Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2501883
Decision Date:	05/27/2025	**Hearing Date:**	03/07/2025
Hearing Officer:	Casey Groff, Esq.	**Record Closed:**	03/28/2025

Appearance for Appellant:
[redacted]

Appearance for MCC:
Julie Balistreri, Sr. Manager Appeals & Grievances, Government Programs, MGBHP
Christina Thompson, Supervisor, Appeals and Grievances, MGBHP
Tianta Thompson, Appeals and Grievances Coordinator, MGBHP
Michaele Freeman, MCO Contract Manager EOHHS

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:**	Managed Care; ACO – Denial of Internal Appeal; DME
Decision Date:	05/27/2025	**Hearing Date:**	03/07/2025
MCC's Reps.:	Julie Balistreri, MGBHP, *et. al.*	**Appellant's Rep.:**	[redacted]
Hearing Location:	Board of Hearings, Remote	**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

Through an internal appeal determination notice dated 12/18/24, Mass General Brigham Health Plan (MGBHP), an Accountable Care Organization (ACO), acting as a managed care contractor (MCC) on behalf of MassHealth, notified Appellant that it upheld its denial of his request for coverage for an InTandem™ Neurorehabilitation System, gait modulation therapy. *See* Exh. 1. On 1/29/25, Appellant filed a timely request for a fair hearing. *See* Exh. 2. An adverse appeal determination by an MCC is valid grounds for appeal.[1] A hearing was held on 3/7/25. The record remained open through 3/28/25 for the parties to submit additional evidence. *See* Exhs. 5-10.

[1] Fair Hearing regulations at 130 CMR 610.032(B) set forth the specific bases under which any enrollee of an MCC, including ACO members, may request a fair hearing. Grounds for appeal include, but are not limited to, the MCC's failure to provide services in a timely manner, a decision to deny or provide limited authorization of a requested service; and a decision to reduce, suspend or terminate a previous authorization for a service. Any member that receives an adverse coverage determination by the ACO and exhausts all remedies through its internal appeal process, may request a fair hearing with the Board of Hearings under 130 CMR 610.000 *et. seq.* *See* 130 CMR §§ 610.002, 610.032(B); *see also* 130 CMR 508.010(B). As Appellant received an adverse Level 1 appeal determination by MGBHP, he is entitled to a fair hearing. *See* 130 CMR 610.032(B).

Action Taken by MCC

Through a level 1 internal appeal, MGBHP, in its capacity as a managed care contractor with MassHealth, upheld its initial determination to partially deny Appellant's request for coverage of an InTandem Neurorehabilitation System on the basis that it was neither a covered nor medically necessary service.

Issue

The appeal issue is whether MGBHP, as a managed care contractor for MassHealth, erred in denying Appellant's request for coverage of an InTandem Neurorehabilitation System.

Summary of Evidence

Representatives for Respondent, Mass General Brigham Health Plan (MGBHP), appeared at the hearing by telephone. Through testimony and documentary submissions, the MGBHP representatives presented the following evidence: Appellant is an adult MassHealth member between the ages of 21 and 65 and is enrolled in a health plan offered through MGBHP – an Accountable Care Organization (ACO) for MassHealth. As an ACO, MGBHP is responsible for coordinating and ensuring the provision of medically necessary MassHealth covered benefits to its enrollees, such as Appellant.

On 11/26/24, MGBHP received a prior authorization (PA) request from [redacted], on behalf of Appellant, seeking coverage for one unit of MedRhythms' InTandem™ Neurorehabilitation System, using HCPCS code E3200: *Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories included, prescription only. See* Exh. 4, pp. 57-61. The PA request was comprised of a prescription and letter of medical necessity (LOMN), signed by Appellant's primary care physician (PCP), as well as Appellant's clinical records and copies of published studies cited in support of the PA request.

According to the clinical records, Appellant's relevant medical history includes an ischemic left middle cerebral artery stroke on [redacted] with right hemiparesis, gait impairment, and combined receptive and expressive aphasia. *Id.* at 122. Additional diagnoses include chronic back pain, asthma, anterior uveitis, ankylosing spondylitis, sarcoidosis, depression, and compression fractures of the L3 vertebra. *Id.* Appellant underwent implantation of a vagus nerve stimulator in [redacted] *Id.*

