Regence

Medical Policy Manual Medicine, Policy No. 175.06

Digital Therapeutic Products for Gait Training

Effective: October 1, 2024

Next Review: September 2025
Last Review: September 2024

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. A digital therapeutic product is a specific type of digital health product that is practitioner-prescribed software that delivers evidence-based therapeutic intervention directly to a patient to prevent, manage, or treat a medical disorder or disease. Digital health products have been proposed to deliver rhythmic auditory stimulation as a component of gait training in rehabilitation.

MEDICAL POLICY CRITERIA

Notes:

- Member contracts for covered services vary. Member contract language takes precedence over medical policy.
- This policy does not address:
  - Software that is used for the function or control of an FDA-cleared or approved stand-alone medical device (e.g., external insulin pump or pacemaker).
  - Applications operated by a health care practitioner for remote health monitoring.
  - Products not meeting the definition of a digital therapeutic (see Policy

Guidelines in Digital Therapeutic Products, Medicine, Policy No. 175).

The use of a digital therapeutic product to administer rhythmic auditory stimulation (RAS) during gait training for rehabilitation is considered **investigational**, including but not limited to InTandem™.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Biofeedback, Allied Health, Policy No. 32
2. General Medical Necessity Guidance for Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS), Durable Medical Equipment, Policy No. 88
3. Digital Therapeutic Products, Medicine, Policy No. 175

BACKGROUND

RHYTHMIC AUDITORY STIMULATION FOR GAIT TRAINING

Rhythmic auditory stimulation (RAS), also called auditory rhythmic stimulation, auditory rhythmic signaling, and acoustic rhythmic cueing, is a treatment technique used for gait training in rehabilitation. During RAS, acoustic rhythms from a metronome or music set the stride rate during walking and signal the user to synchronize their steps to the rhythm. The auditory stimulus enables the central nervous system to more accurately regulate the skeletal muscle response by reinforcing coordination between agonizing-antagonist muscle pairs. Specific effects of RAS are increased step length, cadence (stride rate), symmetry, and gait speed. These effects lead to faster walking and longer strides. RAS has been found to be most effective for people who have had stroke and those with Parkinsons' disease. RAS is also used in gait rehabilitation for other movement disorders, such as cerebral palsy and Huntington's disease.[1]

GAIT IMPAIRMENT AFTER STROKE

Gait impairment is common after a stroke, affecting more than two-thirds of stroke survivors.[2] Stroke causes damage to the neural pathways in the motor cortex, including communication between the motor cortex and the brainstem. Stroke damage leads to muscle weakness, changes in muscle tone, and abnormal movements. Physical therapy-guided gait training interventions can improve function, but high inter-individual variability in treatment response creates the need for individualized gait training.[2, 3]

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) designated InTandem™ as a neurological biofeedback device with a class II designation that is exempt from premarket notification procedures.[4] The InTandem™ device is intended for use in the home to improve walking and ambulation in ambulatory adults with chronic gait impairment from stroke. InTandem™ emulates RAS to cause auditory-motor entrainment which leads to synchronization of the motor and auditory systems in the brain to encourage coordinated movements. The software uses sensors to detect real-time gait data with a proprietary algorithm that delivers an individualized musical stimulus.[5] The device consists of sensors that are worn on the shoes, a

touchscreen device that is preloaded with InTandem™ software, including music; a headset, and charging components.[6]

EVIDENCE SUMMARY

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 patients 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.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

DIGITAL THERAPY TO ADMINISTER RHYTHMIC AUDITORY STIMULATION DURING GAIT TRAINING

Clinical Context and Therapy Purpose

The purpose of digital therapeutic products is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with a movement disorder undergoing gait training during rehabilitation. Issues with established techniques to administer RAS include the need for direct involvement by a clinician to set the appropriate tempo and provide supervision. Digital therapeutics to administer RAS during gait training enable autonomous administration of RAS in the home setting.[7]

