Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2401773
Decision Date:	4/1/2024	**Hearing Date:**	03/11/2024
Hearing Officer:	Susan Burgess-Cox		

Appearance for Appellant:

[redacted]

Appearance for Accountable Care Organization (ACO):
James Farrell, Mary Ann Petrolati & Elaina Horowitz

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
Decision Date:	4/1/2024	**Hearing Date:**	03/11/2024
ACOs Reps.:	James Farrell et. al.	**Appellant's Rep.:**	[redacted]
Hearing Location:	All Parties Appeared by Telephone		

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 October 27, 2023, Health New England, a MassHealth Accountable Care Organization (ACO), denied the appellant's internal appeal regarding a denial of coverage for a Tonic Motor Activation (TOMAC) device. (Exhibit 1; 130 CMR 450.204; 130 CMR 409.000). The appellant filed this appeal in a timely manner on February 6, 2024.[1] (Exhibit 2; 130 CMR 610.015(B)(7)).

A decision of an ACO to "deny or provide limited authorization of a requested service, including the type or level of service, including determinations based on the type or level of service, requirements for medical necessity, appropriateness, setting, or effectiveness of a covered benefit" are valid grounds for appeal. (130 CMR 610.032(B)).

Action Taken by the Accountable Care Organization

Health New England denied the appellant's prior authorization request for a Tonic Motor Activation device as they determined that the device is not medically necessary.

[1] Pursuant to 130 CMR 610.015(B)(7), for appeals of a decision reached by a managed care contractor, an individual has 120 days after the receipt of the managed care contractor's final internal appeal decision where the managed care contractor reached a decision wholly or partially adverse to the member.

Issue

Whether Health New England was correct in denying the appellant's prior authorization request for a Tonic Motor Activation device.

Summary of Evidence

All parties to the hearing appeared by telephone. The appellant appeared with two individuals from the sole global manufacturer and provider of the device. Both parties submitted records. Those submitted by the appellant's representative are duplicative of the submission of the Accountable Care Organization (ACO) who provided additional records. Therefore, the submission of the ACO is incorporated into the hearing record as Exhibit 4. This hearing record will not include the duplicative records submitted by the appellant's provider as a separate exhibit.

The appellant has a diagnosis of "drug refractory restless leg syndrome". Both parties acknowledged that the appellant has exhausted all FDA-approved treatments for her condition. The appellant currently utilizes morphine for relief. The appellant submitted a prior authorization request to cover the purchase of a Tonic Motor Activation (TOMAC) device. The ACO denied this request as it determined that the TOMAC is not the standard of care for the treatment of restless leg syndrome (RLS) and it is experimental/investigational. In their decision, the ACO noted that the standards of care include special therapies for RLS such as dopaminergic drugs, Gabapentin and related medications, and treatment of underlying iron deficiencies. The representatives from the ACO stated while there may not be anything else to offer the appellant for relief, this prior authorization request was denied as there is not enough published information on the efficacy of this device. The representatives from the ACO testified that they would need to see additional clinical rials before authorizing payment for this treatment.

The initial notice from the ACO states that the ACO covers health care services described in the Covered Services List in the Member Handbook. The Member Handbook states that new technology for experimental therapies, medical devices and treatment in clinical trials are reviewed on a case-by-case basis, as well as on a benefit level. Decisions to approve the use of new technology is based on what will give the highest benefit and lowest risk to the member. The review of new technologies includes:

- Consultation with clinic experts to review new technologies that the ACO is considering for coverage;
- A review of regulatory agency approval (such as the Food and Drug Administration);
- Published scientific reviews; and
- National or regional clinical practice recommendations from well-known sources (for example, the National Cancer Institute).

The notice states that the ACO denied the request as it did not meet these standards and while the ACO denied coverage, their decision does not mean that the appellant should not get the requested service, only that she may have to pay for it herself if she chooses to do so.