In the LOMN, Appellant's PCP described InTandem as a home-use, prescription-only medical device, intended to improve walking speed and gait quality in adult patients with chronic stroke-

related walking deficits by providing "rhythmic auditory stimulation," or "RAS." *Id*. at 57-61. RAS, the provider explained, is a type of intervention which uses auditory motor entrainment or rhythm-based auditory cues to improve gait characteristics such as speed, symmetry, and variability for individuals with gait impairments resulting from neurological conditions caused by stroke. *Id*. The device is used as follows:

> During a therapy session, the InTandem System's gait sensors continuously transmit real-time gait data to the control unit, which uses advanced algorithms to analyze the patient's gait characteristics, including cadence, temporal symmetry, and variability. Based on this analysis, the control unit modulates the tempo and rhythmic structure of the music to achieve auditory-motor entrainment and promote gait improvements. The system progressively challenges the patient's gait speed by increasing the tempo of the auditory stimuli by increments that are not consciously detectable (~5% incremental increases), subconsciously increasing walking speed while ensuring that gait quality is maintained or improved.

Exh. 7(b), p. 3.

The device is typically prescribed in 30-minute sessions, three times per week. *Id.* The PCP noted that Appellant previously tried occupational therapy (OT), but it failed to adequately address his gait impairment. *Id.* The provider asserted that in the absence of viable alternatives for home-based neurorehabilitation, InTandem was medically necessary to improve Appellant's capacity to ambulate more safely and independently, which will in turn lower the likelihood of falls and related injuries. *See* Exh. 4, p. 57-61. In further support of the request, Appellant's provider asserted that InTandem's efficacy, safety usability, and cost-effectiveness was supported by studies published in 5 peer reviewed journals, copies of each were enclosed with the LOMN, including: Thaut*, et. al.* 1999, 2015; Awad*, et. al*. 2024; Collimore*, et. al.* 2023*;* and Verghese*, et. al.* 2009*. Id.* at 65-109.

On 11/27/24, MGBHP informed Appellant that it denied his PA request because the item requested was considered a non-covered benefit. *Id.* at 63. In making this determination, MGBHP referred to its ACO Member Handbook and MassHealth regulations at 130 CMR 433.428 which identify "biofeedback" as a noncovered service. *Id.*

On 12/10/24, Appellant filed a level 1 appeal with MGBHP. *Id*. at 130 - 141. The request included an updated LOMN from the provider, clinical records, and supporting studies as previously identified. *Id*.

Pursuant to an internal appeal determination notice dated 12/18/24, MGBHP informed Appellant that it upheld its initial notice of adverse action, stating, in relevant part:

> In response to our findings, Mass General Brigham Health Plan has denied your request because it is not considered a covered benefit under your Mass General Brigham ACO Plan. Please refer to your Mass General Brigham ACO Member Handbook. [MGBHP] used MassHealth's current regulations regarding Biofeedback under the Noncovered Services document to review the request. Based on the clinical information received, the request did not meet medical necessity guidelines.

See Exh. 1.

The MGBHP representatives testified that because InTandem was deemed to be a noncovered service, the PA request was administratively denied without undergoing a substantive review for medical necessity. They noted, however, that Appellant is actively engaged in OT and has supportive durable medical equipment in place. Because the procedure code is not listed within ACO covered service codes and is a type of non-covered biofeedback treatment, it was treated as a straightforward administrative denial.

Appellant's representative appeared at the hearing by telephone and testified that she works for a healthcare company. In her position, she advocates for patients to get access to medical products they need. One of her clients is InTandem through MedRhythms. She has been working with Appellant and believes he is a strong candidate for the treatment it offers.

Appellant's representative first asserted that MGBHP was incorrect in classifying InTandem as "biofeedback" therapy. Appellant's representative explained that biofeedback is a type of psychiatric treatment and is classified as such under MassHealth regulations. Biofeedback works through the use of devices designed to track brain activity and provide feedback on bodily functions – allowing users to consciously modify or self-regulate certain internal states such as muscle tension and heart rate which are otherwise controlled subconsciously. Unlike biofeedback, InTandem does not involve real-time monitoring or self-regulation of physiological functions but rather uses rhythm-based auditory cues to assist with subconscious motor coordination. Appellant's representative testified that effective 10/1/24, InTandem was assigned HCPCS code E3200 by CMS under its durable medical equipment (DME) benefit category.

Appellant's representative provided additional details on the science behind InTandem's use and efficacy, which, she asserted, are based on principles of rhythmic auditory stimulation (RAS) and its ability to induce auditory-motor entrainment (i.e., a temporal locking process in which one system's motion or signal frequency entrains the frequency of another system) and neuroplasticity. When an individual is exposed to consistent rhythmic auditory stimulus it activates the auditory system, which is connected to the motor system.

