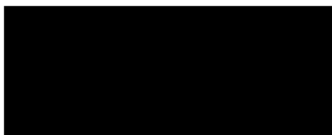


# Office of Medicaid BOARD OF HEARINGS

**Appellant Name and Address:**



<b>Appeal Decision:</b>	Denied	<b>Appeal Number:</b>	2308134
<b>Decision Date:</b>	10/24/2023	<b>Hearing Date:</b>	09/27/2023
<b>Hearing Officer:</b>	Thomas J. Goode	<b>Record Open to:</b>	10/11/2023

**Appearance for Appellant:**  
Pro se

**Appearance for MassHealth:**  
Meghan Serell, Pharm. D., R.Ph.



*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

<b>Appeal Decision:</b>	Denied	<b>Issue:</b>	Prior Authorization
<b>Decision Date:</b>	10/24/2023	<b>Hearing Date:</b>	09/27/2023
<b>MassHealth's Rep.:</b>	Meghan Serell, DUR	<b>Appellant's Rep.:</b>	Pro se
<b>Hearing Location:</b>	Remote	<b>Aid Pending:</b>	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 21, 2023, MassHealth denied Appellant's prior authorization request for the prescription medication Adapalene 0.3% gel (130 CMR 406.422 and Exhibit 1). Appellant filed this appeal in a timely manner on September 11, 2023 (130 CMR 610.015(B) and Exhibit 2). During the pendency of the appeal, a second prior authorization request was submitted and denied (Exhibit 6). Denial of assistance is valid grounds for appeal (see 130 CMR 610.032).

### Action Taken by MassHealth

MassHealth denied Appellant's prior authorization requests for the prescription medication Adapalene 0.3% gel.

### Issue

The appeal issue is whether MassHealth correctly denied Appellant's prior authorization requests for Adapalene 0.3% gel.

## Summary of Evidence

A pharmacist representing MassHealth appeared by telephone and testified that a prior authorization request for Adapalene 0.3% gel was submitted by Appellant's physician on August 21, 2023. The request indicates that Appellant is [REDACTED] years old and is diagnosed with acne vulgaris, chronic, progressive acne with no improvement from over-the-counter medications or other medication. The request states that Appellant has tried Benzacilin pump 1%-5% topical gel from July 25, 2022 to present with inadequate response (Exhibit 1, pp. 4-7). The prior authorization request was denied on August 21, 2023 because medical necessity to treat a MassHealth member over 22 years of age with an acne product had not been established pursuant to the MassHealth Drug List guidelines. The MassHealth representative testified that Adapalene 0.3% gel requires prior authorization. The request was denied because the severity of Appellant's acne was not indicated, and Appellant's medical records do not show a failed trial or unacceptable side effects of a topical tretinoin agent (Exhibit 1, p. 11). The prior authorization request submitted on August 21, 2023 indicates a trial of Benzacilin pump 1%-5% topical gel from July 25, 2022 to present without improvement of Appellant's acne and does not indicate a trial of a topical tretinoin agent (Exhibit 1, at Exhibit A). A new prior authorization request was submitted on September 22, 2023 with a diagnosis of grade II severe chronic and scarring acne which meets MassHealth's diagnosis requirements to approve the medication; however, the second prior authorization request does not document in medical records the duration of a trial of a topical tretinoin agent (Exhibit 6). The September 22, 2023 prior authorization request states a trial of tretinoin 0.025% cream from July 25, 2022-present; and that tretinoin 0.025% cream did not improve severe, chronic, scarring acne (Exhibit 6, pp. 1-5). Medical records submitted with the September 22, 2023 prior authorization request show a prescribed medication list which includes Adapalene 0.3% gel prescribed from July 25, 2022 and Benzacilin Pump 1%-5% topical gel prescribed on July 25, 2022. These medications were also prescribed on March 21, 2023 and June 7, 2023 respectively (Exhibit 6, pp. 18, 23). Medical records also show that Appellant was prescribed tretinoin 0.025% topical cream on August 24, 2023 (Exhibit 6, p. 24); however, the trial and adverse effects of tretinoin 0.025% cream are not documented in Appellant's medical records submitted with the request. Because a trial and adverse effects of a topical tretinoin agent are not documented in medical records, the prior authorization request was denied.

