

Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2301148
Decision Date:	4/25/2023	Hearing Date:	03/16/2023
Hearing Officer:	Patricia Mullen		

Appearance for Appellant:
Pro se

Appearance for MassHealth:
Meghan Serell, R.Ph., Drug Utilization
Review Program (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:	Prior authorization Trospium Chloride ER
Decision Date:	4/25/2023	Hearing Date:	03/16/2023
MassHealth's Rep.:	Meghan Serell, R.Ph., DUR	Appellant's Rep.:	Pro se
Hearing Location:	Quincy Harbor South		

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 February 4, 2023, MassHealth denied the appellant's request for prior authorization for the prescription medication Trospium Chloride ER, because MassHealth determined that there are more cost effective alternatives and therefore the request did not meet MassHealth medical necessity and prior authorization requirements. (see 130 CMR 450.204; 406.422; and Exhibits 1, 6, p. 7). The appellant filed this appeal in a timely manner on February 10, 2023. (see 130 CMR 610.015(B) and Exhibit 2). Denial of a request for prior authorization is valid grounds for appeal (see 130 CMR 610.032).

Action Taken by MassHealth

MassHealth denied the appellant's request for prior authorization for the prescription medication Trospium Chloride ER.

Issue

The appeal issue is whether MassHealth was correct, pursuant to 130 CMR 450.204; 406.422, in determining that the request for prior authorization for Trospium Chloride ER did not meet

MassHealth medical necessity or prior authorization criteria because there are less costly alternatives.

Summary of Evidence

The appellant appeared telephonically. MassHealth was represented telephonically by a pharmacist from MassHealth's DUR program. The appellant is between the ages of 19 and 65 and open on MassHealth CarePlus. (Exhibit 5). The MassHealth representative stated that the appellant's provider, Nurse Practitioner (NP) Marcelle Saurman, submitted a request for prior authorization (PA) for the prescription medication Trospium Chloride ER (extended release) 60 mg capsules, on February 3, 2023. (Exhibit 6, pp. 3-5). NP Saurman noted on the PA request form that the medication was prescribed for the appellant's diagnosis of overactive bladder, diagnosis code N32.81. (Exhibit 6, p. 3). Section 1, part 3 of the PA request form asks if the member has tried other medications to treat the condition and NP Saurman answered no. (Exhibit 6, pp. 3, 4). In an attachment to the PA request form, NP Saurman wrote that the appellant has hypertension and is not a candidate for Myrbetriq; NP Saurman wrote further that the appellant "has diabetes and needs an anticholinergic with the least drying leaving only trospium". (Exhibit 6, p. 5). A denial notification was faxed to NP Saurman from MassHealth's DUR program on February 4, 2023. (Exhibit 6, p. 7). In the comment section of the denial notification, MassHealth wrote that MassHealth has determined that there are more cost effective alternatives to Trospium Chloride ER 60 mg capsules and asked that the provider please consider the use of oxybutynin extended-release, Myrbetriq (mirabegron extended-release), tolterodine extended-release, fesoterodine, or solifenacin, which are available without prior authorization, if clinically appropriate. (Exhibit 6, p. 7). The notification stated further that additional information regarding the MassHealth Drug List and specific prior authorization forms can be found at www.mass.gov/druglist. (Exhibit 6, p. 7). The MassHealth representative stated that MassHealth requires prior authorization for Trospium Chloride ER and needs to see failed trials of lower cost alternatives before a request for Trospium Chloride ER could be approved. The appellant filed a timely appeal of the denial to the Board of Hearings on February 10, 2023 and the Board of Hearings issued a notice of hearing on February 15, 2023. (Exhibits 2, 4).

In preparation for the hearing, MassHealth's DUR program sent the appellant a letter dated February 27, 2023. (Exhibit 6, p. 9). The letter informed the appellant that the requested medication requires prior authorization. (Exhibit 6, p. 9). The letter requested that the appellant contact her medical provider and ask that the provider submit documentation that the appellant has tried two of the following agents, and they did not work, or the appellant had unacceptable side effects, or alternatively, provide a contraindication to all of the following: fesoterodine, Myrbetriq, oxybutynin ER tablet, solifenacin, and tolterodine ER. (Exhibit 6, p. 9).

The MassHealth representative stated that MassHealth received additional information from the appellant's provider on March 13, 2023. (Exhibit 8). The documentation included a request for prior authorization from NP Saurman dated March 10, 2023 for the prescription medication Trospium Chloride ER (extended release) 60 mg capsules. (Exhibit 8, pp. 3-5). NP Saurman noted on the PA request form that the medication was prescribed for the appellant's diagnosis of overactive bladder, diagnosis code N32.81. (Exhibit 8, p. 3). Section 1, part 3 of the PA request

