Medical Policy

Subject:	Gait Modulation Systems Using Rhythmic Auditory Stimulation		
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Description/Scope

This document addresses the use of gait modulation systems using rhythmic auditory stimulation (RAS), also known as neurologic music therapy. RAS has been proposed as a tool to improve gait, balance and other factors of walking during the physical rehabilitation of individuals who have experienced neurological conditions such as stroke. Several devices have been developed to deliver RAS in unique ways.

Note: For information related to other rehabilitation services, please refer to the applicable guidelines used by the plan.

Position Statement

Investigational and Not Medically Necessary:

Gait modulation systems using rhythmic auditory stimulation (RAS), also referred to as neurologic music therapy, is considered **investigational and not medically necessary** for all indications.

Rationale

RAS has been proposed as a rehabilitation tool for individuals with neurological conditions, primarily those with stroke (Gonzalez-Hoelling, 2024). A systematic review and meta-analysis by Wang (2022) describes evidence regarding the use of RAS for stroke rehabilitation. The authors noted that the number of studies meeting their inclusion criteria was limited (n=22) and the sample size of the included studies was generally low (range 11-78). There was high heterogeneity of methods and measured outcomes in the included studies with significant differences in intervention methods, use of control interventions (e.g., drug therapy, neurodevelopmental treatment, treadmill training, etc.), duration of treatment interventions (range 3 to 8 weeks), and the degree of experimental rigor. Some studies were blinded and some were not. The authors concluded that this study suggests that RAS could improve the gait parameters, walking function, and balance function of individuals with stroke, but the quality of studies is insufficient to determine the impact on balance ability of stroke patients. They recommended future studies with more rigorous design “to obtain strong conclusions about the advantages of RAS for the treatment of gait and motor function in stroke.”

The 2024 U.S. Department of Veterans Affairs and U.S. Department of Defense joint clinical practice guideline for management of stroke rehabilitation include the following recommendation for RAS:

> 9. We suggest rhythmic auditory stimulation as an adjunct intervention to improve motor outcomes. (Weak for | Reviewed, New-replaced)

They provide the following rationale for this recommendation:

> The Work Group's confidence in the quality of the evidence was low. The body of evidence had limitations, including unclear allocation concealment, unclear blinding of outcome assessors, and significant variation in control interventions. The benefits slightly outweigh the potential harms/burdens, which do not appear to be any greater than with conventional therapies

Several cohort studies have reported on the use of the InTandem device (MedRhythms Inc., Portland, ME) (Collimore, 2013; Hutchinson, 2020; Smayda, 2023). The Smayda study evaluated the simulated use of the device, reporting on the ability of participants to understand and use the device appropriately. Smayada did not provide data related to the effects of the InTandem device on functional outcomes. The Collimore and Hutchinson studies were cohort studies (n=10 and n=11, respectively) with brief trial periods and no follow-up. While they reported favorable results with regard to step, stance and swing times, energy costs, and walking speeds, the presented data is limited and does not allow conclusions to be drawn about the effects of RAS in diverse populations and over long periods of time.

In 2024, Awad and colleagues reported the results of a prospective randomized controlled trial (RCT) that involved 87 participants older than 50 years of age and more than 6 months post-stroke. Participants were assigned to 5 weeks of walking rehabilitation with and without the InTandem device. A total of 15 30-minute walking sessions, 3 times a week over a 5-week period, were planned. The primary endpoints were the 10-meter walk test (10mWT) and safety. Six participants withdrew after randomization, leaving 81 participants who completed at least one session. Another participant had results outside 3.45 standard deviations of the study pool mean and their results were removed from the analysis. An additional 8 participants were excluded due to COVID related issues. The intent-to-treat analysis included 72 participants who completed at least one training session. The trial included a total of 1015 completed intervention sessions. Of these, 984 sessions (96.9%) were fully complete and 31 (3.1%) were terminated early. Of the 31 sessions terminated early, 15 were ≥ 15 minutes in duration and thus did not require restart or rescheduling as per the trial protocol. A total of 13 sessions were incomplete due to software or system component issues that rapidly resolved, allowing uneventful completion the same day. The InTandem group had a significantly faster 10mWT speed compared to the control group (0.14 ± 0.03 m/s vs. 0.06 ± 0.02 m/s, respectively; p=0.013). The authors considered the Minimal Clinical Important Difference (MCID) for the 10mWT to be 0.16 m/s. Among the 40 InTandem group participants, 16 (40%) improved performance in the 10mWT by more than 0.16 m/s. Only 4 of 32 (12.5%) of the control group improved in the 10mWT by more than 0.16 m/s. However, the study's primary endpoint was the between-group difference in the change in the 10mWT. The InTandem group experienced an average (± standard error) increase in 10 mWT speed of 0.14 ± 0.03 m/s while the active control group's average increase was 0.06 ± 0.02 m/s. This corresponds to a between-group difference of 0.08 m/s which is lower than the MCID of 0.16 m/s. A total of 10 adverse events and 2 serious adverse events were reported for 7 InTandem group participants. The adverse events possibly related to the InTandem device included a fall and hypertension. The serious adverse events included weakness and chest pain. Only the chest pain was deemed possibly related to the InTandem device, as it occurred during a walking session. The event resolved within a day and the participant completed the trial on schedule. In the control group, 7 participants (21.9%) experienced adverse events, 2 of which were considered serious adverse events. However, neither was deemed related to the walking sessions. A total of 6 falls were reported during the trial: 4 in the control group and 2 in the InTandem group. No injuries resulted from the 6 falls. These falls occurred outside of trial visit, and were considered "not related" or "unlikely related" to the RAS therapy. The authors concluded that "further study is warranted to better understand the feasibility and rehabilitative potential of using InTandem in home settings, the ideal length of treatment, the durability of effect, and healthcare resource utilization impact…" This study had several limitations,

