

# Office of Medicaid BOARD OF HEARINGS

Appellant Name and Address:



Appeal Decision:	Denied	Appeal Number:	2512941
Decision Date:	11/26/2025	Hearing Date:	10/06/2025
Hearing Officer:	Mariah Burns		

Appearance for Appellant:

Pro se


Appearances for Mass General Brigham Health Plan (MGB Health Plan):

[Redacted], MD, Medical Director;  
[Redacted], Director, Appeals and Grievances;  
[Redacted], Manager, Appeals and Grievances;  
[Redacted], Program Specialist



*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; Prior Authorization, Durable Medical Equipment
<b>Decision Date:</b>	11/26/2025	<b>Hearing Date:</b>	10/06/2025
<b>MGB Health Plan Reps.:</b>		<b>Appellant's Rep.:</b>	Pro se
<b>Hearing Location:</b>	Video Conference (Quincy)	<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 May 29, 2025, Mass General Brigham (MGB) Health Plan denied the appellant's internal appeal of denied treatment, namely the Tonic Motor Activation (TOMAC) system, DME code E0743. MGB Health Plan determined that the device does not meet the plan's requirements for experimental and investigative treatment. *See* Exhibit 1. The appellant filed this appeal in a timely manner on September 5, 2025. *See* 130 CMR 610.015(B)(7) and Exhibit 2. Denial of a request for prior authorization is valid grounds for appeal. *See* 130 CMR 610.032.

### Action Taken by Mass General Brigham Health Plan

MGB Health Plan denied the appellant's level one appeal of a denied prior authorization request for durable medical equipment (DME).

## Issue

The appeal issue is whether the appellant has demonstrated, by a preponderance of the evidence, that the TOMAC system for restless legs is a covered service under the MassHealth regulations and/or MGB Health Plan policy.

## Summary of Evidence

The appellant is an adult MassHealth member under the age of 65 who is enrolled in the Mass General Brigham (MGB) Health Plan Accountable Care Organization. MGB Health Plan was represented at the hearing by its Medical Director, the Director of Appeals and Grievances, the Manager of Appeals and Grievances and a Program Specialist. All parties appeared by video conference. The following is a summary of the testimony and evidence provided at the hearing.

On or about February 21, 2025, the appellant submitted a prior authorization request for the

On March 5, 2025, MGB Health Plan denied the request after finding the requested device to be an experimental and/or investigational treatment that does not meet the plan's requirements for coverage. The appellant exhausted her administrative remedies, and a final denial of her request was issued by MGB Health Plan on May 29, 2025. The appellant filed this appeal with the Board of Hearings on September 5, 2025.

In support of MGB Health Plan's decision, the plan submitted the appellant's prior authorization request, her various appeal documents, and the clinical documentation and scientific literature provided with her request and her subsequent appeals. The plan also provided its policies related to Experimental and Investigative procedures and its appeals and grievance policy. At the hearing, the medical director reported that, after an independent review requested by the appellant, the plan determined that the requested device does meet the definition of medical necessity. However, the plan still does not cover the device because it is an experimental treatment that is not expressly covered by MassHealth.

The appellant provided a letter from her prescribing physician and medical records contemporaneous with the prior authorization request. The letter states that the requested device received Breakthrough Status by the FDA in 2020 and received de novo clearance on April 17, 2023<sup>1</sup>. The medical records report that, as of January 31, 2025, the appellant was doing well on medication to treat her and was not having breakthrough symptoms. The appellant

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<sup>1</sup> No explanation was given as to the meaning of those statuses, beyond a separate assertion that "TOMAC therapy is FDA approved." See Exhibit 6 at 5.

testified that her [REDACTED] is being managed and is improving, but that she is hopeful that the device can assist with any lingering symptoms.

