Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2405606
Decision Date:	7/3/2024	**Hearing Date:**	05/06/2024
Hearing Officer:	Kimberly Scanlon		

Appearance for Appellant:
Via telephone
Pro se

Appearance for MassHealth:
Via telephone
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:	7/3/2024	**Hearing Date:**	05/06/2024
MassHealth's Rep.:	Phuong Luc	**Appellant's Rep.:**	Pro se
Hearing Location:	Quincy Harbor South 6 (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 April 1, 2024, MassHealth notified the appellant that it denied the prior authorization (PA) request for the prescription medication Mounjaro (130 CMR 406.413; Exhibit 1). The appellant filed this appeal in a timely manner on or about April 5, 2024 (130 CMR 610.015(B); Exhibit 2). Denial of assistance is valid grounds for appeal (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 parties appeared telephonically. MassHealth was represented by a licensed pharmacist with MassHealth's Drug Utilization Review Program (DUR). On April 1, 2024, MassHealth received a PA request on behalf of the appellant for Mounjaro, 2.5 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 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, trials of less-costly alternatives, such as Metformin, Trulicity, or Victoza for at least 90 days of therapy within a 120-day time period (Exhibit 6, pp. 67-68).

The DUR representative reviewed the PA request submitted on the appellant's behalf.[1] The appellant's provider requested Mounjaro (tirzepatide) 2.5 mg/0.5 ml pen to treat the appellant's type 2 diabetes mellitus (Exhibit 6, p. 4). The appellant's provider noted that the appellant's most recent A1c level is 7.9, as of February 22, 2024 (Exhibit 6, p. 5). The appellant's provider further noted that all other antidiabetic medication currently prescribed to him includes the following:

Lantus, dose and frequency is 45 units QD, dates of use states current;
Jenuvia, dose and frequency is 100 mg QD, dates of use states 2015 to current; and
Pieglitazone, dose and frequency states adverse reaction. *Id*.

In response to the question of which additional behavioral health services would be beneficial, the appellant's provider noted that the appellant had an adverse reaction to metformin. On Section 1 of the PA request, the appellant's provider indicated that the appellant tried metformin in combination with at least one of the non-metformin agents in the requested combination. The appellant's provider signed the PA request on March 26, 2024 (Exhibit 6, p. 10). DUR received the request on April 1, 2024. The appellant's provider also indicated in the "additional comments" section that the appellant's diagnosis is: Type 2 diabetes mellitus, the appellant has tried and failed or was unable to tolerate metformin (alone or in combination), his recent hemoglobin A1c is 7.9, and the PA request submitted is for an initiation of therapy. Further, the appellant's prescriber does not believe there has been a positive clinical response while on Ozempic, with a notation that states "you will not cover Ozempic" (Exhibit 6, p. 10).

The DUR representative testified that although the PA request submitted on behalf of the appellant noted that the appellant had an adverse reaction to metformin, the dose and frequency of use for Mounjaro was unclear. Additionally, 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 6, p. 5). Thus, the appellant's PA request was denied and a

[1] At the hearing, the DUR representative noted that there was a total of 5 PA requests submitted on behalf of the appellant from his provider, all of which were received between March and May of 2024.

denial notification was sent to his provider on April 1, 2024 (Exhibit 6, p. 13). After this denial notice was sent to appellant's provider, the DUR representative stated that she received another PA request from the appellant's provider on April 9, 2024 (Exhibit 6, pp. 14-22). The variations between the PA requests received from the appellant's provider on April 1, 2024 and April 9, 2024 included, but is not limited to, the following: on the April 9th PA request, the appellant's provider indicated that the appellant tried metformin and had an adverse reaction prior to becoming a patient of his (Exhibit 6, p. 16). Further, the appellant's provider indicated on the April 9th PA request that the appellant experienced an inadequate response to metformin from 2011-2017 (Exhibit 6, p. 19). The DUR representative explained that although the appellant's provider clarified the time and frequency for the request of Mounjaro, said provider did not submit documentation indicating that the appellant tried less-costly alternatives. As a result, the April 9th PA request was also denied and the appellant's provider was notified of such on that same date (Exhibit 6, p. 23). On the April 1st and April 9th denial notices that MassHealth sent to the appellant's provider the following comment was included:

> Your prior authorization request for MOUNJARO 2.5 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 6, pp. 13, 23).[2]

The DUR representative stated that a letter was sent to the appellant on April 22, 2024, that included the reasoning for the denial and what his provider would need to submit for additional documentation for DUR to consider for approving the PA requests (Exhibit 6, pp. 47-48). To date, DUR has not received any additional documentation from the appellant's provider.

