

# Office of Medicaid BOARD OF HEARINGS

**Appellant Name and Address:**



<b>Appeal Decision:</b>	Denied	<b>Appeal Number:</b>	2405115
<b>Decision Date:</b>	5/13/2024	<b>Hearing Date:</b>	05/09/2024
<b>Hearing Officer:</b>	Thomas J. Goode		

**Appearances for Appellant:**

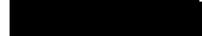


**Appearances for WellSense Health Plan:**

Jacqueline Bigbee, Director Member Appeals & Grievances

Felicia DiSciscio, Manager of Appeal & Grievances

 MD, Physician Advisor

 Physician Advisor

Priya Mehta, Associate General Counsel

Steven Tringale, Associate General Counsel



*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>	Managed Care Organization-Internal Appeal denial
<b>Decision Date:</b>	5/13/2024	<b>Hearing Date:</b>	05/09/2024
<b>WellSense Reps.:</b>	Jacqueline Bigbee et al.	<b>Appellant's Reps.:</b>	[REDACTED]
<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 March 29, 2024, and following an expedited first-level internal appeal, WellSense Health Plan notified the appellant that it had denied prior authorization for the prescription medication Tyvaso DPI (130 CMR 406.413(C), 130 CMR 450.204 *et seq.* and Exhibit 1). The appellant filed this appeal in a timely manner on April 1, 2024 (130 CMR 508.010, 610.015, and Exhibit 2). Denial of an internal appeal of a denial of a prior authorization request by a MassHealth Accountable Care Organization is valid grounds for appeal (130 CMR 508.010, 610.032(B)).

### Action Taken by WellSense Health Plan

WellSense Health Plan notified the appellant that it had denied prior authorization for the prescription medication Tyvaso DPI.

## Issue

The appeal issue is whether, pursuant to 130 CMR 406.413(C), 450.204, WellSense Health Plan correctly denied the appellant's prior authorization request for the prescription medication Tyvaso DPI.

## Summary of Evidence

The appellant is [REDACTED] years old and has been enrolled in WellSense ACO Community Alliance CarePlus A Medicaid plan since March 31, 2028 (Exhibit 7, p. 4). The WellSense Health Plan representative testified to the following chronological summary:

- On March 26, 2024, Express Scripts, received a request from the office of [REDACTED] [REDACTED] for coverage of Tyvaso DPI 16-32-48 cartridge inhalation on behalf of the appellant. [REDACTED] specialty is Pulmonology. The appellant's condition is reported by [REDACTED] to be pulmonary hypertension [REDACTED] [REDACTED]
- On March 26, 2024, Express Scripts denied the request for coverage of Tyvaso DPI 16-32-48 cartridge inhalation because coverage is provided in situations where one of the following are met: Documentation submitted that shows the appellant has had or has an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.
- On March 28, 2024, WellSense Health Plan received an Expedited written appeal submitted by the office of [REDACTED] for coverage of Tyvaso DPI 16-32-48 cartridge inhalation.
- On March 28, 2024, WellSense Health Plan referred the appellant's case to an outside Pulmonologist, MD for review and consultation/recommendation to the Plan as to whether the request for Tyvaso DPI 16-32- 48 cartridge inhalation met clinical criteria for coverage.
- On March 28, 2024, the specialist recommended to deny coverage of Tyvaso DPI 16-32-48 cartridge inhalation because per the plan policy, the use of Tyvaso DPI for pulmonary hypertension [REDACTED] requires medical records documenting inadequate response to Tyvaso inhalation solution (Exhibit 7, pp. 20-23).

- On March 29, 2024, a WellSense Health Plan Physician Reviewer in consultation with the external Pulmonologist, denied the appeal request because the information submitted within the appeal did not show that the appellant has tried, failed, or had an allergic reaction to Tyvaso inhalation solution.
- On March 29, 2024, WellSense Health Plan attempted to call the appellant to relay the appeal decision. The Plan also mailed the appeal denial letter and external appeal rights to the appellant and the requesting provider.
- WellSense Health Plan ACO Member Appeals Policy states in part, "The Plan's Expedited Internal Appeals Process consists of one level of review and will conclude no more than 72 hours from the time the Plan received the Member's or Appeal Representative's request for expedited appeal unless the timeframe is extended." The Expedited Internal Appeal was fully resolved with notification provided by March 29, 2023, which is within 72 hours of the appeal being received at the Plan.