## Findings of Fact

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

1. The appellant is an adult under the age of 65 MassHealth member who is currently enrolled in the Mass General Brigham Health Plan Accountable Care Organization. Exhibit 4, Testimony.
2. The appellant suffers from a diagnosis of [REDACTED] *See generally*, Exhibit 6. On February 21, 2025, she submitted a [REDACTED]  
[REDACTED] On March 5, 2025, MGB Health Plan denied that request on the grounds that it is an experimental and investigational treatment that does not meet the medical necessity guidelines. Exhibit 5 at 61-62.
3. The appellant exhausted her administrative remedies of the March 5, 2025, denial. MGB Health Plan issued a final denial of the request on March 29, 2025. Exhibit 1.
4. The appellant filed a timely request for fair hearing to the Board of Hearings on September 5, 2025. Exhibit 2.
5. According to MGB Health Plan, the device is medically necessary for the appellant, but it cannot be covered by the ACO because it is not specifically covered by MassHealth. Testimony.
6. The device was granted breakthrough status by the Food and Drug Administration (FDA) in 2020. It then received de novo clearance by the FDA on April 17, 2023. Exhibit 6 at 1-2.
7. The appellant is on medication to help combat her [REDACTED]. As of the date of the hearing, they are being managed and are improving. Testimony. Her physician reports that, as of January 31, 2025, the appellant is not having breakthrough [REDACTED]. Exhibit 6 at 4, 20.

## Analysis and Conclusions of Law

Federal law permits MassHealth to contract with individual private insurance companies, referred to as managed care organizations (MCOs), to deliver care to relevant members under the regulations. *See* 130 CMR 508.000. One such type of MCO is an accountable care organization (ACO), which is typically a private insurance company that contracts with MassHealth “wherein the entity is held financially accountable for the cost and quality of care for an attributed or enrolled

member population.” 130 CMR 501.001.

An ACO has specific statutory and regulatory requirements by which it must abide regarding the scope of its coverage. Namely, the ACO must make “the services it provides to its Medicaid enrollees as accessible (in terms of timeliness, amount, duration, and scope) as those services are to other Medicaid beneficiaries within the area served by the entity.” 24 CFR § 438.2 (definition of managed care organization). Put otherwise, the ACO must provide everything under the MassHealth regulations and may have services or coverage that exceeds the scope of those provided by MassHealth. Typically, “[a]ll medical services to members enrolled in an MCO...are subject to the prior authorization and referral requirements of the MCO.” 130 CMR 508.004(2).

Specifically related to this appeal, MassHealth “covers [durable medical equipment (DME)] provided to eligible MassHealth members, subject to the restrictions and limitations described in 130 CMR 409.000 and 130 CMR 450.000.” 130 CMR 409.403(A). That includes “medically necessary DME that can be appropriately used in the member’s home or setting in which normal life activities take place...All DME must be approved for community use by the federal Food and Drug Administration (FDA).” 130 CMR 409.413(A). MassHealth also 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.” *Id.* at 409.413(B).<sup>2</sup> DME code number E0743 is not included in either of those documents.

MassHealth does not pay for the following, relevant, DME:

- (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);
- (F) DME that is not of proven quality and dependability, consistent with 130 CMR 409.404(B)(12);

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<sup>2</sup> Subchapter 6 of the DME Manual may be found here: <https://www.mass.gov/doc/durable-medical-equipment-dme-subchapter-6-2/download> (last update 10/01/20240; The DME and Oxygen Payment and Coverage Guideline Tool may be found here: <https://www.mass.gov/doc/masshealth-dme-and-oxy-payment-and-coverage-guideline-tool-v46-0/download>.

(H) DME that has not been approved by the federal Food and Drug Administration (FDA) for community use;

130 CMR 409.414 (emphasis added).

A service is determined to be 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...

...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.

...Additional requirements about the medical necessity of MassHealth services are contained in other MassHealth regulations and medical necessity and coverage guidelines.

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

According to the MGB Health Plan “Medical Policy – Experimental and Investigational,” the plan covers “services, procedures, devices, biologic products, and drugs...when there is sufficient scientific evidence to support their use or when the treatment is required by regulation.” Exhibit 5 at 187. To summarize the guidelines, sufficient evidence exists to support a treatment when 1) The treatment has received final approval from an appropriate government body such as the FDA, 2) The scientific evidence must use sound scientific study methodology, and 3) the treatment must be proven to be safe and effective. *Id.* With respect to MassHealth members enrolled in MGB Health Plan, the plan “uses guidance from MassHealth for coverage determinations of its MassHealth ACO members. When there is no guidance from MassHealth for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.” *Id.* at 188.

