Medical Policy Manual Durable Medical Equipment, Policy No. 95

Lower Extremity Sensory Prostheses

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

Lower extremity sensory prostheses are designed to improve balance and restore a steady gait in people with peripheral neuropathy. The devices have the potential to restore peripheral nerve sensation during ambulation and, thus, might improve functional status, quality of life, and health status for such patients.

MEDICAL POLICY CRITERIA

Use of a lower extremity sensory prosthesis is considered **investigational**.

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

CROSS REFERENCES

1. Definitive Lower Limb Prostheses, Durable Medical Equipment, Policy No. 18
2. Myoelectric Prosthetic and Orthotic Components for the Upper Limb, Durable Medical Equipment, Policy No. 80
3. Powered and Microprocessor-Controlled Knee and Ankle-Foot Prostheses, and Microprocessor-Controlled Knee-Ankle-Foot Orthoses, Durable Medical Equipment, Policy No. 81
4. Powered Exoskeleton for Ambulation and Rehabilitation, Durable Medical Equipment, Policy No. 89

5. Upper Extremity Rehabilitation System with Brain-Computer Interface, Durable Medical Equipment, Policy No. 94

BACKGROUND

Sensory prostheses are designed to restore or improve sensory function in individuals who have lost or impaired sensation in their lower extremities. These devices use advanced technology to provide tactile feedback, proprioception, and other sensory information to the user, allowing them to better sense their environment and move with greater confidence and control.

One type of sensory prosthesis is the Walkasins® prescription-based, lower extremity sensory prosthesis. Walkasins® is a non-invasive, wearable prescription-based sensory prosthesis indicated for patients with sensory peripheral neuropathy. Walkasins® detects pressure between the foot and ground and is designed to signal sensory information to the brain to aid in balance and gait control. The system consists of a receptor sole and haptic module, which analyzes pressure information and provides tactile stimulation to the lower leg through vibratory actuators, replacing part of the lost plantar sensation.

REGULATORY STATUS

The Walkasins® lower extremity sensory prosthesis is exempt from the premarket notification procedures regulated by the United States Food and Drug Administration (FDA).

EVIDENCE SUMMARY

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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. Randomized controlled trials (RCTs) are preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs 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.

Pre-post study designs (patient as their own control) are most likely to provide evidence on the effects of a sensory prosthesis on health outcomes. Outcomes of interest are the safety of the device, the effect of the sensory prosthesis on balance, steadiness of gait, and the downstream effect of these changes on other health outcomes (e.g., overall ambulation, quality of life, and activities of daily living).

Issues which need to be assessed include the device's performance over the longer-term when walking compared with other mobility interventions and the user's usual movements outside of the laboratory setting. Adverse events (e.g., falling, tripping) can impact both safety and psychological security and also need to be assessed.

RANDOMIZED CONTROLLED TRIALS

Koehler-McNicholas (2019) investigated the short-term effects of the Walkasins® lower extremity sensory prosthesis on balance and gait outcomes in 31 male veterans, ages 56 to 84, with peripheral neuropathy and balance problems.[1] Participants were randomly assigned to wear Walkasins® while the device was either on or off, and short-term effects on balance training were assessed. Cross-over outcomes were then assessed after a one hour rest period. Functional Gait Assessment scores changed from 15.2 ± 4.8 at initial assessment to 21.1 ± 5.2 after final assessment ($p<0.001$). At the end of the two treatment sessions, 16 of the 31 individuals improved their Functional Gait Assessment score beyond 23, indicating normal fall-risk status. This study is limited by lack of long-term outcomes, lack of participant and assessor blinding, small sample size, and limited generalizability to other patient groups. Additional studies of long-term outcomes and comparisons to other interventions for improving gait are needed to assess the health outcomes of Walkasins® use.

NONRANDOMIZED STUDIES

Oddsson (2022) published 26-week outcomes from 44 participants in the walk2Wellness trial.[2] Earlier outcomes were assessed for these participants in Oddsson (2020), discussed below. 30 participants completed in-person testing of clinical outcomes. After 26 weeks of Walkasins® use, improvements in Functional Gait Assessment scores were similar to 10-week outcomes (15.0 to 19.1). Overall, 39 falls were reported; 31 of them did not require medical treatment and four caused severe injury. Participants who reported falls over six months prior to the study had a 43% decrease in fall rate during the study as compared to self-report six-months pre-study (11.8 vs. 6.7 falls/1000 patient days, respectively, $p<0.004$), similar to the 46% decrease reported after 10 weeks of use. This study is limited by lack of a control group and small sample size.