Appellant appeared telephonically and testified that he recently changed insurance due to aging out of his former coverage. Appellant added that he has tried several acne medications including tretinoin cream which he tried 7 or 8 years ago. Appellant added that tretinoin made his skin dry and did not improve his acne condition. Appellant stated that he has been using Adapalene and it is effective.

The hearing record remained open until October 11, 2023 to allow Appellant to submit a letter of medical necessity outlining the previous trial and inadequate response to a topical tretinoin agent (Exhibit 4). On October 20, 2023, DUR/MassHealth submitted a response stating that no additional

information was submitted by Appellant's medical provider (Exhibit 7).

## Findings of Fact

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

1. A prior authorization request for Adapalene 0.3% gel was submitted by Appellant's physician on August 21, 2023 and denied on August 21, 2023.
2. Appellant is [REDACTED] years old and is diagnosed with acne vulgaris, chronic, grade II progressive acne.
3. The prior authorization request submitted on August 21, 2023 was denied because the severity of Appellant's acne was not indicated, and Appellant's medical records do not show a failed trial or unacceptable side effects of a topical tretinoin agent.
4. The prior authorization request submitted on August 21, 2023 indicates a trial of Benzacilin pump 1%-5% topical gel from July 25, 2022 to present without improvement of Appellant's acne. The prior authorization request does not indicate a trial of a topical tretinoin agent.
5. A new prior authorization request was submitted on September 22, 2023 with a diagnosis of grade II severe chronic and scarring acne which meets MassHealth's diagnosis requirements for Adapalene.
6. The September 22, 2023 prior authorization request states a trial of tretinoin 0.025% cream from July 25, 2022-present, and that tretinoin 0.025% cream did not improve severe, chronic, scarring acne.
7. Medical records submitted with the September 22, 2023 prior authorization request show a prescribed medication list which includes Adapalene 0.3% gel prescribed from July 25, 2022 and Benzacilin Pump 1%-5% topical gel prescribed on July 25, 2022. These medications were prescribed again on March 21, 2023 and June 7, 2023 respectively (Exhibit 6, pp. 18, 23).
8. Medical records submitted with the September 22, 2023 prior authorization request show that Appellant was prescribed tretinoin 0.025% topical cream on August 24, 2023. The trial and adverse effects of tretinoin 0.025% cream are not documented in Appellant's medical records submitted with the prior authorization request.
9. The hearing record remained open until October 11, 2023 to allow Appellant's physician to submit a letter of medical necessity outlining the previous trial and inadequate response to

a topical tretinoin agent (Exhibit 4). On October 20, 2023, DUR/MassHealth submitted a response stating that no additional information was submitted by Appellant (Exhibit 7).

10. No additional information has been received at the Board of Hearings.

## Analysis and Conclusions of Law

### 130 CMR 406.422: 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.

### 130 CMR 450.204: Medical Necessity

The MassHealth agency will 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, 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. 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 acute inpatient hospital admissions are contained in 130 CMR 415.414.

(130 CMR 450.204(A)-(D)).