██████████ a WellSense Health Plan Senior Medical Director testified that Tyvaso and Tyvaso DPI are the same medication in different forms. Tyvaso is an inhalation solution and Tyvaso DPI is an inhalation powder. ██████████ testified that WellSense Health Plan must follow restrictions outlined in the MassHealth Drug List which require a documented failed trial of Tyvaso that shows that it is contraindicated due to the inability to tolerate the medication or an adverse reaction to the medication. ██████████ added that Tyvaso DPI cannot be approved solely because it is more convenient for patients to administer. ██████████ testified that for authorization of Tyvaso DPI for the treatment of pulmonary hypertension ██████████ the MassHealth Drug List requires an appropriate diagnosis, a prescription by a pulmonologist, and medical records documenting an inadequate response, adverse reaction or contraindication to Tyvaso inhalation solution (Exhibit 7, p. 75).

██████████ testified that he is a pulmonologist at ██████████ and has prescribed Tyvaso DPI for the treatment of pulmonary hypertension ██████████ many times without encountering a denial based on a requirement to first try Tyvaso inhalation solution. ██████████ testified that Tyvaso and Tyvaso DPI are both administered 4 times per day. He added that Tyvaso inhalation solution is delivered through a device that weighs about 5 pounds and is inconvenient for patients because the device is not portable and must be cleaned after each use. Tyvaso DPI is a powder formulation that is delivered through a device similar to an asthma inhaler weighing about 8 ounces and is more convenient and portable, which results in greater patient compliance with the medication regimen. ██████████ testified that Tyvaso DPI was FDA approved in April 2022 for the treatment of pulmonary hypertension ██████████ ██████████ testified that it is unlikely that a patient will be able to show a failed clinical trial of Tyvaso to allow approval of Tyvaso DPI because the medication is the same.

## Findings of Fact

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

1. The appellant is [REDACTED] years old and has been enrolled in WellSense ACO Community Alliance CarePlus A Medicaid plan since March 31, 2028.
2. On March 26, 2024, Express Scripts, received a request from the office of [REDACTED] [REDACTED] for coverage of Tyvaso DPI 16-32-48 cartridge inhalation on behalf of the appellant. [REDACTED] specialty is Pulmonology. The appellant's condition is reported by [REDACTED] to be pulmonary hypertension associated with [REDACTED].
3. On March 26, 2024, Express Scripts denied the request for coverage of Tyvaso DPI 16-32-48 cartridge inhalation because coverage is provided in situations where one of the following are met: Documentation shows the appellant has had or has an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.
4. On March 28, 2024. WellSense Health Plan received an expedited written appeal submitted by the office of [REDACTED] for coverage of Tyvaso DPI 16-32-48 cartridge inhalation.
5. On March 28, 2024, WellSense Health Plan referred the appellant's case to an outside Pulmonologist, MD for review and consultation/recommendation to the Plan as to whether the request for Tyvaso DPI 16-32- 48 cartridge inhalation met clinical criteria for coverage.
6. On March 28, 2024, the specialist recommended to deny coverage of Tyvaso DPI 16-32-48 cartridge inhalation because per the plan policy, the use of Tyvaso DPI for pulmonary hypertension associated [REDACTED] requires medical records documenting inadequate response to Tyvaso inhalation solution.
7. On March 29, 2024, a WellSense Health Plan Physician Reviewer, MD in consultation with the external Pulmonologist, MD, denied the appeal request because the information submitted within the appeal did not show that the appellant has tried, failed, or had an allergic reaction to Tyvaso inhalation solution.

8. On March 29, 2024, WellSense Health Plan attempted to call the appellant to relay the appeal decision. The Plan also mailed the appeal denial letter and external appeal rights to the appellant and the requesting provider.
9. WellSense Health Plan ACO Member Appeals Policy states in part, "The Plan's Expedited Internal Appeals Process consists of one level of review and will conclude no more than 72 hours from the time the Plan received the Member's or Appeal Representative's request for expedited appeal unless the timeframe is extended." The Expedited Internal Appeal was fully resolved with notification provided by March 29, 2023, which is within 72 hours of the appeal being received at the Plan.

