Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2177505
Decision Date:	1/19/2022	**Hearing Date:**	12/14/2021
Hearing Officer:	Casey Groff		

Appearance for Appellant:
Pro se

Appearance for MassHealth:
Kristen Danis, Pharm.D., R.Ph., Consultant Pharmacist IV, Drug Utilization Program (DUR); Meghan Serell, Pharm.D., R.Ph. Consultant Pharmacist IV, 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
Decision Date:	1/19/2022	**Hearing Date:**	12/14/2021
MassHealth's Rep.:	Kristen Danis, Pharm.D., R.Ph.; Meghan Serell, Pharm.D., R.Ph.	**Appellant's Rep.:**	*Pro se*
Hearing Location:	Telephonic	**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

On September 23, 2021, Appellant submitted a fair hearing request to the Board of Hearings (BOH). See Exhibit 1. On October 6, 2021, BOH dismissed the hearing request for failing to demonstrate the existence of an appealable action. See Exhibit 2; 130 CMR 610.034. On October 25, 2021, Appellant requested the dismissal be vacated and included a copy of a MassHealth notice dated September 8, 2021, which denied Appellant's prior authorization (PA) request for coverage of buprenorphine/naloxone 8mg/2mg sublingual tablets. See Exh. 3. Denial of a request for prior authorization is a valid basis for appeal. See 130 CMR 610.032. Given the timeliness of Appellant's initial September 23, 2021 fair hearing request, BOH scheduled a hearing on the matter for December 14, 2021. See Exh. 4; see also 130 CMR 610.015(B) and Exhibit 1.

Action Taken by MassHealth

MassHealth denied Appellant's PA request for coverage of buprenorphine/naloxone 8mg/2mg sublingual tablets.

Issue

The appeal issue is whether MassHealth was correct in denying Appellant's PA request for buprenorphine/naloxone 8mg/2mg sublingual tablets.

Summary of Evidence

A registered pharmacist from MassHealth's Drug Utilization Review (DUR) Program appeared via telephone. Through testimony and documentary submissions, MassHealth presented the following evidence: On September 7, 2021, Appellant's provider submitted a prior authorization (PA) request seeking coverage of buprenorphine/naloxone 8mg/2mg sublingual tablets in connection with his treatment for opioid dependance. See Exh. 5, p. 3. The FDA approved buprenorphine, a partial opioid agonist, and naloxone, an opioid antagonist, for the maintenance treatment of opioid dependence. Id. at 27. According to the PA request, Appellant is an adult MassHealth member under the age of 65. Id.

The DUR representative explained that MassHealth requires PA for this drug as specified in the Table 36 of the MassHealth Drug List pertaining to drug and alcohol cessation agents. Id. at 11-12. Additionally, when reviewing a PA request, MassHealth considers if there is a designated "preferred" drug (either generic or brand-name) within the same therapeutic class of the drug requested. Id. at 11. According to its Supplemental Rebate/Preferred Drug List, MassHealth designated "Suboxone buprenorphine/naloxone film" (Suboxone film) as the preferred drug within the therapeutic class of drug and alcohol cessation agents. See id. at 22-23. Because Appellant requested a different variant (i.e. tablet) of the preferred drug (Suboxone film), MassHealth requires documentation indicating the member has had an inadequate response or adverse reaction to the preferred version. Id. at 11, 14-15. Additionally, MassHealth generally requires a trial of the preferred drug or clinical rational for prescribing a non-preferred drug within a therapeutic class. Id. at 15. According to the MassHealth Drug List, a request for buprenorphine/naloxone tablet $\leq$ 24 mg/day must the following documentation:

- appropriate diagnosis; **and**
- medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature or cannot be expected or managed during the course of buprenorphine therapy.

Id. at 15.

In his PA request, Appellant's prescriber answered affirmatively that Appellant has had a previous allergic reaction to the Suboxone film, commenting that that taking it in this form causes him gastrointestinal (GI) distress. Id. at 4. However, no accompanying documentation or medical records were included in the PA request.