The MassHealth Drug List specifies the drugs that are payable by MassHealth and designates which drugs require prior authorization.<sup>1</sup> Any drug that does not appear on the MassHealth

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<sup>1</sup> According to the MassHealth Drug List, drugs may require PA for a variety of reasons. MassHealth determines the PA status of drugs on the List on the basis of the following. MassHealth program requirements; and ongoing evaluation of the drugs' utilization, therapeutic efficacy, safety, and cost. Drugs are evaluated first on safety and effectiveness, and second on cost. Some drugs require PA because MassHealth and the Drug Utilization Review Board have concluded that there are more cost-effective alternatives. With regard to all such drugs, MassHealth also has concluded that the more costly drugs have no significant clinically meaningful therapeutic advantage in terms of safety, therapeutic efficacy, or clinical outcome compared to those less-costly drugs used to treat the same condition. Evaluation of a drug includes a thorough review by physicians and pharmacists using medical literature and consulting with specialists, other physicians, or both. References used may include AHFS Drug Information; Drug Facts and Comparisons, Micromedex; National Comprehensive Cancer Network (NCCN); literature from peer-reviewed medical journals; Drug Topics Red Book, Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book"); the Massachusetts List of Interchangeable Drug Products, and manufacturers' product information. MassHealth may impose PA requirements in therapeutic classes in which it has designated a preferred product on the MassHealth Brand Name Preferred Over Generic Drug List or the MassHealth Supplemental Rebate/Preferred Drug List pursuant to the supplemental rebate agreement and preferred brand-name policies described above. The MassHealth Pharmacy Online Processing System (POPS) uses diagnosis codes from medical claims for some drug classes when processing claims at pharmacies. This means that a prescriber may not need to submit a paper PA form if a member's diagnosis in POPS meets the criteria for that drug. MassHealth uses technical software called Smart PA to link diagnosis codes from medical claims during pharmacy claims adjudication. Smart PA is used in the MHDL to identify drugs for which this process is currently available. For this reason, MassHealth requests pharmacies to submit all claims through POPS, as some drugs that are designated as requiring PA on the MHDL will process at the pharmacy without a paper PA submitted. In addition, if the limitations on covered drugs specified in 130 CMR 406.412(A) and 406.413(A) and (C) would result in

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 (130 CMR 406.422(E)).

For members over 22 years of age, MassHealth requires prior authorization for the prescription medication Adapalene (See MassHealth Drug List, and Exhibit 1, p. 23). In addition to diagnosis requirements, prior authorization for Adapalene requires **“medical records documenting an adverse reaction or inadequate response to a topical tretinoin agent”** (MassHealth Drug List, and Exhibit 1, p. 28). The prior authorization requests submitted on August 21, 2023 and September 22, 2023 do not show a trial and adverse effects of a topical tretinoin agent documented in Appellant’s medical records (Exhibits 1, 6). Medical records submitted with the September 22, 2023 prior authorization request show that Appellant was prescribed tretinoin 0.025% topical cream on August 24, 2023 (Exhibit 6, p. 24), and adverse effects are noted in the prior authorization request; however, the trial and adverse effects are not further documented in Appellant’s medical records (Exhibit 6, pp.6-27).<sup>2</sup> The hearing record remained open until October 11, 2023 to allow Appellant to submit a letter of medical necessity from his medical provider documenting the trial and inadequate response to a topical tretinoin agent (Exhibit 4). On October 20, 2023, DUR/MassHealth submitted a response stating that no additional information was submitted by Appellant (Exhibit 7). No additional documentation was submitted to the Board of Hearings. As Appellant has not met prior authorization requirements demonstrating medical necessity for Adapalene, the appeal must be DENIED. However, Appellant’s medical provider can submit to MassHealth a new prior authorization request with updated medical records at any time.

## Order for MassHealth

None.

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inadequate treatment for a diagnosed medical condition, the prescriber may submit a written request, including written documentation of medical necessity, to MassHealth for prior authorization for an otherwise noncovered drug. [www.mass.gov/druglist](http://www.mass.gov/druglist).

<sup>2</sup> See Exhibit 6, p. 27 which shows only instructions for applying “one pea sized amount of tretinoin to whole face,” but no other discussion of efficacy or adverse effects.

## 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.

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Thomas J. Goode  
Hearing Officer  
Board of Hearings

cc:

Appeals Coordinator: Drug Utilization Review Program