including the entry criteria selected participants were able to walk at speeds between 0.50 m/s and 0.80 m/s. Generalizability to individuals not able to walk at these baseline speeds is unknown. The study's measurement period was only 5 weeks and there was no follow-up or reassessment period, so longer-term effects are unknown. This industry-sponsored study's lack of blinding of assessors increases the possibility that observer bias may have influenced some of the results.

Overall, the evidence regarding the clinical utility of the InTandem device, and gait modulation systems using RAS is limited and non-generalizable. Additional data in the form of rigorously designed and executed studies is need.

Background/Overview

Rhythmic auditory stimulation (RAS), or neurologic music therapy, is a rehabilitation service that involves the use of rhythmic auditory cues in the form of regular, patterned sounds or metrically accentuated music to coordinate an individual's pattern of movement with the goal of improving motor and physical function following neurological impairment. This has been said to target the automatic processes in the central and peripheral nervous system to induce auditory motor entrainment, described as a neurally-mediated process where the timing of motor movements is involuntarily synchronized with the timing of a rhythmic auditory stimulus. The has been said to unconsciously reprogram and synchronize the auditory and motor systems and improve motor function in the targeted anatomical system.

Several devices have been developed to deliver RAS. While RAS may be delivered using a simple metronome or carefully selected music, more recently new technologically advanced methods for delivering RAS have been proposed. The MedRhythms Inc. InTandem autonomous neurorehabilitation system has been proposed to deliver RAS for walking rehabilitation of individuals who have experienced a stroke. The system is composed of three parts: shoe-worn inertial sensors, a control unit, and a headset. The control unit is loaded with a proprietary RAS-based treatment algorithm and music. Data from the shoe sensors regarding stride, step tempo, and other factors, is delivered and processed by the control unit's algorithm, which then provides automatically adjusted music-based rhythmic cues to the headset in real time to influence an individual's gait. The system senses therapy progression and automatically adjusts the auditory stimulation to align with an individual's performance and needs in a closed-loop fashion, with the goal of individualizing the delivered therapy without the need for a clinician's intervention.

According to the manufacturer, the InTandem system is a prescription-only medical device intended for individuals 6 months or more post-stroke for gait impairment, slow walking speed, asymmetry, and effortful gait, factors associated with fall risk, reduced ability to perform ambulation-related ADLs. The device is supposed to be used 3 times per week for 30 minutes each session.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
For the following procedure code, or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

HCPCS

E3200	Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

1. Awad LN, Jayaraman A, Nolan KJ, et al. Efficacy and safety of using auditory-motor entrainment to improve walking after stroke: a multi-site randomized controlled trial of InTandem™. Nat Commun. 2024; 15(1):1081.
2. Collimore AN, Roto Cataldo AV, Aiello AJ, et al. Autonomous control of music to retrain walking after stroke. Neurorehabil Neural Repair. 2023; 37(5):255-265.
3. Gonzalez-Hoelling S, Reig-García G, et al. The effects of rhythmic auditory stimulation on functional ambulation after stroke: a systematic review. BMC Complement Med Ther. 2024; 24(1):45.
4. Hutchinson K, Sloutsky R, Collimore A, et al. A music-based digital therapeutic: proof-of-concept automation of a progressive and individualized rhythm-based walking training program after stroke. Neurorehabil Neural Repair. 2020; 34(11):986-996.
5. Smayda KE, Cooper SH, Leyden K, et al. 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; 10:e50438.
6. Wang L, Peng JL, Xiang W, et al. Effects of rhythmic auditory stimulation on motor function and balance ability in stroke: A systematic review and meta-analysis of clinical randomized controlled studies. Front Neurosci. 2022; 16:1043575.

Government Agency, Medical Society, and Other Authoritative Publications:

1. U.S. Department of Veterans Affairs and U.S. Department of Defense. VA/DoD clinical practice guideline for management of stroke rehabilitation. 2024. Available at: https://www.healthquality.va.gov/guidelines/Rehab/stroke/index.asp. Accessed on May 8, 2025.

Websites for Additional Information

1. Centers for Disease Control and Prevention. Treatment and Intervention for Stroke. May 15, 2024. Available at: https://www.cdc.gov/stroke/treatment/index.html. Accessed on February 28, 2025.
2. National Institute of Neurological Disorders and Stroke. Stroke recovery. Last reviewed on July 19, 2024. Available at: https://www.ninds.nih.gov/health-information/stroke/recovery. Accessed on May 8, 2025.

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MedRhythms InTandem
Neurologic music therapy
RAS
Rhythmic auditory stimulation

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
New	05/08/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.