Policy Number	**DME101.054**
Policy Effective Date	**6/16/2026**

Brain Computer Interface Rehabilitation Devices

Table of Contents

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

Brain computer interface rehabilitation devices, including but not limited to electroencephalography (EEG)-driven upper extremity powered exercisers (e.g., the IpsiHand® Upper Extremity Rehabilitation System) **are considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Brain computer interface (BCI) devices create a communication link between the brain and peripheral devices. They capture and process brain activity, translating it into commands for providing feedback or controlling devices. They may be invasive (using intracortical electrodes or electrocorticography) or non-invasive (using electroencephalography, function near-infrared spectroscopy, or magnetoencephalography). Many types of BCI systems are in development and/or in clinical trials. An example of BCI technology is as an aid for recovery in individuals who have had a stroke, translating brain signals into movement of paralyzed limbs or into the control of orthotic devices.

The IpsiHand® Upper Extremity Rehabilitation System, consisting of an isometric electroencephalogram headset, a powered upper extremity range of motion assist device, and a microprocessor control unit containing therapy software, allows for delivery of thought-actuated therapy for chronic upper extremity disability in patients with strokes.

Regulatory Status

In 2021, the U.S. Food and Drug Administration (FDA) classified the IpsiHand® Upper Extremity Rehabilitation System (Neurolutions®) as a Class II device through the de Novo classification process under the generic name of an electroencephalography (EEG)-driven upper extremity powered exerciser (DEN200046). The device type was defined as a "non-invasive prescription device intended for rehabilitation by driving movement or exercise of an impaired upper extremity in response to the detection of purpose oriented electrical activity produced by the patient's brain." (1)

Rationale

IpsiHand® Upper Extremity Rehabilitation System

A 2017 feasibility study by Bundy et al. tested whether a powered exoskeleton driven by a brain–computer interface (BCI), using neural activity from the unaffected cortical hemisphere, could affect motor recovery in chronic hemiparetic stroke survivors. (2) Ten chronic hemiparetic stroke survivors with moderate-to-severe upper-limb motor impairment (mean Action Research Arm Test=13.4) used a powered exoskeleton that opened and closed the affected hand using spectral power from electroencephalographic signals from the unaffected hemisphere associated with imagined hand movements of the paretic limb. Patients used the system at home for 12 weeks. Motor function was evaluated before, during, and after the treatment. The BCI-driven approach resulted in a statistically significant average increase of 6.2 points in the Action Research Arm Test, which correlated with improvements in BCI control. Secondary outcomes of grasp strength, Motricity Index, and the Canadian Occupational Performance Measure also significantly improved. The authors stated that the findings demonstrate the therapeutic potential of a BCI-driven neurorehabilitation approach using the unaffected hemisphere in this uncontrolled sample

of chronic stroke survivors. They also stated that BCI-driven neurorehabilitation can be effectively delivered in the home environment, thus increasing the probability of future clinical translation.

There were several limitations in this study. Due to the home-based settings, it was impossible to ensure that data were free from artifacts. Although most patients had good-quality EEG recordings in most sessions, a few patients met this standard in <50% of sessions. In addition, because the study sample is small and was restricted to those with enough motivation to complete the study protocol, the scope and generalizability of the results is uncertain. Also, pinch strength, all Motricity Index subcomponents, ARAT pinch and gross subcomponents, and AROM did not improve. The study was also uncontrolled. The authors concluded that although this study represents an important step toward developing and translating BCI-driven rehabilitation protocols for chronic stroke survivors, the effectiveness of BCI-driven therapies must be proven in large randomized controlled trials before full acceptance.

A preliminary study published by Rustamov et al., (2022) examined changes in the coordination of brain rhythms during use of the IpsiHand system. (3) The study included 17 individuals who had a stroke at least 6 months prior to study participation. Other eligibility criteria included intact cognitive ability, unilateral upper extremity weakness and normal sensation in the affected upper extremity. Participants used the IpsiHand system for 12 weeks as part of a rehabilitation therapy program. Brain signal measurements were taken at the beginning of therapy and every 4 weeks during therapy. The investigators found that the coordination between theta and gamma brain rhythms improved in both left and right brain regions controlling movement, and the improvement in brain rhythms were associated with improvements seen during therapy sessions. The study was not designed to evaluate whether use of the IpsiHand system improved clinical outcomes. It did not include a control group of individuals who did not use the IpsiHand system and therefore it is unclear whether changes in motor functioning were due to the use of the device or some other factor such as added attention given to trial participants.