On September 8, 2021, MassHealth notified Appellant and his provider that it denied the request for coverage of buprenorphine/naloxone 8mg/2mg tablets because there was insufficient documentation to establish medical necessity for the requested formulation. See Exh. 3; Exh. 5, p. 7. The denial notice stated that the "[p]rescriber may resubmit a new prior authorization request with medical records/office notes documenting an allergic reaction to Suboxone (buprenorphine/naloxone film)" and noted that the film equivalent requires no PA to obtain approval. See Exh. 5, p. 7. The MassHealth pharmacy representative further testified that although the PA request referred to Appellant's "allergic reaction" to the film in the form of GI distress, MassHealth requires the underlying medical records documenting such response.[1]

Appellant submitted a timely appeal of the September 8th denial which prompted BOH to notify all parties of the scheduled hearing. See Exh. 1. In an attempt to resolve the matter in advance of the hearing, MassHealth, through a November 18, 2021 letter, requested his provider send the missing medical documentation (i.e. adverse reaction to the film) and potentially approve his request. See Exh. 5 at 9. As of the hearing date, MassHealth had not received any additional documentation from the Appellant or his provider concerning the requested medication.

Appellant appeared by telephone and testified as follows: Appellant stated that following the denial, he has made continuous requests to his provider to resubmit the documentation. The provider's office confirmed that all requested documentation has been sent multiple times and that they are not going to continue sending the same until they get a response. Appellant testified that this whole problem started when he recently switched from his managed care plan to MassHealth Standard. Under his prior plan, this drug was always covered and there was never an issue. Before he switched to Standard, everyone assured him that this specific drug would still be covered. Since the denial, he has been paying $1,500 per month out of pocket for the drug. Appellant stated that he absolutely cannot tolerate the film version as he experienced severe side effects, including vomiting when taking it. He also stated that he cannot be expected to do a trial with the film and an antiemetic. He is prescribed so many medications because of his illness and cannot take another pill. He has had great success with the requested tablet formula and does not want to try anything new. It is medically necessary and does not understand why MassHealth does not have the documentation that his providers sent many times.

In response, the MassHealth representative stated that she re-checked Appellant's claims and prior authorizations both before and during the hearing. The only PA request ever received by MassHealth was the September 7th PA prompting this appeal. She has nothing on file either before or after the September 7th PA; nor did MassHealth receive any additional records to accompany this request. She would be able to access such records if they were in fact sent as requested. The parties discussed whether it was possible the documents were mistakenly directed through a prior authorization unit at his previous plan; however, it was unclear where his providers directed the additional requests and documentation. Appellant did not provide any

[1] The MassHealth pharmacy representative stated that because GI distress is a common reaction to any new medication, MassHealth typically requires documentation to show the film, or "preferred" version was trialed with an antiemetic.

specific dates or documentation to reflect when his provider attempted to send the requested information.

Findings of Fact

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

1. Appellant is an adult MassHealth member under the age of 65.

2. On September 7, 2021, Appellant's provider submitted a PA request seeking coverage of buprenorphine/naloxone 8mg/2mg sublingual tablets in connection with his treatment for opioid dependance.

3. Buprenorphine, a partial opioid agonist, and naloxone, an opioid antagonist, is FDA approved for the maintenance treatment of opioid dependence.

4. Buprenorphine/naloxone tablets appears in the MassHealth Drug List under Table 36 pertaining to "drug and alcohol cessation agents" and is marked as requiring prior authorization.

5. MassHealth designated "Suboxone buprenorphine/naloxone film" as the preferred drug within the therapeutic class of drug and alcohol cessation agents.

6. In the PA request, Appellant's prescriber answered affirmatively that Appellant has an allergic reaction to Suboxone film in the form of GI distress; however, he did not include any medical records with the request to document the adverse response.

7. On September 8, 2021, MassHealth notified Appellant and his provider that it denied the request for coverage of buprenorphine/naloxone 8mg/2mg tablets because there was insufficient documentation to establish medical necessity for the requested formulation.

