Office of Medicaid
BOARD OF HEARINGS

Appellant Name and Address:

[redacted]

Appeal Decision:	Denied	**Appeal Number:**	2506916
Decision Date:	6/11/2025	**Hearing Date:**	6/5/2025
Hearing Officer:	David Jacobs		

Appearance for Appellant:
[redacted]

Appearances for MGBHP:
Dr. David Lyczkowsky, Medical Director
Christina Thompson, Appeals and Grievances Supervisor
Julie Balistreri, Sr. Manager Appeals & Grievances
Michaele Freeman, MCO Contract Manager (MassHealth)

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 – Gait Modulation System
Decision Date:	6/11/2025	**Hearing Date:**	6/5/2025
MGBHP Reps.:	Dr. David Lyczkowsky, Christina Thompson, Julie Balistreri, Michaele Freeman	**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 March 13, 2025, Mass General Brigham Health Plan (MGBHP), an Accountable Care Organization (ACO), acting as a managed care contractor (MCC) on behalf of MassHealth, notified the appellant that it upheld its denial of his request for coverage for an InTandem Gait Modulation System (Exhibit 1). The appellant filed a timely request for a fair hearing (Exhibit 2). An adverse appeal determination by an MCC is valid grounds for appeal.

Action Taken by MassHealth

MassHealth denied the appellant's prior authorization request for the InTandem Gait Modulation System.

Issue

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

Summary of Evidence

The appellant submitted a request for an InTandem Gait Modulation to MGBHP on January 27, 2025 (Exhibit 8, pg. 122). On January 31, 2025, MGBHP denied the request because the item requested was considered a non-covered benefit *id*. On February 14, 2025, the appellant internally appealed the denial to MGBHP *id*. On March 13, 2025, MGBHP informed the appellant that it upheld its initial notice of adverse action. That same day, the appellant appealed this final denial from MBBHP to the Board of Hearings *id*.

[redacted] appeared telephonically at the hearing and testified primarily for [redacted] He testified that the appellant is a male over the age of [redacted] enrolled in [redacted] with a recent history of stroke who is requesting the gait modulation system to potentially improve his ability to walk. However, [redacted] denied the request because it is a biofeedback device which is defined as a noncovered service in accordance with 130 CMR 433.428. It was also denied because it is not listed as a covered item in Subchapter 6 of MassHealth's Durable Medical Equipment (DME) provider manual. The InTandem Gait Modulation System is registered with the FDA as a biofeedback device and should be considered as such for insurance coverage purposes. It works by placing sensors on the user's shoes to measure their gait as they walk. This information is then sent to a device that plays music to the user at a tempo that allegedly subconsciously improves the user's walking speed.

[redacted] appeared telephonically for the appellant and read the following into the record in part:

"The health plan refers to Massachusetts Code of Regulations 130 CMR, § 433.428, Which is entitled Psychiatric Services.

We disagree with this denial because the MedRhythms InTandem device is not a biofeedback device. It does not involve the real-time monitoring and feedback of physiological processes to enable self-regulation of those processes, and should not be considered a psychiatric treatment in any way. The application of that policy to this request is inappropriate.

Biofeedback devices are specifically designed to track and provide feedback on bodily functions—such as heart rate, muscle tension, or brain activity—allowing users to consciously modify these internal states.

In contrast, the InTandem device uses rhythm-based auditory cues to assist with sub-conscious motor coordination, particularly for individuals with gait impairments due to neurological conditions caused by stroke.

While the InTandem device provides auditory guidance to synchronize movement, it does not measure or respond to internal physiological states like muscle tension, heart rate, or brain wave activity. Therefore, it is not related to biofeedback in any way, and utilizes a completely different mechanism of action. The device renders therapy closer to occupational physical therapy, as opposed to psychiatric.