The representative testified that Appellant presents with a slow and effortful gait typical for a stroke survivor. His gait impairment interferes with activities of daily living that involve walking. He has participated in OT for over 6 months, which, alone, has not helped. The goal of the requested service is to see improvement in Appellant's functional ambulation category ("FAC") scores to the extent that safe community ambulation is possible, which it is not at this time.

When given an opportunity to respond, the MGBHP representatives did not explicitly refute Appellant's argument that InTandem was not a biofeedback device, nor did they explain the reasons that prompted this designation. Given that this served as the sole basis for the PA denial, the record was left open for the parties to submit additional information on whether the requested item was or was not appropriately deemed a non-covered biofeedback device, and/or whether it fell within Appellant's covered DME benefits. *See* Exh. 5.

Pursuant to a record open period, Appellant first submitted additional documentation, including Appellant's updated clinical records. *See* Exhs 7(a)-(e). On review, MGBHP asserted that it appropriately denied the PA request as it is not covered under Appellant's DME benefit per MassHealth DME coverage guidelines and ACO medical policy which excludes coverage of "investigational and experimental" treatments. *See* Exh. 10. In support of its position, MGBHP submitted the findings of an enlisted clinical specialist, with board certifications in physical medicine & rehabilitation and neuromusculoskeletal medicine, related to their review of all documentation submitted on behalf of Appellant. In particular, the review focused on the published studies cited by Appellant and related articles, including a pivotal randomized controlled trial of InTandem by Awad *et. al*., and articles by Bohannon *et. al.* and Fulk *et. al.* regarding clinically significant improvements in gait speed. The reviewer determined that, despite the medical literature available, there was "not a body of high-quality evidence showing that InTandem produces a clinically meaningful increase in gait speed among patients with a history of stroke compared with the control intervention." *See* Exh. 9(a).[2] Regarding the Awad study, the reviewer found that InTandem was not associated with improvements in other clinically meaningful outcomes for individuals with stroke such as a reduction in falls or functional improvements in completion of ADLs. *Id.* Moreover, in reviewing Appellant's clinical records, there was no objective data regarding his walking speed, and therefore it could not be established whether Appellant would meet the Awad trial inclusion criteria, i.e., walking speeds of .50m/s and 0.80m/s. *Id.* In summary, MGBHP concluded that the requested treatment was not covered or medically necessary per medical policy no. 021 as it is "investigational and experimental." *Id.*

Appellant's representative was given an opportunity to submit a final rebuttal to address any

[2] The specialty reviewer noted that "the study by Bohannon is not relevant to the importance of walking speed in patients with stroke since it only included 3 participants with stroke and therefore cannot be applied to this patient population with certainty. The study by Fulk *et al.* concluded that a change in gait speed of 0.175 m/s or greater is likely to exhibit a meaningful improvement in walking ability. While this is likely, it is not definitive and the study by Awad demonstrated walking speed less than 0.175 m/s or 0.14 m/s." *Id*.

new issue(s) raised through MGBHP's submission. Appellant's representative initially sought an extension to gather more information; however, ultimately declined to submit a response, asserting that they would stand on the evidence already presented. *See* 10(a).

Findings of Fact

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

1. Appellant is an adult MassHealth member between the ages of 21 and 65 enrolled in MGBHP's ACO plan.

2. On 11/26/24, MGBHP received PA request from [redacted], on behalf of Appellant, seeking coverage for one unit of MedRhythms' InTandem™ Neurorehabilitation System, using HCPCS code E3200: *Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories included, prescription only.*

3. Appellant's relevant medical history includes an ischemic left middle cerebral artery stroke on [redacted] with right hemiparesis, gait impairment, and combined receptive and expressive aphasia; with additional diagnoses include chronic back pain, asthma, anterior uveitis, ankylosing spondylitis, sarcoidosis, depression, and compression fractures of the L3 vertebra; vagus nerve stimulator implantation in [redacted]

4. Appellant received at least 6 months of OT services, but he continues to have gait impairment.

5. On 11/27/24, MGBHP informed Appellant that it denied his PA request because the item requested was considered a non-covered benefit based on the ACO Member Handbook and MassHealth regulations at 130 CMR 433.428 which identify "biofeedback" as a noncovered service.

6. On 12/10/24, Appellant filed a level 1 internal appeal with MGBHP.

7. Pursuant to an internal appeal determination notice dated 12/18/24, MGBHP informed Appellant that it upheld its initial notice of adverse action.