As part of the internal appeal process, the ACO had a review performed by the Medical Review Institute of America (MRIoA). This review also concluded that TOMAC is not considered a standard of care for restless leg syndrome. The review notes that TOMAC was evaluated in a small, randomized sham-controlled trial and while it was shown to be safe and effective in the reduction of RLS, additional clinical trials are needed with larger sham-controlled trials showing long-term efficacy comparable to that of pharmacological therapies. Several articles provided by the ACO discuss small, randomized sham-controlled trials of patients with severe RLS. Although the parties were asked repeatedly to provide context to some of the evidence contained in the exhibits, such as the medical articles, the parties responded that the hearing officer's review of the records should be sufficient in making a decision.

The representative from the manufacturer submitted a cover sheet with the request for hearing noting that they are "the sole global manufacturer and provider of the device, as such, there is no in-network provider in the ACO's network that can service [the appellant]". (Exhibit 4). The manufacturer stated that they were willing to negotiate a rate for the device via a letter of agreement when approved. (Exhibit 4). The appellant's provider submitted a letter to the ACO noting that this is a promising treatment option for members who have not responded to at least one medication. The provider states that TOMAC therapy represents a medically necessary intervention as it offers a promising solution to alleviate symptoms, improve sleep quality and enhance overall quality of life. A letter from the appellant's provider notes that TOMAC therapy was "granted breakthrough status by the [Food and Drug Administration (FDA)]" as well as "DeNovo 510K" clearance. A letter from the FDA granting the manufacturer's DeNovo classification states that the decision to grant the DeNovo request does not mean that the FDA has made a determination that the device complies with other requirements for the Food and Drug and Cosmetic (FD&C) Act or any other Federal statutes or regulations.

The representative from the manufacturer stated that there are other health care plans that cover this treatment and the appellant should be provided with individual consideration in approving coverage for the use of this device. The representative noted again that there was peer-review literature about the effectiveness of the device but did not clearly cite to any of the articles or directly relate their findings to the prior authorization request at issue.

Findings of Fact

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

1. The appellant has a diagnosis of "drug refractory restless leg syndrome".

2. The appellant has exhausted all FDA-approved treatments for her condition.

3. The appellant currently utilizes morphine for relief.

4. The appellant submitted a prior authorization request to cover the purchase of a Tonic Motor Activation (TOMAC) device.

5. The ACO denied this request as it determined that the TOMAC is not the standard of care for the treatment of restless leg syndrome (RLS) and it is experimental/investigational.

6. The ACO determined that there was not enough published information on the efficacy of the device.

7. The ACO Member Handbook states that new technology for experimental therapies, medical devices and treatment in clinical trials are reviewed on a case-by-case basis, as well as on a benefit level.

8. The ACO Member Handbook states that decisions to approve the use of new technology is based on what will give the highest benefit and lowest risk to the member.

9. The ACO's review of new technologies includes:

    a. Consultation with clinic experts to review new technologies that the ACO is considering for coverage;
    b. A review of regulatory agency approval (such as the Food and Drug Administration);
    c. Published scientific reviews; and
    d. National or regional clinical practice recommendations from well-known sources (for example, the National Cancer Institute).

10. As part of the internal appeal process, the ACO had a review performed by the Medical Review Institute of America (MRIoA).

11. MRioA also determined that TOMAC is not considered a standard of care for restless leg syndrome.

Analysis and Conclusions of Law

Pursuant to 130 CMR 508.001(A), MassHealth members who are younger than 65-years old must enroll in a MassHealth managed care provider available for their coverage type. Members enrolled in a managed care provider are entitled to a fair hearing under 130 CMR 610.000 to appeal a determination by an Accountable Care Organization (ACO), if the member has exhausted all remedies available through the contractor's internal appeal process. (130 CMR 508.010). The appellant is entitled to a fair hearing under 130 CMR 610.000 as she has exhausted the internal appeal process offered through the ACO. As MassHealth's agent, Health New England is required to follow MassHealth laws and regulations pertaining to a member's

care. As an ACO, Health New England can provide more benefits to members than MassHealth allows but not less.

