
Medical Policy



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***Current Policy Effective Date: 5/1/26**
(See policy history boxes for previous effective dates)

Title: GAIT MODULATION AND RHYTHMIC AUDITORY STIMULATION System (i.e. InTandem™)

Description

InTandem™ is designed to deliver rhythmic auditory stimulation (RAS) therapy in a home environment.

Medical Policy Statement

The use of gait modulation and rhythmic auditory stimulation system (i.e. InTandem™) is **experimental/investigational** for all indications including stroke. There is insufficient evidence to determine that the technology results in an improvement in net health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

NA

Other codes (investigational, not medically necessary, etc.):

E3200

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Background

The InTandem™ system includes wearable, clinical-grade gait sensors and a hardware control unit that utilizes adaptive algorithms and clinically optimized music to provide therapy. This approach aims to improve gait quality and speed, focusing on principles such as individualization, progression, and challenge to enhance health outcomes for post-stroke patients. Persistent walking impairment following a stroke is common. Although rehabilitative interventions exist, few exist for use at home in the chronic phase of stroke recovery. InTandem™ (Med Rhythms, Inc) is a neurorehabilitation system intended to improve walking and community ambulation in adults with chronic stroke walking impairment.¹

Summary of Evidence

For individuals who are post stroke and receive InTandem™, the evidence includes a 2-arm randomized controlled trial, validation study, feasibility study, systematic review and meta-analysis. Awad et al. conducted a multi-site randomized controlled trial, on the InTandem™ system with 87 total participants. Results showed significant improvements in walking speed, gait symmetry, and endurance among 43 participants using InTandem™ compared to a treatment matched control group of 44 participants. The validation study by Smayda et al (2023) examined the usability, safety, and effectiveness of the InTandem™ neurorehabilitation systems for improving walking in individuals with chronic stroke. Results indicated that the system is user-friendly, safe, and effective, with 15 participants demonstrating improvements in walking speed, balance, and overall gait quality. Cullimore et al (2023) in the feasibility study, explored the use of rhythmic auditory stimulation (RAS) in post-stroke gait rehabilitation.. Relevant outcomes were functional status, rhythmic auditory cueing on gait, musical rhythms in real-time to match and improve patients' gait patterns. The findings suggest that RAS can be an effective intervention for improving motor function and balance in various neurological conditions. Although all the studies showed this technology has potential, longer studies with larger sample sizes and RCTs compared with standard of care are needed. As a result, we find the current available evidence insufficient to determine that the technology results in an improvement in the net health outcome.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific

outcomes that are important to individuals and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. The following is a summary of the key literature to date.

The multi-site, prospective, interventional, 2-arm randomized controlled trial (NCT04121754) study by Awad et al (2024) investigates the efficacy and safety of auditory-motor entrainment for improving walking ability in individuals recovering from a stroke. Conducted as a multi-site randomized controlled trial, the research evaluates the use of the InTandem™ system, a device that combines auditory cues with motor tasks to enhance walking performance. Results showed significant improvements in walking speed, gait symmetry, and endurance among 87 participants using InTandem™ compared to control groups. The study also confirmed the intervention's safety and tolerability.³ These findings suggest that auditory-motor entrainment could be an effective therapeutic strategy for stroke rehabilitation. Larger RCT's are needed to determine the effectiveness of this device.

The validation study by Smayda et al (2023) examines the usability, safety, and effectiveness of the InTandem™ neurorehabilitation systems for improving walking in individuals with chronic stroke. The research focuses on validating the system's design and its ability to deliver auditory-motor entrainment to enhance gait performance. Results indicate that the system is user-friendly, safe, and effective, with 15 participants demonstrating improvements in walking speed, balance, and overall gait quality.⁴ The findings support the potential of InTandem™ as a practical tool for long-term stroke rehabilitation. Larger RCT's are needed to determine the effectiveness of this device.