8. On November 18, 2021 MassHealth reached out Appellant to request his provider send the missing medical documentation needed to approve the requested drug prior to hearing; specifically, medical records showing Appellant has had an adverse reaction or inadequate response to the Suboxone film.

9. As of the hearing date, MassHealth had not received any of the requested medical records, or any new PA requests from Appellant's provider.

Analysis and Conclusions of Law

MassHealth covers the cost of prescription drugs for eligible MassHealth members, subject to restrictions and limitations described in its regulations. See 130 CMR 406.403. Through its published "Drug List," MassHealth identifies the commonly prescribed medications/drugs that are payable under MassHealth and indicates whether coverage for such drugs must be requested through MassHealth's prior authorization (PA) process. See 130 CMR 406.412; see also 130 CMR 406.402. Additionally, the MassHealth Drug List identifies whether there is a designated "preferred" drug version within each therapeutic class. See Exh. 5, p. 11; see also 130 CMR 406.413. Typically, the "preferred" drug (whether generic or brand-name) has been designated as such because it is the less-costly version.[2] See 130 CMR 406.413(A)(3); see Exh. 5, p. 11. However, when such a limitation on covered drugs "would result in inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including documentation of medical necessity, to the MassHealth agency for prior authorization for an otherwise noncovered drug." 130 CMR 406.422. Thus, when requesting a non-preferred drug over a designated preferred version, MassHealth requires the prescriber to provide "medical records documenting an inadequate response or adverse reaction to the preferred version, in addition to satisfying the criteria for the drug itself." Exh. 5, at 14-15.

In the instant case, Appellant sought approval for buprenorphine/naloxone 8mg/2mg sublingual tablets for the treatment of opioid dependence via a PA request dated September 7, 2021. See Exh. 5, p. 3. According to its Supplemental Rebate/Preferred Drug List, MassHealth designated "Suboxone (buprenorphine/naloxone film)" as the preferred drug within the therapeutic class of drug and alcohol cessation agents. See id. at 22-23. Because Appellant requested a "non-preferred" drug, he was required to include medical documentation of an adverse reaction or inadequate response to "preferred" Suboxone film. See 130 CMR 406.422. Specifically, the MassHealth Drug List sets forth the following criteria when requesting buprenorphine/naloxone tablet ≤ 24 mg/day:

- Documentation of all of the following is required:
    - appropriate diagnosis; **and**
    - medical records documenting an adverse reaction to buprenorphine/naloxone film that is allergic in nature or cannot be expected or managed during the course of buprenorphine therapy.

Id. at 15.

Although Appellant's provider noted in the PA request[3] that the "[Suboxone] film causes [Appellant] GI distress," he did not submit any accompanying medical records to document this adverse response. The regulations above clearly indicate that MassHealth will not approve a request for a non-preferred drug – such as the buprenorphine/naloxone tablets at issue here – unless there is adequate medical records documenting why the member cannot take the less-costly "preferred"

[2] Typically, the generic is the "preferred" when available, unless MassHealth designates the brand-name drug as preferred "because the net cost of the brand-name drug after consideration of all rebates, is less than the cost of the generic equivalent." Id.

[3] The "PA request" is a standard form the prescriber is required to fill out and submit to MassHealth.

version. In an attempt to resolve the matter prior to hearing, MassHealth requested Appellant have his provider send the specific medical records needed for approval. MassHealth, however, did not receive any response. Despite Appellant's credible testimony at hearing that he is unable to tolerate the film and thus needs the tablet formulation which has been effective, MassHealth simply did not have any medical documentation in its possession to reflect that Appellant satisfied the criteria for approving the non-preferred drug. MassHealth did not err in denying Appellant's September 7th PA request.

This 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.

Casey Groff
Hearing Officer
Board of Hearings

cc:
MassHealth Representative: UMMS Drug Utilization Review, Commonwealth Medicine, 333 South Street, Shrewsbury, MA 01545