Upper Extremity Rehabilitation System with Brain-Computer Interface

Effective: April 1, 2024

Next Review: March 2025
Last Review: March 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

An upper extremity rehabilitation system with brain-computer interface is a powered robotic exoskeleton device used for maintaining or increasing range of motion in patients with chronic stroke. The technology includes a brain-computer interface that detects motor intent and provides input to the exoskeleton device.

MEDICAL POLICY CRITERIA

The use of an upper extremity rehabilitation system with brain-computer interface is considered **investigational** for any indication.

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

CROSS REFERENCES

1. Powered Exoskeleton for Ambulation, Durable Medical Equipment, Policy No. 89.

BACKGROUND

Stroke is the fifth most common cause of death in the U.S. and a leading cause of long-term

disability affecting more than 800,00 people a year. Approximately 15-30% of survivors of stroke are left with severe disability and approximately 44% of individuals aged 18-50 experience moderate disability after stroke, requiring at least some assistance with activities of daily living (ADL) and/or mobility.[1]

Brain-Computer Interface (BCI) integrates powered, robotic exoskeletons with brain signals utilizing various sensing technologies including electroencephalogram (EEG). The EEG provides direct communication between the brain and an exoskeleton powered device to assist with movement and recovery of the affected limb. The Neurolutions Upper Extremity Rehabilitation System with Brain-Computer Interface (IpsiHand™) is an example of an EEG based device that is designed to sense signals from the unaffected, ipsilateral, areas of the brain and signal movement in the robotic powered hand to improve motor function and range of motion of the arm and hand.

REGULATORY STATUS

In 2021, IpsiHand™ (Neurolutions) was granted de novo 510(k) classification (DEN200046) as an electroencephalography (EEG)-driven upper extremity powered exerciser by the U.S. Food and Drug Administration (FDA) (Class II; FDA product code: QOL).[2] De novo classification allows novel products with moderate- or low-risk profiles and without predicates that would ordinarily require premarket approval as a Class III device to be down-classified in an expedited manner and brought to market with a special control as a Class II device.

The IpsiHand™ is indicated for use in chronic stroke patients (≥ 6 months post-stroke) age 18 or older undergoing stroke rehabilitation, to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity.

The Neurolutions System (IpsiHand™) is contraindicated for use in patients having any of the following conditions: [3]

- Severe spasticity or rigid contractures in the wrist and/or digits that would prevent the Neurolutions Handpiece from being properly fit or positioned for use.
- Skull defects due to craniotomy or craniectomy.

The safety and effectiveness of the Neurolutions System (IpsiHand™) has not been evaluated in the following patient populations:[3]

- Patients with Dementia, or who are too cognitively impaired to understand tasks
- Patients with severe, receptive aphasia who have difficulty understanding written or spoken language, or who are unable to follow written instructions
- Patients with severe unilateral visual inattention (neglect) that would visually limit use of the Tablet.

The Neurolutions System (IpsiHand™) should be used with caution in patients with nerve or sensory impairment that may limit or interfere with the patient's ability to sense pain in response to potential pressure points on the Handpiece.

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. 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.

Pre-post study designs (patient as their own control) are most likely to provide evidence on the effects of an upper extremity rehabilitation systems with brain-computer interface on health outcomes. Outcomes of interest are the safety of the device, the effect of the device on the ability to improve function including range of motion in the upper extremity. Of importance in recovery from stroke is the impact of this technology on activities of daily living, which can promote independence and improved quality of life.

UPPER EXTREMITY REHABILITATION SYSTEM WITH BRAIN-COMPUTER INTERFACE

Systematic Reviews/Meta-Analysis

Nojima (2022) published a meta-analysis to evaluate the effect sizes of clinical studies clinical studies investigating the use of BCI-based rehabilitation interventions in restoring upper extremity function and effective methods to detect brain activity for motor recovery.[4] They include 16 articles involving 382 participants. A significant effect of neurofeedback intervention for the paretic upper limb was observed (standardized mean difference = 0.48, [0.16-0.80], P = 0.006). However, the effect estimates were moderately heterogeneous among the studies (I^2 = 45%, P = 0.03). Subgroup analysis of the method of measurement of brain activity indicated the effectiveness of the algorithm focusing on sensorimotor rhythm. The authors indicated that the studies included were limited by high risk of bias and large degree of heterogeneity due to the differences in BCI interventions and technology and the participants.