## **Analysis and Conclusions of Law**

The appellant is a MassHealth member currently enrolled in WellSense Health Plan which is an Accountable Care Organization. When a MassHealth member selects or is assigned to an Accountable Care Partnership Plan, that Accountable Care Partnership Plan will deliver the member's primary care, determine if the member needs medical or other specialty care from other providers, and determine referral requirements for such necessary medical services. All medical services to members enrolled in an Accountable Care Partnership Plan (except those services not covered under the MassHealth contract with the Accountable Care Partnership Plan, family planning services, and emergency services) are subject to the authorization and referral requirements of the Accountable Care Partnership Plan (130 CMR 508.006(A)(2)(a)(b)). As such, WellSense Health Plan is responsible for authorizing all covered services for the appellant. As MassHealth's agent, WellSense Health Plan is required to follow MassHealth regulations. Members enrolled in a managed care contractor have a right to request a fair hearing as further described in 130 CMR 610.032(B), provided the member has exhausted all remedies available through the managed care contractor's internal appeals process (130 CMR 508.010(B)). The appellant has exhausted the expedited internal appeals process through WellSense Health Plan, which timely resolved the appellant's internal expedited hearing request (130 CMR 508.012). The appellant is therefore entitled to a fair hearing pursuant to the above regulations. Appellant has the burden of proving by a preponderance of the evidence the invalidity of the determination by the MassHealth agency or the ACO contracting with MassHealth.<sup>1</sup>

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:

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<sup>1</sup> See Fisch v. Board of Registration in Med., 437 Mass. 128, 131 (2002) (burden is on the appellant to demonstrate the invalidity of an administrative determination).

(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)).

Regulation 130 CMR 406.413(C) 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](http://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*.

The MassHealth Drug List specifies the drugs that are payable by MassHealth and designates which drugs require prior authorization (130 CMR 406.412).<sup>2</sup> 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 406.422(E)).

The appellant's pulmonologist submitted a request for Tyvaso DPI 16-32-48 cartridge inhalation on behalf of the appellant for treatment of pulmonary hypertension associated with [REDACTED]. The request for coverage of Tyvaso DPI 16-32-48 cartridge inhalation was denied by WellSense Health Plan because the request did not meet the criteria set forth in the MassHealth Drug List as required. For prior authorization of Tyvaso DPI (Trepstinil inhalation powder) for a diagnosis of [REDACTED], the MassHealth Drug list requires that the following criteria be met:

- appropriate diagnosis; and
- prescriber is a pulmonologist or cardiologist, or prescriber provides consultation notes from a pulmonologist or cardiologist regarding the diagnosis; and
- for Tyvaso DPI, medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution.

(See [www.mass.gov/druglist](http://www.mass.gov/druglist), and Exhibit 7, p. 75).

WellSense Health Plan testified that the first two elements for prior authorization have been satisfied; however, the appellant has not submitted medical records documenting an inadequate response, adverse reaction, or contraindication to Tyvaso inhalation solution. The appellant and his physician affirmed that a trial of Tyvaso inhalation solution has not been

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<sup>2</sup> The MassHealth Drug List ("the List") is an alphabetical list of commonly prescribed drugs and therapeutic class tables. The List specifies which drugs need prior authorization (PA) when prescribed for MassHealth members. The PA requirements specified in the List reflect MassHealth's policy described in the pharmacy regulations and other communications from MassHealth, as well as MassHealth's and the Drug Utilization Review (DUR) Board's review of drugs within certain therapeutic classes. See [www.mass.gov/druglist](http://www.mass.gov/druglist).

documented. The appellant has not carried the burden of showing that the prior authorization requirements for Tyvaso DPI have been met. WellSense Health Plan must comply with the prior authorization requirements set forth in the MassHealth Drug List. Therefore, WellSense Health Plan correctly denied the prior authorization request and internal appeal for Tyvaso DPI.

The appeal is DENIED.

## **Order for WellSense Health Plan**

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.

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Thomas J. Goode  
Hearing Officer  
Board of Hearings

cc: WellSense, Member Appeals & Grievances, Attn: Felicia DiSciscio, 529 Main Street, Ste. 500, Charlestown, MA 02129