MassHealth regulations apply to ACOs and provide that “[m]embers are entitled to a fair hearing under 130 CMR 610.00: MassHealth Fair Hearing Rules to appeal...a determination by...one of the...ICOs...if the member has exhausted all remedies available through the contractor’s internal appeals process.” 130 CMR 508.010(B). The appellant has the burden of proof at such a hearing “to demonstrate the invalidity of the administrative determination.” *Andrews v. Division of Medical Assistance*, 68 Mass. App. Ct. 228, 231 (2006). The fair hearing decision, established by a preponderance of evidence, is based upon “evidence, testimony, materials, and legal rules, presented at hearing, including the MassHealth agency’s interpretation of its rules, policies and regulations.” 130 CMR 610.082(A) and (B).

After careful review of the evidence and the relevant policies and regulations for the MGB Health Plan and MassHealth, I find that the appellant has not met her burden of proof in demonstrating that MGB Health Plan erred in denying her request for coverage of the TOMAC System (DME code E0743).

### **MassHealth’s Coverage of the Requested DME**

Although I disagree with MGB Health Plan’s assertion that because E0743 is not specially enumerated in Subchapter 6 of the MassHealth DME Manual, the device cannot be covered, I do not find that the appellant has shown that the device meets MassHealth medical necessity criteria. As noted, *supra*, MassHealth will cover DME that is listed in Subchapter 6, but the agency will also cover medically necessary DME that is approved by the FDA for community use. 130 CMR 409.413(A). While the requested device may have received FDA approval<sup>3</sup>, MassHealth requires any requested treatment meet both prongs of the medical necessity regulations – the clinical and financial standards. I find that the appellant has demonstrated, and MGB Health Plan appears to agree, that the requested device would prevent the worsening of or alleviate the appellant’s [REDACTED]. See 130 CMR 452.204(A)(1). However, by the appellant’s own testimony and the medically documentation submitted by her provider in support of the prior authorization request, the appellant’s [REDACTED] is being managed and is improving with medication and other lifestyle changes. The appellant’s provider noted on January 31, 2025, that the appellant “does not tend to have [REDACTED] breakthrough symptoms” anymore. See Exhibit 6 at 4. Thus, I find that the appellant has not demonstrated that she meets the second prong of the MassHealth medical necessity requirement, namely that there is no other medical service of comparable effect that is a less-costly alternative than the requested treatment. See 130 CMR 450.204(A)(2). For those reasons, I find that there is not sufficient evidence in the record to show that E0743 meets the MassHealth medical necessity requirements.

### **MGB Health Plan’s Coverage of the Requested Device**

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<sup>3</sup> There is no testimony or physical evidence in the record that FDA classification received by the device meets the specific requirements listed at 130 CMR 409.414(H).

As of the date of the notice issued by MGB Health Plan in this case, it considered the requested device to be experimental and investigational, as it is not specifically enumerated as a covered service. The Health Plan does cover experimental and investigational treatment, but only when there is sufficient scientific evidence to support its use or when the treatment is required by regulation.<sup>4</sup> At the hearing, the Health Plan Medical Director reported that, although the treatment requested by the appellant “meets the definition of medical necessity,” it cannot be covered by MGB Health Plan because it is not specifically covered by MassHealth. While I note that that the plan’s policy states that experimental treatment is covered when it is scientifically indicated *or* required by regulation, deference must be given to the ACO’s interpretation of its policies and prior authorization procedures.<sup>5</sup> See 130 CMR 508.004(2) and 130 CMR 610.082(B). The record does not contain sufficient information to show, by a preponderance of the evidence, that the requested treatment should be covered by MGB Health Plan’s policies and procedures.

Thus, I am unable to find any error in MGB Health Plan’s decision to deny the appellant’s prior authorization request for the TOMAC system device, DME code E0743. For the foregoing reasons, the appeal is hereby DENIED. The appellant may, at any time, submit a new request for prior authorization should any additional information become available.

## **Order for Mass General Brigham Health Plan**

None.

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<sup>4</sup> It is unclear what “required by regulation” means, but a reasonable interpretation would be consistent with the plan’s testimony that experimental treatment is not covered unless it is specifically codified and covered by MassHealth regulations.

<sup>5</sup> MGB Health Plan may, at any time, reconsider its decision in this case.

## **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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Mariah Burns  
Hearing Officer  
Board of Hearings

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