In biofeedback, the patient is being consciously trained to utilize relaxation and conscious control of their parasympathetic nervous system to override circumstances when their sympathetic nervous system is being triggered. The sympathetic nervous system speeds things up in the body, like heart rate and muscle tension, in response to triggers like anger, fear, anxiety and excitement. Essentially it's preparing the body for fight or flight. By consciously activating their parasympathetic nervous system, the patient is able to stay calmer and avoid triggering that fight or flight response.

In contrast, The autonomic nervous system regulates involuntary physiologic processes like respiration, heart function, and digestion. It cannot be consciously controlled, as no one can forcefully will their heart to stop, their stomach to stop digesting or their lungs to not breathe. Because it does not involve the monitoring or self-regulation of physiological functions, the MedRhythms InTandem device cannot be classified as a biofeedback device.

The neuroscience behind the InTandem System's efficacy is grounded in the principles of Rhythmic Auditory Stimulation and its ability to induce auditory-motor entrainment and neuroplasticity. When an individual is exposed to a consistent, rhythmic auditory stimulus, it activates the auditory system, which is connected to the motor system.

This connection allows the external auditory stimulus to engage the motor system subconsciously, causing the auditory and motor systems to fire in synchrony with the rhythmic stimulus, a phenomenon known as auditory-motor entrainment.

'Entrainment is defined by a temporal locking process in which one system's motion or signal frequency entrains the frequency of another system. This process is a universal phenomenon that can be observed in physical (e.g., pendulum clocks) and biological systems (e.g., fire flies). However, entrainment can also be observed between human sensory and motor systems. The function of rhythmic entrainment in rehabilitative training and learning was established for the first time by [redacted] *and colleagues in several research studies in the early 1990s. It was shown that the inherent periodicity of auditory rhythmic patterns could entrain [unconscious] movement patterns in patients with movement disorders. Physiological, kinematic, and behavioral movement analysis showed very quickly that entrainment cues not only changed the*

timing of movement but also improved spatial and force parameters.' (Thaut 2015)

The science behind InTandem is based on entrainment. The involuntary motor control of a person is clinically proven to subconsciously align with rhythmic auditory sounds. Indeed, auditory-motor neural circuits cause rhythmic motor output to be attracted to, and eventually lock on to, the frequency of an external rhythmic auditory signal.

The InTandem System is a home-use, prescription-only medical device, demonstrated to improve gait quality and speed in chronic stroke patients through Rhythmic Auditory Stimulation. This scientifically and clinically recognized therapeutic method utilizes auditory-motor entrainment to improve gait characteristics (speed, symmetry, variability).

Stroke is a leading cause of long-term disability, worldwide. Chronic stroke gait impairment is characterized by slow walking speed, asymmetry, and effortful gait, and is associated with a significantly higher risk of falls, reduced ability to perform ambulation-related activities of daily living, as well as worse long-term health outcomes, including more frequent hospitalizations and increased mortality rates.

After the initial stroke recovery period in the hospital, most patients go on to facility- or community-based rehabilitation programs depending on their stroke severity, home situation, and insurance coverage.

For those who go on to outpatient, community-based rehabilitation options are limited and wait times long at a crucial time of their recovery when patients are left with a slow, unsteady, and effortful gait. A retrospective review found that three quarters of stroke survivors lacked physical capacity for 4 skills required to walk independently in the community at the time of discharge from inpatient rehabilitation.

Community ambulation is defined as "independent mobility outside the home" and includes confidently navigating uneven terrain, private venues, shopping centers, and other public settings. As many as 85% of individuals with chronic stroke impairment have at least some limitation in community ambulation.

InTandem gives this population of underserved, compromised stroke patients access to therapy that will enable them to re-train their bodies to walk with more stability, strength and reliability. This in turn will enable them to regain their mobility closer to their baseline prior to their stroke, participate in normal activities independently, reduce their high risk of falls and ultimately, lower their hospitalizations and mortality risks.