form asks if the member has tried other medications to treat the condition and NP Saurman answered yes. (Exhibit 8, p. 3). NP Saurman noted that the appellant tried Vesicare 10 mg from February 7, 2023 to February 25, 2023 and had the adverse reaction of bothersome drying side effects. (Exhibit 8, p. 3). In an attachment to the PA request form, NP Saurman wrote that the appellant was not a candidate for Myrbetriq due to poor blood pressure control. (Exhibit 8, p. 5). NP Saurman wrote further that due to the appellant's other medical issues including hypothyroidism, adrenal insufficiency, diabetes mellitus, and the treatments for these conditions, the appellant reports significant baseline drying side effects. (Exhibit 8, p. 5). NP Saurman noted that in terms of anticholinergic medications, Trospium is thought to have the least drying side effects profile out of all the anticholinergic medications, especially when taken in an extended formulation. (Exhibit 8, p. 5). The appellant submitted a list of her medications and other medical conditions. (Exhibit 8, p. 6). The appellant reports that she has type II diabetes, asthma, allergies, skin conditions, ankle instability, right knee instability, and right hand instability. (Exhibit 8, p. 6).

The MassHealth representative stated that the MassHealth Drug List requires documentation of inadequate response or adverse reaction to two or contraindications to all of the following before Trospium Chloride would be covered: fesoterodine, Myrbetriq, oxybutynin extended-release, solifenacin, and tolterodine extended-release. (Exhibit 6, p. 14). The MassHealth representative noted that the appellant submitted documentation of the failed trial of Vesicare, which is solifenacin, but needs to document inadequate response or adverse reaction to fesoterodine, oxybutynin extended-release, or tolterodine extended-release. The MassHealth representative noted that the appellant's provider indicated that Myrbetriq is contraindicated, but there is no medical documentation supporting that the appellant has uncontrolled blood pressure. The MassHealth representative noted that Myrbetriq is not recommended for patients with severe, uncontrolled high blood pressure. The MassHealth representative pointed out that no blood pressure medication was reported by NP Saurman. (Exhibits 6, 8). The MassHealth representative stated that even if Myrbetriq is contraindicated, the appellant would still need to try one of the other 3 medications noted in the MassHealth Drug List.

In her appeal request, the appellant noted that due to existing severe dryness and other drying medical conditions, she needs the least drying medicine to help her. (Exhibit 2). The appellant stated that she did not know she needed to try two alternatives until she received MassHealth/DUR's letter dated February 27, 2023. The appellant stated that she has dry skin, dry hair, and dry nails and has diagnoses including hypothyroidism and diabetes and she doesn't think she should have to try two alternative medications. The appellant stated that she suffered from constipation which caused pain and hemorrhoids while she was taking solifenacin. The appellant stated that she does not want to try a more drying medication. The appellant noted that she does not take blood pressure medication, but has had somewhat high blood pressure readings. The appellant stated that her medical provider believes Myrbetriq would be the best medication, but her blood pressure is too high. The MassHealth representative advised the appellant to discuss her blood pressure, and the contraindications for Myrbetriq, with her physician to see if it might be an acceptable alternative.

Findings of Fact

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

1. The appellant's provider, NP Marcelle Saurman, submitted a PA request for the prescription medication Trospium Chloride ER 60 mg capsules, on February 3, 2023.
2. NP Saurman noted that the medication was prescribed for the appellant's diagnosis of overactive bladder, diagnosis code N32.81; NP Saurman noted that the appellant had not tried other medications to treat the condition.
3. NP Saurman wrote that the appellant has hypertension and is not a candidate for Myrbetriq; NP Saurman wrote further that the appellant "has diabetes and needs an anticholinergic with the least drying leaving only trospium".
4. The appellant is not taking blood pressure medication.
5. A denial notification was faxed to NP Saurman from MassHealth's DUR program on February 4, 2023; the denial notice stated that MassHealth determined that there are more cost effective alternatives to Trospium Chloride ER 60 mg capsules and asked that the provider please consider the use of oxybutynin extended-release, Myrbetriq (mirabegron extended-release), tolterodine extended-release, fesoterodine, or solifenacin, which are available without prior authorization, if clinically appropriate.
6. The denial notification stated further that additional information regarding the MassHealth Drug List and specific prior authorization forms can be found at www.mass.gov/druglist.
7. In preparation for the hearing, MassHealth's DUR program sent the appellant a letter dated February 27, 2023; the letter informed the appellant that the requested medication requires prior authorization and requested that the appellant contact her medical provider and ask that the provider submit documentation that the appellant has tried two of the following agents, and they did not work, or the appellant had unacceptable side effects, or alternatively, provide a contraindication to all of the following: fesoterodine, Myrbetriq, oxybutynin ER tablet, solifenacin, and tolterodine ER.
8. On March 13, 2023, MassHealth received a second PA request for Trospium Chloride ER from NP Saurman.
9. NP Saurman noted on the PA request form that the medication was prescribed for the appellant's diagnosis of overactive bladder, diagnosis code N32.81, and noted that the appellant tried Vesicare (solifenacin), 10 mg from February 7, 2023 to February 25, 2023 and had the adverse reaction of bothersome drying side effects.
10. NP Saurman wrote that due to the appellant's other medical issues including hypothyroidism, adrenal insufficiency, diabetes mellitus, and the treatment for these conditions, the appellant reports significant baseline drying side effects.