8. During a record-open period and after further review of the medical records and medical literature provided by Appellant, MGBHP relayed its conclusion that InTandem remains non-covered and medically unnecessary because it is experimental and investigative.

9. Appellant was given an opportunity to address any newly issues raised in MGBHP's post-hearing submission; however, Appellant ultimately declined to submit additional evidence or arguments for consideration.

Analysis and Conclusions of Law

Appellant is a MassHealth beneficiary enrolled in an Accountable Care Organization (ACO), operated by MGBHP. Pursuant to its contract with the Executive Office of Health and Human Services (EOHHS), MGBHP, as an ACO, must "[a]uthorize, arrange, coordinate, and provide to Covered Individuals all Medically Necessary ACO Covered Services listed [therein], in accordance with the requirements of the Contract, and in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to Members under MassHealth fee-for-service." *See Second Amended and Restated Accountable Care Partnership Plan Contract* ("MGBHP-*ACPPC*"), § 2.7(A)(1), p. 135; [3] *see also* 130 CMR 501.001. Thus, MGBHP must provide its members with the full range of covered health services they are entitled to under their MassHealth coverage type.

As a general rule, MassHealth does not cover any medical service unless it is medically necessary. 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.

See 130 CMR 450.204(A).

Medically necessary services are further defined as services that are "of a quality that meets professionally recognized standards of health care." *Id.* Moreover, "***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***

[3] A copy of the executed contract is available online, at:
https://www.mass.gov/doc/2nd-amended-and-restated-acpp-contract-mgbhp-mgbaco/download

calculated to have the effect described in 130 CMR 450.204(A)(1)." 130 CMR 450.204(e)(emphasis added).

At issue in this appeal is whether MGBHP correctly denied Appellant's request for prior authorization of an InTandem Neurorehabilitation System on grounds that it was neither medically necessary nor covered under Appellant's ACO benefit. As stated in MGBHP's internal appeal notice, this decision was based on non-coverage rules applicable to "biofeedback" treatment under 130 CMR 433.428. *See* Exh. 1.

Appellant argued that the entire premise of MGBHP's denial is incorrect because InTandem cannot be classified as a type of "biofeedback" treatment. Appellant correctly notes that 130 CMR 433.428 pertains to a subsection of the MassHealth physician regulations, which governs MassHealth coverage of psychiatric services. It states, in relevant part, that MassHealth "does not pay a physician or PCNS for nonmedical services including, but not limited to, … (f) biofeedback." 130 CMR 433.428(B). The regulations do not define "biofeedback." In attempting to differentiate InTandem from biofeedback treatments, Appellant's representative asserted that "InTandem does not involve the real-time monitoring and feedback of physiological processes to enable self-regulation of such functions" – features that, Appellant asserts, are a principal component of biofeedback therapy. The evidence indicates, however, that InTandem works, in part, through its gait sensors which "continuously transmit real-time data to analyze the patient's gait," which in turn, provides feedback to allow the device to modulate the tempo of the music to achieve auditory-motor entrainment and promote gait improvements. *See* Exh. 7(b). While neither party submitted sufficient evidence to conclude whether InTandem can appropriately be classified as biofeedback, the evidence suggests that, at a minimum, it shares many of the same features that are characteristic of biofeedback treatment.

Nevertheless, it is unnecessary to decide whether InTandem is a "biofeedback" device for purposes of determining whether MGBHP correctly denied it as a non-covered and medically unnecessary device. The evidence indicates that effective 10/1/24 the Centers for Medicare and Medicaid Services (CMS) assigned HCPCS code E3200 to identify InTandem under Medicare's durable medical equipment (DME) benefit category. Given its classification as a DME product, the question of whether it is a covered ACO/MassHealth benefit is governed by MassHealth DME regulations and applicable ACO policies.

MassHealth covers medically necessary DME subject to the requirements and limitations set forth in 130 CMR 409.000 *et. seq.* As a threshold requirement, "all [DME] ***must be non-experimental, non-investigational, of proven quality and dependability, and must conform to all applicable federal and state product standards."*** 130 CMR 409.403 (emphasis added). In addition, all DME must be approved for community use by the FDA. *See* 130 CMR 409.413(B).

MassHealth covers all DME service codes listed in Subchapter 6 if its *DME Manual*, as well as the

DME and Oxygen Payment and Coverage Guideline Tool, and any successor guidance issued by MassHealth or its designee. *Id.* The absence of a service code in either source does not, automatically, preclude coverage. Rather, a provider may still request coverage for an unrecognized DME service code, *if medically necessary*, through the prior authorization process outlined in 130 CMR 409.418. *See* 130 CMR 413(B).

