

Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



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| Appeal Decision: | Denied | Appeal Number: | 2309642 |
| Decision Date: | 03/19/2024 | Hearing Date: | 11/14/2023 |
| Hearing Officer: | Kimberly Scanlon | Record Open to: | 12/19/2023 |

Appearance for Appellant:

Via telephone

Pro se

Appearances for MassHealth:

Via telephone

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

Kyle Semmel, Pharm.D., MassHealth Drug Utilization Review (DUR) Program (observing)



*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

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|----------------------------|---------------------------------|--------------------------|--|
| Appeal Decision: | Denied | Issue: | Prior Authorization; Drug Utilization Review; Mounjaro |
| Decision Date: | 03/19/2024 | Hearing Date: | 11/14/2023 |
| MassHealth's Reps.: | Phuong Luc; Kyle Semmel | Appellant's Rep.: | Pro se |
| Hearing Location: | Quincy Harbor South (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 August 18, 2023, MassHealth notified the appellant that it denied the prior authorization for the prescription medication Mounjaro (130 CMR 406.413; Exhibit 1). The appellant filed this appeal in a timely manner on October 12, 2023 (130 CMR 610.015(B); Exhibit 2). Denial of assistance is valid grounds for appeal (130 CMR 610.032). At the conclusion of the hearing, the record was left open until December 19, 2023 for the appellant's provider to submit additional documentation (Exhibit 8).

Action Taken by MassHealth

MassHealth notified the appellant that it denied the prior authorization for the prescription medication Mounjaro.

Issue

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

Summary of Evidence

The appellant appeared telephonically. MassHealth was represented telephonically by two licensed pharmacists with MassHealth's Drug Utilization Review Program (DUR). On August 18, 2023, MassHealth received a prior authorization request on behalf of the appellant for Mounjaro, 5 mg/0.5 ml pen to treat type 1 diabetes mellitus. Mounjaro, an injectable prescription medication, is a glucose-dependent insulintropic 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, MassHealth requires a diagnosis of type 2 diabetes, appropriate dose and frequency, trials of less-costly alternatives, and documentation that it will not be used in combination with another GLP-1 agonist. For a diagnosis other than type 2 diabetes, DUR also requires documentation of clinical rationale for use, including current peer-reviewed journal articles documenting the safety and efficacy of Mounjaro for the provided indication, and any previous drug trials.

The DUR representative reviewed the prior authorization request submitted on the appellant's behalf. The appellant's provider requested Mounjaro (tirzepatide) 5 mg/0.5 ml pen to treat the appellant's type 1 diabetes mellitus (Exhibit 6, p. 4). The appellant's provider notes that the appellant's most recent A1C level is 10. The DUR representative referred to Section II of the request, which applies to requests for Mounjaro and seeks information about trials with less costly medications; she stated that this section of the request was left blank (Exhibit 6, p. 5). The provider indicates on the request that the appellant has diagnoses including type 1 diabetes mellitus and obesity (Exhibit 6, p. 10). The provider notes in his comments that the appellant had a failed trial with or contraindication/intolerance to metformin therapy and will not be taking metformin in combination with Mounjaro. Additionally, her provider indicates that she will not be taking Mounjaro in combination with another GLP-1 receptor agonist and has not had a failed trial with another GLP-1 receptor agonist. He writes that the request is for a continuation of therapy and that he believes that the appellant has had a positive response while on Mounjaro (Exhibit 6).

The appellant's medical provider provided some medical records in which he notes that the appellant's medications include, *inter alia*, Trulicity 0.75 mg/0.5 ml pen injector; 0.75 mg every week by subcutaneous route for 30 days (Exhibit 6, p. 13). The appellant's past medical history includes type 1 diabetes mellitus, uncontrolled, with an onset date of [REDACTED] (Exhibit 6, p. 14). The appellant's provider reported that appellant had a transient loss of appetite on Trulicity 0.75 mg weekly and is now back to baseline. The appellant noted improvement in sugars, but her weight is unchanged. The provider recommended an increase in Trulicity to 1.5 mg weekly and

insulin adjustments as needed (Exhibit 6, p. 16).

The DUR representative testified that MassHealth denied the prior authorization request because the appellant does not have type 2 diabetes. Although trials of metformin and Trulicity (the less costly alternatives) were mentioned, the appellant's provider did not include the exact dates these trials took place. Additionally, it remains unclear whether metformin was taken in combination with Trulicity. Lastly, the appellant's provider did not provide clinical rationale for use, including peer-reviewed articles to support the use of Mounjaro for the listed indication of type 1 diabetes. On August 18, 2023, MassHealth sent a denial notice to the appellant's provider with the following comment:

Your prior authorization request for MOUNJARO 5 MG/0.5 ML PEN is denied. Information provided did not contain sufficient information to determine medical necessity. Prescriber may resubmit a new prior authorization request with additional clinical documentation (e.g. medical records, diagnosis, previous drug trials with dates of therapy). Additional information regarding the MassHealth Drug List and specific prior authorization forms can be found at www.mass.gov/druglist.

(Exhibit 6, p. 18).