Oddsson (2020) published results from the walk2Wellness trial which investigated the effects of long-term, home-based daily use of the Walkasins® lower extremity sensory prosthesis.[3] This study included 52 participants with peripheral neuropathy and lost plantar sensation, gate and balance problems, a Functional Gait Assessment score less than 23 (high fall risk), and ability to sense tactile stimuli above the ankle. No additional balance interventions were allowed during the study period. Clinical outcomes included Functional Gait Assessment, Gait Speed, Timed Up & Go and Four-Stage Balance Test. Evaluations were performed at baseline and after 2, 6, and 10 weeks. 45 participants completed clinical outcome assessments. Functional Gait Assessment scores improved from 15.0 to 19.1 ($p<0.0001$), normal and fast gait speed from 0.86 meters per second to 0.95 meters per second ($p<0.0001$) and 1.24 m/s to 1.33 m/s ($p=0.002$), respectively, and Timed Up & Go from 13.8 s to 12.5 s ($p=0.012$). Four-Stage Balance Test scores did not improve. Several patient-reported outcomes were unchanged, including Vestibular Disorders Activities of Daily Living Scale scores, and pain ratings. Subjects who reported falls in the prior 6 months ($n=25$) showed a decrease in the number of fall-risk factors (5.1 to 4.3, $p=0.023$) and a decrease in fall rate (13.8 to 7.4 falls/1000 days, $p=0.014$). Four pre-study non-fallers ($n=20$) fell during the 10 weeks. This study is limited by lack of a control group and small sample size.

SECTION SUMMARY

The evidence for lower extremity sensory prostheses for peripheral neuropathy includes one RCT and two nonrandomized prospective studies. The current evidence is limited by small sample size, lack of participant and assessor blinding, and lack of long-term outcomes in the RCT. Additional studies of long-term outcomes and comparisons to other interventions for improving gait are needed to assess the health outcomes of Walkasins® use.

PRACTICE GUIDELINE SUMMARY

AMERICAN GERIATRICS SOCIETY/BRITISH GERIATRICS SOCIETY

In 2011, The American and British Geriatrics Societies published the Clinical Practice Guideline for Prevention of Falls in Older Persons.[4] These guideline recommendations are also included in the Centers for Disease Control and Prevention (CDC) Stopping Elderly Accidents, Deaths, and Injuries (STEADI) Algorithm for fall risk screening, assessment, and intervention, which were updated in 2019.[5] These guidelines recommend physical therapy, exercise programs, and education on shoe fit, traction, insoles, and heal height. These clinical practice guidelines do not address lower extremity sensory prostheses.

SUMMARY

There is not enough evidence to recommend a lower extremity sensory prosthesis for peripheral neuropathy. Additionally, no evidence-based clinical practice guidelines recommend these devices. Therefore, lower extremity sensory prostheses are considered investigational.

REFERENCES

1. Koehler-McNicholas SR, Danzl L, Cataldo AY, et al. Neuromodulation to improve gait and balance function using a sensory neuroprosthesis in people who report insensate feet - A randomized control cross-over study. *PLoS One.* 2019;14(4):e0216212. PMID: 31039180
2. Oddsson LIE, Bisson T, Cohen HS, et al. Extended effects of a wearable sensory prosthesis on gait, balance function and falls after 26 weeks of use in persons with peripheral neuropathy and high fall risk-The walk2Wellness trial. *Front Aging Neurosci.* 2022;14:931048. PMID: 36204554
3. Oddsson LIE, Bisson T, Cohen HS, et al. The Effects of a Wearable Sensory Prosthesis on Gait and Balance Function After 10 Weeks of Use in Persons With Peripheral Neuropathy and High Fall Risk - The walk2Wellness Trial. *Front Aging Neurosci.* 2020;12:592751. PMID: 33240077
4. Summary of the Updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. *J Am Geriatr Soc.* 2011;59(1):148-57. PMID: 21226685
5. Prevention CfDCa. CDC STEADI Algorithm for Fall Risk Screening, Assessment, and Intervention. [cited 09/10/2024]. 'Available from:' https://www.cdc.gov/steadi/media/pdfs/STEADI-Algorithm-508.pdf.

CODES

Codes	Number	Description
CPT	None	
HCPCS	L8720	External lower extremity sensory prosthesis, cutaneous stimulation of mechanoreceptors proximal to the ankle, per leg
	L8721	Receptor sole for use with l8720, replacement, each

Date of Origin: *September 2024*