Specific categories of DME that MassHealth covers related to gait impairments include "ambulatory equipment, such as crutches and canes;" as well as "mobility equipment and seating systems." *Id.*

Under 130 CMR 409.414, MassHealth sets forth specific categories of products that it considers non-covered DME services. The regulation states, in relevant part, the following:

> MassHealth does *not* pay for any of 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 450.204***. 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 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);
> ….

See 130 CMR 409.414 (emphasis added).

The service being requested here - HCPCS code E3200 - cannot be found in either Subchapter 6 of MassHealth's *DME Manual* or its *DME and Oxygen Payment and Coverage Guideline Tool*. As such, Appellant's provider had to seek coverage through the prior authorization process outlined in 130 CMR 409.418. *See* 130 CMR 409.413(B).

Included in Appellant's PA request was a letter of medical necessity signed by Appellant's PCP, asserting that use of the InTandem neurorehabilitation system, in consideration of his current level of gait impairment, was medically necessary to improve his capacity to ambulate more safely and independently. *See* Exh. 4, p. 136-140. The letter cited various studies regarding the use of RAS as a clinical intervention for stroke rehabilitation, which, according to the provider, supported the safety and efficacy of the InTandem device.

In consideration of the totality of evidence presented, Appellant did not adequately demonstrate MGBHP erred in denying his PA request. MGBHP's conclusion that InTandem was a noncovered/medically unnecessary service was not solely based on rules pertaining to

biofeedback; but rather, it was also based on the rules that exclude coverage of services that are "experimental and investigational." According to MGBHP Policy No. 021, a "treatment" (such as a device, procedure, etc.) is "experimental or investigational," when the scientific evidence to support its use is insufficient. *See MGBHP Medical Policy No. 021.* To determine the extent to which scientific evidence is sufficient, MGBHP sets forth the following guidelines:

1. The treatment must have a final approval from the appropriate governmental regulatory body, such as the FDA;
2. The scientific evidence must demonstrate that conclusions pertaining to a treatment are based on sound scientific study methodology published in credible, peer-reviewed English-language journals ….[4]
3. The treatment must be proven to be safe and effective, described as follows:
    a. Beneficial effects on health outcomes must outweigh any harmful effects.
    b. Health outcomes are superior or comparable to established alternatives
    c. Improvement in health outcomes have the potential to be realized outside the investigational setting
    d. It is as cost effective as established treatments that produce similar outcomes.

Id.

During the record open period, an MGBHP specialty reviewer, board certified in physical medicine & rehabilitation and neuromusculoskeletal medicine, found that despite the medical literature available, there was not an adequate body of high-quality evidence to conclude that InTandem was effective in producing clinically meaningful outcomes such as increased gait speed, functional improvement in the completion of ADLs, or reduced falls for patients with a history of stroke. Moreover, there was no objective data regarding Appellant's walking speed to assess whether he met the inclusion criteria that had been used in the Awad study. *See* Exh. 10(a).

Through pre-hearing submissions and oral testimony offered at hearing, Appellant asserted that studies cited therein supported the efficacy, safety, usability, and cost-effectiveness of InTandem. Appellant, however, declined to respond to the specific points raised by MGBHP in its post-hearing submission. Given that MGBHP provided a clear and well-articulated basis for why it considers InTandem to be experimental and investigational, and absent any opposing argument to refute this conclusion, the ACO appropriately denied Appellant's PA request on the basis that it was neither covered nor medically necessary under MassHealth regulations and ACO coverage rules. *See* 130 CMR §§ 450.204(E), 409.403, and 409.414(A)-(B).

Based on the foregoing, this appeal is DENIED.

[4] For purposes of the 2nd guideline "the following hierarchy of reliable evidence is used: "(a) Systematic reviews and/or high-quality meta-analyses of randomized controlled trials with definitive results; (b) Formal high-quality technology assessments; (c) Well-designed, randomized, controlled, double-blind studies; (d) Cohort studies; (e) High quality case-control studies; and finally (f) Expert opinion from national professional medical societies or national medical policy organizations in the absence of definitive scientific data…" *Id.*

Order for MCC

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, Esq.
Hearing Officer
Board of Hearings

[redacted]

MassHealth Representative: Mass General Brigham Health Plan, Attn: Christina Thompson, 399 Revolution Drive, Suite 810, Somerville, MA 02145

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