The appellant testified that he previously took metformin for several years until he began to experience adverse reactions. At that time, his former provider advised him to stop taking that medication. The appellant took his advice and stopped taking metformin. This occurred years before the appellant began seeing his current provider, who submitted the PA requests described above. The appellant acknowledged that the PA requests were denied, for the reasoning set forth above. As to the combination therapy of metformin and either Trulicity or Victoza for at least 90 days within a 4-month period (including specific dates of use), the appellant stated that Victoza

[2] The DUR representative testified that she received another PA request from the appellant's provider the evening of April 9, 2024, which did not contain any additional information (See, Exhibit 6, pp. 25-32). This request was denied for the same reasoning set forth in the April 1st and April 9th denial letters (Exhibit 6, p. 35). Additionally, the DUR representative testified that she received 2 more PA requests from the appellant's provider on April 17, 2024, and on May 1, 2024, respectively. Although the appellant's provider indicated on the April 17th and May 1st PA requests that the appellant has tried metformin used in combination with Byette, Trulicity, or Victoza, said provider did not include any additional details in his submission to DUR (See, Exhibit 6, p. 39).

was taken off the market for some time and now includes a black box warning. The appellant explained that he does not want to take a medication that causes extreme side effects. He stated that he wants to take Mounjaro, which is covered by his insurance. He does not understand the reason for the denial of the PA requests. The appellant is a type 2 diabetic and has been for over 10 years. Further, his A1c level has increased, and his weight has increased. The appellant testified that he feels that he should (is entitled to) receive Mounjaro because it is affecting his health. He feels that the entire waiting process with MassHealth has been ridiculous and is simply looking to get his health back on track by decreasing his blood sugars, A1c levels, and his weight. The appellant has not attempted to take Trulicity. He stated that while all these medications cause side effects, he believes that Mounjaro is one of the better medications. The appellant stated that he does not understand why MassHealth wants him to take all these other medications in combination for 90 days, rather than simply approving him for Mounjaro. The appellant testified that he is a father and wants to live a while longer. Therefore, he is trying to do everything he can to improve his health. He expressed his confusion regarding the reason for MassHealth asking him to try other medications when Mounjaro is the medication that he wants. Furthermore, it is the medication that his provider requested for approval.

The DUR representative acknowledged the appellant's concerns surrounding Victoza and clarified that Mounjaro also has a black box warning for thyroid cancer. She explained that all drugs have risks and side effects. Additionally, the regulations and clinical guidelines mandate that less-costly alternatives must be tried if comparable to treatment for type 2 diabetes.

The appellant stated that his friend was instantly approved for Mounjaro, without the need to try less-costly alternatives. He asked why DUR is giving him such a hard time. The appellant stated that the PA requests submitted by his provider include all the information needed for approval. His provider never mentioned less-costly alternatives, nor does he wish to try any other medications except for Mounjaro. The appellant stated that he feels it's all about money and that MassHealth is trying to get him to take a less expensive medication. He reiterated that Victoza has a black box warning and stated that Mounjaro does not have any warnings that he has seen. The appellant expressed his frustration with the denial of his PA requests and stated that his health has not improved in the interim. His providers feel that Mounjaro will be beneficial to him, and the appellant wants to live as long as he can.

Findings of Fact

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

1. The appellant is an adult male who receives MassHealth Standard coverage.

2. On April 1, 2024, the appellant's provider submitted a prior authorization request seeking coverage for the prescription medication Mounjaro (tirzepatide), 2.5 mg/0.5 ml pen, to treat

the appellant's type 2 diabetes.

3. On April 1, 2024, MassHealth denied the appellant's request.

4. The appellant's provider submitted an additional 4 PA requests on behalf of the appellant, all of which MassHealth denied.

4. On April 5, 2024, the appellant timely appealed MassHealth's denial of the April 1, 2024 PA request.

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 metformin, 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."[3] 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.*

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

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

Mounjaro

- Documentation of the following is required for the diagnosis of type 2 diabetes:
  - appropriate diagnosis; **and**
  - one of the following:
    - inadequate response (defined as greater than or equal to 90 days of therapy within a 120-day time period) to Byetta, Trulicity, or Victoza, **or**
    - adverse reaction or contraindication to metformin and inadequate response (defined as greater than or equal to 90 days of therapy within a 120-day time period) to Byette, Trulicity, or Victoza; **or**
    - inadequate response (defined as greater than or equal to 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and adverse reaction to Byetta, Trulicity, or Victoza, **or**
    - inadequate response (defined as greater than or equal to 90 days of therapy within a 120-day time period), adverse reaction, or contraindication to metformin and contradiction to to Byetta, Trulicity, and Victoza, **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 for exceeding FDA-approved dosing.

(See, Exhibit. 6, p. 67-68; 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 medication Mounjaro 2.5 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 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 his provider believes it will help him lower his 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, his 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.* Additionally, the appellant testified that he does not want to try other

medications. 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.[4]

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.

Kimberly Scanlon
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, 774-455-3200

[4] 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.