On November 2, 2023, DUR notified the appellant that the prior authorization request for Mounjaro was denied because DUR did not receive enough information (Exhibit 6, p. 20). DUR requested that the appellant contact her doctor to see if he could provide, in summary, the following information: Documentation that she has a diagnosis of type 2 diabetes mellitus, as well as documentation that she has trialed less costly alternatives. Alternatively, for a diagnosis other than type 2 diabetes, DUR requested documentation of the clinical rationale for use including current peer-reviewed journal articles documenting safety and efficacy of Mounjaro for the provided indication, and previous drug trials. The notice also states that MassHealth does not pay for any drug used for the treatment of obesity (Exhibit 6, pp. 20-21).

The DUR representative stated that on November 13, 2023, DUR received documentation from the appellant. She explained, however, that DUR needs documentation from the medical provider to establish medical necessity. To date, DUR has not received additional documentation from the appellant's medical provider.

The appellant testified that her medical provider recently left the practice. She stated that he initially told her that she was a type 2 diabetic, as she had experienced gestational diabetes during pregnancies that resolved after she gave birth. She then began seeing a different medical provider upon the former's departure who informed her that she is in fact a type 1 diabetic. The appellant explained that her most recent A1C level was 10.6 and she is fearful that she will die. Mounjaro is the only medication that helps with her symptoms. She used an insulin pump for 20 years and it

stopped working for her. She explained that she has tried metformin, and it does not help regulate her blood sugar. The appellant tried Trulicity and lost a few pounds, however, she had adverse reactions to this medication and could no longer continue. Mounjaro is the only medication that assisted with lowering her blood sugar levels.

The DUR representative responded and stated that DUR would review additional information from the appellant's medical provider. Specifically, DUR seeks clarification on whether the appellant has type 1 or type 2 diabetes. Further, additional information is needed regarding the length of time she tried metformin and Trulicity, as well as any adverse reactions or inadequate response she experienced. The record was left open for a brief period for the appellant's current provider(s) to submit the additional information; no additional information was submitted during the record-open period (Exhibits 8 and 9).

Findings of Fact

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

1. The appellant is an adult female who receives MassHealth Care Plus coverage.
2. On August 18, 2023, the appellant's provider submitted a prior authorization request seeking coverage for the prescription medication Mounjaro (tirzepatide), 5 mg/0.5 ml pen, to treat the appellant's type 1 diabetes.
3. On August 18, 2023, MassHealth denied the appellant's request.
4. On October 12, 2023, the appellant timely appeal MassHealth's denial of this prior authorization 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 insulinitropic 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. For those with a diagnosis other than type 2 diabetes, MassHealth also requires documentation of clinical rationale for use, including current peer-reviewed journal articles

documenting the safety and efficacy of Mounjaro for the provided indication, and any previous drug trials.

7. The appellant has a documented diagnosis of type 1 diabetes.
8. The appellant did not include any specifics about trials with metformin or Trulicity, including dates, duration, and/or whether these medications were taken separately or together.
8. The appellant's medical provider did not submit clinical rationale for use, including peer-reviewed articles to support the use of Mounjaro for type 1 diabetes.

Analysis and Conclusions of Law

MassHealth covers pharmacy services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations (130 CMR 406.403). Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303: *Prior Authorization* (130 CMR 406.422(A)). At issue in this case is MassHealth's denial of a request for the injectable prescription medication Mounjaro 5 mg/0.5 ml pen. MassHealth denied the request on the basis that this medication is currently only FDA-approved to treat type 2 diabetes mellitus, a diagnosis that the appellant has not documented that she carries. Instead, the appellant seeks coverage of the drug to treat type 1 diabetes, and MassHealth does not pay for drugs used "off-label" unless the use has been determined to be effective and safe. The appellant argues that MassHealth should pay for the medication because it is the only medication that has successfully lowered her blood sugar levels.

Under 130 CMR 406.413(C)(3), MassHealth does not pay for does not pay for any drug prescribed for other than the FDA approved indications as listed in the package insert, except as the MassHealth agency determines to be consistent with current medical evidence (130 CMR 406.413(C)(3)). Here, the appellant's provider did not submit any evidence, such as peer-reviewed studies, to demonstrate that Mounjaro is safe and effective to treat type 1 diabetes. Without this documentation, the appellant has not demonstrated that MassHealth should authorize payment for Mounjaro pursuant to this regulation.¹

MassHealth regulations also provide that 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

¹ To the extent that the appellant seeks coverage of Mounjaro to treat her diagnosis of obesity, MassHealth covers drugs that are not explicitly excluded under 130 CMR 406.413(B) (130 CMR 406.4013(C)). Per 130 CMR 406.413(B)(4), the MassHealth agency does not pay for any drug used for the treatment of obesity.

medical necessity, to the MassHealth agency for prior authorization for an otherwise noncovered drug (130 CMR 406.422(A)).

Per 130 CMR 450.204(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: *Potential Sources of Health Care*, or 517.007: *Utilization of Potential Benefits*.

Here, the appellant has not demonstrated that the requested medication is medically necessary. As noted above, she has not submitted evidence to confirm that Mounjaro is safe and effective to treat type 1 diabetes. Further, she has not fully documented trials with less costly alternatives including metformin and/or Trulicity (130 CMR 450.204(A)(1) and (2)).

On this record, the appeal is denied.²

Order for MassHealth

None.

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

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

cc:

MassHealth Representative: Drug Utilization Review Program, ForHealth Consulting at UMass Chan Medical School, P.O. Box 2586, Worcester, MA 01613-2586, 774-455-3200