The article is a feasibility study "Autonomous Control of Music to Retrain Walking After Stroke" by Cullimore et al, (2023)⁵, explores the use of rhythmic auditory stimulation (RAS) in post-stroke gait rehabilitation. RAS involves using rhythmic cues, such as music, to enhance motor functions, particularly walking. The study introduces an autonomous system that adjusts musical rhythms in real-time to match and improve patients' gait patterns. This personalized approach aims to facilitate neuroplasticity and improve walking abilities in stroke survivors. The finding suggests that such autonomous music-based interventions could be a promising tool in neurorehabilitation, offering a non-invasive and engaging method to support recovery. This study builds upon previous research indicating the benefits of RAS in improving gait parameters like speed, stride length, and symmetry in individuals with neurological impairments. For instance, Ghai and Ghai (2019)⁶ conducted a systematic review and meta-analysis demonstrating the positive effects of music-based rhythmic auditory cueing on gait and posture post-stroke. A joint consensus concerning the influence of auditory cueing-based therapy and effective training dosages for recovering gait post-stroke are still warranted.

Regulatory Status

The InTandem™ system was granted breakthrough device designation by the US Food and Drug Administration (FDA) in 2020. Listed subsequently as a Class II medical device in July 2023, intended for use in improving walking and ambulation in individuals with chronic stroke.²

Government Regulations

National:

There is no national coverage determination (NCD)

Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations First Biannual (B1), 2025 HCPCS Coding Cycle

Local:

There is no local coverage determination (LCD).

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Durable Medical Equipment
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References

1. InTandem's Website <https://medrhythms.com/event/intandem-to-improve-walking-and-ambulation/> accessed 1/23/26
2. FDA [MedRhythms Announces FDA Listing of InTandem™ \(MR-001\) to Improve Walking and Ambulation in Adults with Chronic Stroke MedRhythms secures new CMS reimbursement code for InTandem system](#) accessed 1/23/26
3. Awad LN, Jayaraman A, Nolan KJ, Lewek MD, Bonato P, Newman M, Putrino D, Raghavan P, Pohlig RT, Harris BA, Parker DA, Taylor SR. Efficacy and safety of using auditory-motor entrainment to improve walking after stroke: a multi-site randomized controlled trial of InTandem™. Nat Commun. 2024 Feb 8;15(1):1081. doi: 10.1038/s41467-024-44791-5. PMID: 38332008; PMCID: PMC10853163.
4. Smayda KE, Cooper SH, Leyden K, Ulaszek J, Ferko N, Dobrin A. Validating the Safe and Effective Use of a Neurorehabilitation System (InTandem) to Improve Walking in the Chronic Stroke Population: Usability Study. JMIR Rehabil Assist Technol. 2023 Nov 20;10:e50438. doi: 10.2196/50438. Erratum in: JMIR Rehabil Assist Technol. 2024 Feb 21;11:e56041. doi: 10.2196/56041. PMID: 37983080; PMCID: PMC10696501.
5. Collimore AN, Roto Cataldo AV, Aiello AJ, et al. Autonomous Control of Music to Retrain Walking After Stroke. Neurorehabilitation and Neural Repair. 2023;37(5):255-265. doi:10.1177/15459683231174223
6. Ghai, S., Ghai, I. Effects of (music-based) rhythmic auditory cueing training on gait and posture post-stroke: A systematic review & dose-response meta-analysis. Sci Rep 9, 2183 (2019). <https://doi.org/10.1038/s41598-019-38723-3>

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2026, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/25	2/18/25		Joint policy established (jf) Vendor Managed: NA
5/1/26	2/17/26		Routine maintenance (jf) Vendor Managed: NA • Formatting changes made: ○ Sections rearranged for better flow ○ Added new header on page 1 of medical policy ○ Added Description and Background separated ○ MPS edited

Next Review Date: 1st Qtr, 2027

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: GAIT MODULATION AND RHYTHMIC AUDITORY STIMULATION
SYSTEM (I.E. INTANDEM™)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not Covered
BCNA (Medicare Advantage)	See Government Regulations Standards
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.