Cervera (2018) published a meta-analysis to evaluate the clinical effectiveness of BCI-based post-stroke motor rehabilitation.[5] A total of nine studies (235 post-stroke survivors) using different motor intent detection technology such as EEG, near infrared spectroscopy as well as a variety of external devices such as orthosis robot, neuromuscular electrical stimulation, and visual display (i.e. virtual reality) were included in the meta-analysis. Motor improvements, mostly quantified by the upper limb Fugl-Meyer Assessment (FMA-UE), exceeded the minimal clinically important difference (MCID=5.25) in six BCI studies, while such improvement was reached only in three control groups. Overall, the BCI training was associated with a standardized mean difference of 0.79 (95% CI: 0.37 to 1.20) in FMA-UE compared to control conditions, which is in the range of medium to large summary effect size. In addition, several studies indicated BCI-induced functional and structural neuroplasticity at a subclinical level.

They conclude that BCI technology could be an effective intervention for post-stroke upper limb rehabilitation. More studies with larger sample size are required to increase the reliability of these results.

Randomized Controlled Trials

No additional RCTs were identified that were not included in the Meta-Analysis reported above.

Nonrandomized Studies

Bundy (2017) published a prospective, non-randomized, self-controlled study performed in two phases at one investigational site.[6] Ten chronic (≥ 6 months) hemiparetic (Modified Ashworth Scale of 1+ or less of elbow flexion in the affected upper extremity) stroke survivors utilized the BCI IpsiHand System at home for 12 weeks. The primary outcome measure was the Action Research Arm Test (ARAT). Secondary outcome measures included: the Canadian Occupational Performance Measure, the Motricity Index, the modified Ashworth Scale at the elbow joint, grip strength, pinch strength, and the active range of motion (AROM) at the metacarpophalangeal joint of digits 2 to 5. Motor function was collected before, during, and upon completion of use of the Neurolutions IpsiHand System. The BCI approach resulted in improvements in the Action Research Arm Test (ARAT) which correlated with improvements in BCI control. Pinch strength, AROM, and the ARAT pinch subcomponent did not change. No adverse events were reported. Limitations include high loss to follow-up, home based setting for device use, quality of data recordings due to artifact, small sample size, and the study was funded by the device manufacturer.

Section Summary

The evidence for using an upper extremity rehabilitation system with brain-computer interface includes two meta-analyses and a prospective, non-randomized, self-controlled study. The current evidence is limited by small sample size, high risk of bias, heterogeneity of device technology, setting of device use (home vs. rehabilitation center) and participant characteristics, such as stroke lesion and timing of rehabilitation. Further high-quality studies are needed to evaluate the safety and improvement of health outcomes with the use of BCI upper extremity rehabilitation systems in chronic stroke recovery.

PRACTICE GUIDELINE SUMMARY

American Heart Association & American Stroke Association

The 2016 Guidelines for Adult Stroke Rehabilitation and Recovery recommends that robotic therapy is reasonable to consider to deliver more intensive practice for individuals with moderate to severe upper limb paresis (Class of evidence: IIa, level of evidence: A).[7] These guidelines do not address brain-computer interface robotic upper extremity rehabilitation systems.

Veterans Affairs and Department of Defence (VA/DoD)

The 2019 Veterans Affairs and Department of Defence guidelines for Clinical Practice Guideline for the Management of Stroke Rehabilitation recommend offering robot-assisted movement therapy as an adjunct to conventional therapy in patients with deficits in upper limb

function to improve motor skill (Strength of evidence: Weak).[1] The guidelines do not address upper extremity rehabilitation systems with brain-computer interface.

SUMMARY

There is not enough evidence to recommend a brain computer interfaced upper extremity rehabilitation system for stroke rehabilitation. Additionally, there are no evidence based clinical guidelines that recommend these devices. Therefore, upper extremity rehabilitation systems with brain computer interface are considered investigational.

REFERENCES

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5. Cervera MA, Soekadar SR, Ushiba J, et al. Brain-computer interfaces for post-stroke motor rehabilitation: a meta-analysis. *Ann Clin Transl Neurol.* 2018;5(5):651-63. PMID: 29761128
6. Bundy DT, Souders L, Baranyai K, et al. Contralesional Brain-Computer Interface Control of a Powered Exoskeleton for Motor Recovery in Chronic Stroke Survivors. *Stroke.* 2017;48(7):1908-15. PMID: 28550098
7. Winstein CJ, Stein J, Arena R, et al. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals From the American Heart Association/American Stroke Association. *Stroke.* 2016;47(6):e98-e169. PMID: 27145936

CODES

Codes	Number	Description
CPT	None	
HCPCS	E0738	Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories

Date of Origin: *March 2024*