REVIEW OF EVIDENCE

Randomized Controlled Trials

Awad (2024) published a multi-site, prospective randomized controlled trial (RCT) comparing use of the InTandem™ device to walking without RAS in 72 people with a past history of stroke.[8] Subjects were randomized to walk with the InTandem™ gait modulation system or walk without InTandem™ (control). The average time since stroke was 8.1± 7.1 years. The primary endpoint was a between-group difference in the change in self-selected walking speed. While subjects in both arms showed a significant increase in walk speed, use of the InTandem™ resulted in a larger increase in 10-meter walk test (10 mWT) speed (InTandem™ 10mWT speed: 0.14± 0.03m/s, $p<0.001$; Control 10mWT speed: 0.06± 0.02m/s, $p<0.001$; between group difference: $F(149) = 6.58$, $p=0.013$). InTandem™ was also associated with a

greater number of subjects who increased their 10 mWT speed past the minimal clinical important difference (MCID) (40% vs. 13%; p=0.01). Seven participants in each arm experienced adverse events, including two serious adverse events (SAE) in each arm. One SAE in the treatment arm, severe chest pain/diaphoresis/tachycardia that resolved within one day, was deemed possibly related to the InTandem™ device. The authors concluded that use of the InTandem device improved walking during the chronic phase of stroke and was safe. Limitations of the study include lack of blinding and lack of comparison to RAS delivered using other methods.

Nonrandomized Studies

Collimore (2023) reported the development of an autonomous gait rehabilitation system that can be administered without direct involvement by a clinician.[9] Ten adults with chronic post-stroke hemiparesis completed at least one three-hour session that included 30 minutes of overground gait training followed by a treadmill evaluation. After training participants had a significant reduction in step time (Δ:-12±26%, p=0.027), stance time (Δ: -22±10%, p=0.04), and swing time (Δ: -15±10%, p=0.006); however individual limb spatial asymmetries (p>0.05) and cadence (Δ: 0.4±1.1%, p=0.625) were not significantly different. The authors concluded that automated gait training leads to improvement in temporal control of walking similarly to manual administration of auditory-motor entrainment. Limitations of the study include that the treadmill evaluation may not accurately capture the treatment effect. Larger randomized studies are needed to evaluate the efficacy of the autonomous gait rehabilitation system.

Hutchinson (2020) conducted a feasibility study in 11 subjects with chronic poststroke hemiparesis.[7] All 11 participants completed one session of music-based, rhythmic locomotor training using a digital therapeutic. A subset of seven participants completed two additional training visits and a walking evaluation. Walking speed in the subset of seven subjects increased by 0.12±0.03 m/s. No serious adverse events were recorded. On subject reported knee pain while training that resolved after the number of required turns was reduced. The authors concluded that the sensor-automated, individualized rhythmic locomotor training program was safe and can effectively train walking speed after stroke.

Section Summary

The evidence for administration of RAS in gait training using a digital therapeutic device consists of one RCT and two small uncontrolled studies that focus on feasibility. Relevant outcomes are walking speed, step time, and adverse events. Questions remain about the use of this treatment, including adherence, and importantly, how use of a digital therapeutic device compares to conventional delivery of RAS during gait training. The current evidence is insufficient to determine that RAS delivered autonomously in the home setting improves health outcomes as much as or more than established methods of delivering RAS.

PRACTICE GUIDELINE SUMMARY

THE ACADEMY OF NEUROLOGIC PHYSICAL THERAPY

In, 2020, the Academy of Neurologic Physical Therapy published a Clinical Practice Guideline to Improve Locomotor Function Following Chronic Stroke, Incomplete Spinal Cord Injury, and Brain Injury.[10] The guideline included rhythmic auditory stimulation as an intervention that shows promise but was not included in the current guideline due to insufficient evidence.

THE U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)

The VA published a clinical practice guideline in 2024 on the management of stroke rehabilitation, which states, “We suggest rhythmic auditory stimulation as an adjunct intervention to improve motor outcomes” (Strength: weak evidence).[11]

SUMMARY

There is not enough research to show that use of a digital therapeutic device (e.g., InTandem™) to administer rhythmic auditory stimulation (RAS) during gait training for rehabilitation improves health outcomes compared to other methods of administering RAS. No clinical guidelines recommend use of a digital therapeutic device for gait training during rehabilitation. Therefore, use of a digital therapeutic device for the delivery of rhythmic auditory stimulation to improve gait is considered investigational.

REFERENCES

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CODES

Codes	Number	Description
CPT	None	
HCPCS	E3200	Gait modulation system, rhythmic auditory stimulation, including restricted therapy software, all components and accessories, prescription only

Date of Origin: *September 2024*