUR board. *Id.*

As published in its Drug List, MassHealth has imposed the following PA criteria for coverage of Mounjaro:

Mounjaro

- Documentation of all of the following is required for the diagnosis of type 2 diabetes:
    - appropriate diagnosis; **and**
    - one of the following:
        - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to metformin used in combination with Byetta, liraglutide (generic Victoza), or Trulicity; **or**
        - adverse reaction or contraindication to metformin and inadequate response (defined as ≥ 90 days of therapy within a 120-day time period) to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
        - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, liraglutide (generic Victoza), or Trulicity; **or**
        - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contraindication to Byetta, liraglutide (generic Victoza), or Trulicity; **and**
    - inadequate response (defined as ≥ 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to Ozempic; **and**
    - the requested agent will not be used in combination with a GLP-1 receptor agonist; **and**
    - if requested quantity exceeds quantity limits, clinical rationale why dose cannot be consolidated or for exceeding FDA-approved dosing.

(*See* Exhibit. 5, p. 29-44; the MassHealth Drug List, Table 26 (www.mass.gov/druglist)).

At issue in this case is MassHealth's denial of a PA request for the injectable prescription

[1] *See* https://mhdl.pharmacy.services.conduent.com/MHDL/

medication Mounjaro 12.5 mg./0.5 ml. pen. MassHealth denied the request on the basis that the appellant's provider did not submit any documentation indicating that the appellant tried combination therapy of less-costly alternatives such as metformin and either Byette, Trulicity, or Victoza therapy for at least 90 days within a 4-month time period (including specific dates of use). The appellant does not dispute this fact but argues that MassHealth should pay for the medication because the appellant's provider believes it will help the appellant lower their blood sugars, A1C level and weight.

Based on the evidence in the record, MassHealth did not err in denying the appellant's PA request. While there is no question that the appellant has been diagnosed with type 2 diabetes, the appellant's provider did not submit documentation to establish the requisite criteria that the appellant has had an "inadequate response…or adverse reaction to all other stimulant and non-stimulant medications." *Id.* Thus, I find that the appellant has not demonstrated, by a preponderance of the evidence, that MassHealth should authorize payment for Mounjaro in accordance with the pertinent regulations set forth above. On this record, the appeal is denied.[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.

Amy B. Kullar, Esq.
Hearing Officer
Board of Hearings

MassHealth Representative: Drug Utilization Review Program, ForHealth Consulting at UMass Chan Medical School, P.O. Box 2586, Worcester, MA 01613-2586

[2] This denial does not preclude the appellant's medical provider from submitting a new prior authorization request to DUR, including all supporting documentation for review.