Based on a thorough evaluation of [the appellant's] medical history and physical examination, the InTandem Neurorehabilitation System is the best next step in his treatment plan. The safety and efficacy of this technology has been demonstrated in several publications, which were

submitted previously with our appeal. The available data highlights the strong correlation between walking speed, ambulation ability and overall health outcomes, including fall risk.

As a result of his stroke, gait impairment interferes with the patient's walking ability. He is physically impaired by his condition, with compromised Strength, Biomechanics and Speed. We would like to see his FAC improve to the extent that safe community ambulation is possible.

He is therefore an excellent candidate for InTandem as a home-use gait modulation system to improve his capacity to ambulate more safely and independently.

The clinical documentation was attached to the appeal documentation for reference.

The InTandem System consists of: (1) a durable, locked hardware control unit with preloaded software and algorithms, (2) wireless, clinical-grade, shoe-worn gait sensors, and (3) a bone conduction headset. The InTandem System is indicated for use by chronic stroke patients in their homes, without the direct involvement of a clinician after the initial prescription.

The proprietary software is fully integrated with the durable control unit and enables delivery of individualized RAS therapy sessions for patients diagnosed with chronic stroke-related gait deficits. 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."

(Exhibit 7)

The appellant's representative summarized her position by stating, regardless of the FDA registration, the InTandem Gait Modulation System is not a psychiatric treatment or biofeedback device because it uses music cues to train the user to improve his or her walking subconsciously, which is closer to physical therapy than psychiatric treatment. Therefore, 130 CMR 433.428 should not apply. She argues that a true biofeedback device gives internal feedback of the appellant's bodily functions such as muscle tension, heart rate, or brain waves in real time. Contrary to that, the InTandem Gait Modulation System gives external feedback through sensors on the user's shoes to regulate the music the user is hearing to improve his or her gait. When the hearing officer asked why sensors on the shoes are not considered real-time feedback, the appellant's representative did not give an answer.

The [redacted] doctor testified that he is not an expert on biofeedback devices, but he does not believe that an external vs. internal monitoring is a meaningful distinction. The user's gait is just another body parameter, not dissimilar to muscle tension, heart rate, or brain waves. The InTandem system measures the user's gait through sensors on the shoes and provides feedback from that information to the music that is playing for the user to hear to modulate gait. It is using biological data feedback to function and is thus a biofeedback device.

The [redacted] doctor further testified that even if the InTandem device at issue is not considered a biofeedback device, it would still not be covered as it is experimental, and [redacted] does not cover experimental services. He argued that the primary research used to support the InTandem system is a *Awad* study performed in 2024. According to that study, the average improvement on gait speed of the users of the InTandem system was 0.08 meters per second. He argued that for most studies in walking speed a meaningful increase in walking speed should be at least 0.1 to 0.2 meters per second. As such, he does not believe the data is strong enough to suggest the appellant would receive a meaningful benefit from this device. He agreed with the appellant's representative's statement that if it did reduce the risk of falling, that would be a meaningful factor to consider. However, the studies provided provide no data for the InTandem system's effect on the risk of falling.

The appellant's representative responded that the InTandem device has been approved by the FDA and believes there is strong evidence in the studies that it improves the standard of living for those who have suffered a stroke. The [redacted] doctor responded that FDA approval just shows that the device is safe to use, not that it is effective.

Lastly, the [redacted] doctor testified that even if the InTandem device is not a biofeedback device and is not experimental, [redacted] does not have enough information on the record to make a determination of medical necessity. No baseline data for the appellant's gait speed was submitted. Therefore, [redacted] does not even know whether the appellant has a gait speed that needs improvement. The appellant's representative chose not to respond to the [redacted] doctor's final testimony.

Findings of Fact

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

1. The appellant is an adult MassHealth member between the ages of 21 and 65 enrolled in [redacted] ACO plan.

2. The appellant has a history of stroke.

3. The appellant submitted an initial request for an InTandem Gait Modulation to MGBHP

on January 27, 2025.