11. The appellant reports that she has type II diabetes, asthma, allergies, skin conditions, ankle instability, right knee instability, and right hand instability.

Analysis and Conclusions of Law

Medical Necessity

The MassHealth agency does 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: Potential Sources of Health Care, or 517.007: Utilization of Potential Benefits.

(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. A provider must make those records, including medical records, available to the MassHealth agency upon request. (See 42 U.S.C. 1396a(a)(30) and 42 CFR 440.230 and 440.260.)

(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.

(E) Any regulatory or contractual exclusion from payment of experimental or unproven services refers to any service for which there is insufficient authoritative evidence that such service is reasonably calculated to have the effect described in 130 CMR 450.204(A)(1).

(130 CMR 450.204).

Service Limitations.

(1) MassHealth covers drugs that are not explicitly excluded under 130 CMR 406.413(B). The limitations and exclusions in 130 CMR 406.413(B) do not apply to medically necessary drug therapy for MassHealth Standard and CommonHealth enrollees under age 21. The MassHealth Drug List specifies those drugs that are payable under MassHealth.

Any drug that does not appear on the MassHealth Drug List requires prior authorization, as set forth in 130 CMR 406.000. The MassHealth Drug List can be viewed online at www.mass.gov/druglist, and copies may be obtained upon request. See 130 CMR 450.303: Prior Authorization.

(2) The MassHealth agency does not pay for the following types of drugs, or drug therapies or non-drug products without prior authorization:

(a) immunizing biologicals and tubercular (TB) drugs that are supplied to the provider free of charge through local boards of public health or through the Massachusetts Department of Public Health (DPH); and

(b) any drug, drug therapy, or non-drug product designated in the MassHealth Drug List as requiring prior authorization.

(3) The MassHealth agency 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.

(4) The MassHealth agency does not pay for any drugs that are provided as a component of a more comprehensive service for which a single rate of pay is established in accordance with 130 CMR 450.307: Unacceptable Billing Practices.

(130 CMR 406.413(C)).

Prior Authorization

(A) Prescribers must obtain prior authorization from the MassHealth agency for drugs identified by MassHealth in accordance with 130 CMR 450.303: Prior Authorization. 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 medical necessity, to the MassHealth agency for prior authorization for an otherwise noncovered drug.

(B) All prior-authorization requests must be submitted in accordance with 130 CMR 450.303: Prior Authorization. and the instructions for requesting prior authorization in the Pharmacy Online Processing System (POPS) billing guide, the MassHealth Drug List, and any other applicable guidance. The MassHealth agency will notify the requesting provider and the member, in writing, of its decision.

(C) The MassHealth agency will authorize at least a 72-hour emergency supply of a prescription drug to the extent required by federal law. (See 42 U.S.C. 1396r-8(d)(5).) The MassHealth agency acts on requests for prior authorization for a drug within a time period consistent with federal regulations.

(D) Prior authorization does not waive any other prerequisites to payment such as, but not limited to, member eligibility or requirements of other health insurers.

(E) The MassHealth Drug List specifies the drugs that are payable under MassHealth and designates which drugs require prior authorization. Any drug that does not appear on the MassHealth Drug List requires prior authorization. The MassHealth agency evaluates the prior

authorization status of drugs on an ongoing basis, and updates the MassHealth Drug List accordingly.

(F) If the pharmacy does not dispense a drug or non-drug product because the prescriber did not submit a request for prior authorization, the pharmacy must take reasonable steps to notify both the patient and prescriber of the need for prior authorization, and make a contemporaneous record of having done so.

(130 CMR 406.422).

The MassHealth Drug List requires prior authorization for Trospium Chloride ER. (Exhibit 6, p. 12). The MassHealth Drug List evaluation criteria for approval of Trospium Chloride ER states that documentation of all of the following is required:

- Appropriate diagnosis; and
- Inadequate response or adverse reaction to two or contraindications to all of the following: fesoterodine, Myrbetriq, oxybutynin ER tablet, solifenacin, and tolterodine ER; and
- Requested quantity is less than or equal to one unit/day.

(Exhibit 6, p. 14).

MassHealth has accepted that the appellant had an adverse reaction to solifenacin. Based on the MassHealth Drug List evaluation criteria, the appellant must document an inadequate response or adverse reaction to fesoterodine, Myrbetriq, oxybutynin ER tablet, or tolterodine ER, or show contraindications to all of the following, fesoterodine, Myrbetriq, oxybutynin ER tablet, solifenacin, and tolterodine ER, before PA for Trospium Chloride ER could be approved. The appellant has not met MassHealth's criteria for PA approval for Trospium Chloride ER. MassHealth's denial is upheld and the appeal is denied.

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.

Patricia Mullen
Hearing Officer
Board of Hearings

cc: MassHealth Representative: UMMS Drug Utilization Review, Commonwealth Medicine,
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