MassHealth covers medically necessary Durable Medical Equipment (DME) that can be appropriately used in the member's home or setting in which normal life activities take place, and in certain circumstances described in 130 CMR 409.415 for use in facilities. (130 CMR 409.413(A)), All DME must be approved for community use by the federal Food and Drug Administration (FDA). (130 CMR 409.413(A)). DME that is appropriate for use in the member's home may also be used in the community. (130 CMR 409.413(A)).

MassHealth covers the DME listed in Subchapter 6 of the Durable Medical Equipment Manual, the DME and Oxygen Payment and Coverage Guideline Tool, and any successor guidance issued by the MassHealth agency or its designee. (130 CMR 409.413(B)). Providers may request prior authorization for medically necessary DME if the corresponding service code is not listed in Subchapter 6 or the DME and Oxygen Payment and Coverage Guideline Tool. (130 CMR 409.413(B)). In this case, neither party noted that this device was listed in Subchapter 6 of the Durable Medical Equipment Manual or the DME and Oxygen Payment and Coverage Guideline Tool, or successor guidance issued by MassHealth or its designee. Therefore, the provider had to request prior authorization for coverage of the equipment. (130 CMR 409.413(B)).

MassHealth does not pay for the following:

(A) DME that is experimental or investigational in nature;
(B) DME that is determined by the MassHealth agency not to be medically necessary pursuant to 130 CMR 409.000 and 130 CMR 450.204: Medical Necessity. This includes, but is not limited to items that:

    (1) cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness, disability, or injury;
    (2) are more costly than medically appropriate and feasible alternative pieces of equipment; or
    (3) serve the same purpose as DME already in use by the member with the exception of the devices described in 130 CMR 409.413(D). (130 CMR 409.414).

MassHealth also does not pay for DME that has not been approved by the federal Food and Drug Administration (FDA) for community use. (130 CMR 409.414(H)). In this case, the agency determined that the equipment was experimental or investigational in nature and not medically necessary. (130 CMR 409.414).

The regulations at 130 CMR 450.204(A) state that 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.

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. (130 CMR 450.204(B)). The regulations also state that 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(E)). In this case, the ACO determined that the service did not have sufficient authoritative evidence that it is reasonably calculated to have the effect to prevent, diagnose, prevent the worsening of, alleviate, correct or cure conditions in the appellant. The appellant's representatives did not demonstrate by a preponderance of the evidence that this decision was not correct. (130 CMR 610.082(B)).

As noted above, the ACO Member Handbook states that new technology for experimental therapies, medical devices and treatment in clinical trials are reviewed on a case-by-case basis, as well as on a benefit level. ACO decisions to approve the use of new technology is based on what will give the highest benefit and lowest risk to the member. The ACO also demonstrated that they followed this process for review of new technologies in making the decision that this device will not provide the highest benefit and lowest risk to the member.

At hearing, the ACO representatives offered clear testimony and evidence regarding their decision while the appellant's representatives seemed to want the Hearing Officer to draw their own conclusions based on the documentation without clearly articulating and referencing those documents within their argument. Simply stating that there have been studies and they are included in the hearing record does not demonstrate by a preponderance of the evidence that the ACO's decision was not correct. Additionally, simply stating that other health insurance companies cover this device does not demonstrate that the decision made by this ACO is not correct.

The ACO clearly articulated that the device was evaluated in a small, randomized sham-controlled trial and while it was shown to be effective in the reduction of RLS in those small trials, additional clinical trials are needed with larger sham-controlled trials showing long-term efficacy comparable to that of pharmacological therapies. The ACO clearly articulated that this device was still experimental and investigational in nature and the appellant's representatives failed to refute that argument. Therefore, the decision made by the ACO was correct.

This appeal is denied.

Order for the Accountable Care Organization

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.

Susan Burgess-Cox
Hearing Officer
Board of Hearings

cc:
MassHealth Representative: Health New England, James Farrell, Complaints & Appeals, One Monarch Place, #1500, Springfield, MA 01144-1500
[redacted]