4. On January 31, 2025, MGBHP denied the request because the item requested was considered a non-covered benefit.

5. On February 14, 2025, the appellant internally appealed the denial to [redacted]

6. On March 13, 2025, [redacted] informed the appellant that it upheld its initial notice of adverse action.

7. On March 13, 2025, the appellant appealed this final denial from [redacted] to the Board of Hearings.

8. The InTandem Gait Modulation system is a device that uses sensors on the user's shoes to measure their gait and uses that information to modulate rhythmic music to sub-consciously improve the user's walking speed.

9. The InTandem Gait Modulation system was registered with the FDA as a biofeedback device.

10. A biofeedback device is a device that uses biological data in real-time to produce some kind of effect.

Analysis and Conclusions of Law

The appellant is a MassHealth beneficiary enrolled in an Accountable Care Organization (ACO), operated by [redacted] Pursuant to its contract with the Executive Office of Health and Human Services (EOHHS), [redacted], 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 ("[redacted]"), § 2.7(A)(1), p. 135[1]; 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] A copy of the executed contract is available online, at: https://www.mass.gov/doc/2nd-amended-and-restated-acpp-contract-mgbhp-mgbaco/download

(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 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 [redacted] correctly denied the appellant's request for prior authorization of an InTandem Gait Modulation System on grounds that it was neither medically necessary nor covered under the 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 (Exhibit 1)

The appellant argued that the premise of [redacted] denial is incorrect because the requested device cannot be classified as "biofeedback" treatment. The appellant correctly points out 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." The appellant's representative argues that there are two factors of the InTandem system that are not consistent with a biofeedback device: it uses data from an external biological function (here: gait speed) and it is not measured in real-time. In her submission, the appellant's representative writes: "[The InTandem Gait Modulation System] does not measure or respond to internal physiological states like muscle tension, heart rate, or brain wave activity" which she argues are requirements for a biofeedback device. She cites no authority for this position. [redacted] disagreed and argued that there is no meaningful difference whether the device collects internal biological data or external biological data. The [redacted] doctor persuasively argued that there is no meaningful difference between gait speed and other body parameters such as muscle tension, heart rate, or brain wave activity. Further, the evidence indicates that

the InTandem system 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. Thus, while neither party submitted sufficient evidence to conclude whether this system 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.

However, whether the requested device is appropriately characterized as a "biofeedback" device is ultimately not determinative for purposes of determining whether [redacted] correctly denied it as a non-covered and medically unnecessary device. [redacted] noted in its testimony that the device was also denied because it is not listed as a covered item in Subchapter 6 of MassHealth's DME provider manual. [redacted] classification of the device as DME is reasonable, and 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. 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.

Considering all of the evidence presented, the appellant did not adequately demonstrate MGBHP erred in denying his prior authorization request. [redacted] 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 DME that that is "experimental and investigational." First, [redacted] persuasively argued that the InTandem system's promise of an average of 0.08 meters per second increase in gait speed is not a clinically meaningful improvement. The [redacted] physician's medical opinion that a meaningful increase of gait speed must be at least 0.1 to 0.2 meters per second is persuasive. Importantly, the appellant has not even submitted information related to his gait speed for [redacted] to determine that it is need of improvement. Second, the appellant's representative highlighted a reduction in the risk of falling in her argument that the InTandem system is medically necessary (Exhibit 7). However, the [redacted] physician argued, without rebuttal from the appellant's representative, that the submitted studies contain no statistics on the actual rate of reduction of the risk of falling. He argues that a reduction of falling would be a very meaningful statistic in considering whether the InTandem System would increase his quality of life, but the submitted studies contain no such data.

In conclusion, there is insufficient evidence to show that the InTandem system is 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 the appellant's walking speed to assess whether he met the inclusion criteria that had been used in the *Awad* study. Thus, the appellant has not met his burden to show that the InTandem Gait Modulation system is medically necessary.

Based on the foregoing, this appeal is DENIED.

Order for MGBHP

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.

David Jacobs
Hearing Officer
Board of Hearings

cc:

[redacted]