In 2025 Rustamov et al. published results of a single-arm study evaluating IpsiHand. (4) Participants were eligible if they had experienced a stroke at least 6 months prior and had unilateral upper extremity weakness. Of the 100 individuals initially agreeing to participate, 31 did not meet all eligibility criteria, and 15 could not consistently produce identifiable BCI control signals during baseline screening. This left 54 participants who began the intervention. Out of those, 24 participants (44%) dropped out, and 30 individuals completed the 12-week treatment program. Motor function was assessed prior to treatment and at 12 weeks by physical and occupational therapists. Participants were then trained how to use the BCI device. Participants were instructed to use the device for an hour a day, 5 days a week, for 12 weeks. At the end of the trial, the participants were reassessed by the same therapist who conducted their initial evaluation. The primary tool used to assess motor outcomes was the upper extremity Fugl-Meyer tool (UEFM).The mean

increase in the UEFM score was 8.1 points which exceeded the minimal clinically significant difference (MCID) threshold of 5.25 points. Of the 26 individuals with available data, 18 (69%) showed an improvement of at least 5.25 points. The change in UEFM score was significantly correlated with reported usage of the BCI device during the trial. This trial lacked a control group, follow-up beyond the 12 week intervention period, and had a very high dropout rate. Additionally, 15 of the 69 individuals screened for participation (22%) could not produce identifiable BCI control signals, raising concern about the potential applicability and generalizability of the study's results.

Prasad et al. (2026) published results of a retrospective study evaluating real-world outcomes in stroke survivors ≥6 months post-stroke who were prescribed IpsiHand® and completed regular Upper Extremity Fugl-Meyer (UEFM) assessments as part of routine care. (5) Patients were categorized as early responders (achieving the minimal clinically important difference [MCID] of 5.25 points in UEFM score by 6 weeks), intermediate responders (achieving MCID by 12 weeks but not at 6), or early non-responders (not reaching MCID by 12 weeks). Early responders showed statistically significant improvement in upper extremity function compared to early non-responders at both 18 weeks ($p < 0.01$) and 24 weeks ($p < 0.05$, Kruskal-Wallis test). Early responders also showed numerically greater improvement than intermediate responders. Overall, 70% (39/56) of participants achieved MCID over the 55-week observation period. These findings suggest that the majority of chronic stroke survivors experienced meaningful functional gains with IpsiHand™ over time, including beyond 12 weeks. While longer use may benefit some individuals who initially did not respond, further prospective research is warranted to determine optimal treatment duration and identify characteristics of responders.

Summary of Evidence

There is limited scientific evidence on the effectiveness of the IpsiHand device in improving health outcomes. Including the feasibility study, published research on individuals with a history of stroke includes a small study evaluating brain rhythm coordination, a larger single-arm trial evaluating some clinical outcomes, and a retrospective study evaluating real-world outcomes in stroke survivors. Findings of these studies suggest that the device may improve brain rhythm coordination and motor function in stroke survivors. However, the studies lacked control groups, had high dropout rates, and did not assess long-term outcomes, limiting the reliability and generalizability of their findings. Furthermore, a significant number of individuals were unable to generate the BCI signals needed for the device to function, raising questions about its broader applicability. More rigorous, controlled research is needed to establish the clinical value of IpsiHand and of BCI rehabilitation technologies more generally. Brain computer interface rehabilitation devices, including but not limited to electroencephalography (EEG)-driven upper extremity powered exercisers (e.g., the IpsiHand® Upper Extremity Rehabilitation System) are considered experimental, investigational and/or unproven.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	None
HCPCS Codes	E0738

*Current Procedural Terminology (CPT®) ©2025 American Medical Association: Chicago, IL.

References

1. U.S. Food and Drug Administration. Neurolutions IpsiHand Upper Extremity Rehabilitation System (DEN022246). Available at accessdata.fda.gov (accessed May 22, 2026).
2. 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 (jul;48(7):1908-1915. PMID 28550098
3. Rustamov N, Humphries J, Carter A, et al. Theta-gamma coupling as a cortical biomarker of brain-computer interface-mediated motor recovery in chronic stroke. Brain Commun. 2022 May 25;4(3):fcac136. PMID 35702730
4. Rustamov N, Souders L, Sheehan L, et al. IpsiHand Brain-Computer Interface Therapy Induces Broad Upper Extremity Motor Rehabilitation in Chronic Stroke. Neurorehabil Neural Repair. 2025 Jan;39(1):74-86. PMID 393451148
5. Prasad NK, Perry NJ, Goldring AL, et al. A retrospective analysis of post-stroke rehabilitation with real world use of brain-computer interface. J Neuroeng Rehabil. 2026 Jan 21;23(1):68. PMID 41566501

Centers for Medicare & Medicaid Services

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A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at cms.hhs.gov.

Policy History/Revision

Date	Description of Change
6/16/2026	New medical document. Brain computer interface rehabilitation devices, including but not limited to electroencephalography (EEG)-driven upper extremity powered exercisers (e.g., the IpsiHand® Upper Extremity Rehabilitation System) are considered experimental, investigational and/or unproven.