

**Sample Letter Of Medical Necessity**

[*Date]*

*ATTN: [Contact Title/Medical Director] [Contact Name (if available)]*

*[Payer Name]*

*[Address]*

*[City, State, Zip]*

*Re: Prior Authorization for the The IpsiHand™ Upper Extremity Rehabilitation System (IpsiHand)*

*Device HCPCS Code: HCPCS E0738: Upper extremity rehabilitation system providing active assistance to facilitate muscle re-education, include microprocessor, all components and accessories*

*Patient Name: [Patient First and Last Name]*

*Date of Birth: [MM/DD/YYYY]*

*Subscriber ID Number: [Insurance ID Number]*

*Subscriber Group Number: [Insurance Group Number]*

*Case ID Number: [Case ID Number]*

*Dates of Service: [Dates]*

*Dear [Contact Name],*

*I am writing on behalf of my patient, [Patient First and Last Name], to document the medical necessity for treatment with IpsiHand. This letter provides information about the patient’s medical history, rationale for the treatment, plan, and summary.*

***Patient’s Medical History***

*[Patient Name] has been diagnosed with [condition] as of [date]. They have been in my care since [date], having been referred to me by [referring physician name] for [reason].*

***Rationale for Treatment***

*[Summary of the rationale for treatment with IpsiHand should include a brief description of the patient’s diagnosis, the severity of the patient’s condition, prior treatments, durations, and responses, the rationale for discontinuation, as well as other factors or, underlying health issues that have affected prior treatment selection. Also include the impact on the beneficiary’s and caregiver’s life. Note the limitations without the requested device].*

***Treatment plan***

*In April 2020, the FDA classified IpsiHand as a breakthrough device and subsequently granted a De Novo market authorization in 2022, making IpsiHand the first brain-computer-interface (BCI) controlled therapy to be awarded an FDA market authorization. IpsiHand is indicated for use in chronic stroke patients (≥ six months post-stroke), age 18 or older, undergoing rehabilitation to facilitate muscle re-education and for maintaining or increasing range of motion in the upper extremity.*

*IpsiHand is a prescription-only class-II medical device that consists of a dry electrode EEG headset, a hand-worn powered motion assist device, and a tablet computer containing therapy software. The tablet prompts the patient to visualize hand movements; the headset detects their intention to move non-invasively using EEG and instructs the handpiece to complete the intended motion; the handpiece-actuated motion is simultaneously observed and felt by the patient. This thought-actuated therapy is self-administered in the patient’s home five days per week as a one-hour therapy module.*

*For stroke survivors like [patient name] who retain their ability to intend to move, but are unable to do so due to the absence of a functional motor circuit, IpsiHand delivers clinically-proven therapeutic benefits beyond the capabilities of standard care through Hebbian learning, a process of synaptic plasticity, rewiring neurons and neuronal circuits by repeatedly firing them simultaneously while externally circumventing the impaired motor circuit, helping rebuild connections between cortical activation of the intent to move and realized movement. [Include specific benefits resulting increased function and other physical or quality of life benefits that support the use of IpsiHand in this specific case].*

***Summary***

*In summary, IpsiHand is the only clinically-proven, non-invasive, at-home therapeutic solution for upper extremity rehabilitation and is the most appropriate option to improve this patient’s functional abilities. I believe IpsiHand is appropriate and medically necessary for this patient and request that you provide coverage for this treatment. If you have any further questions about this matter, please get in touch with me at [Physician Phone Number] or via email at [Physician email]. Thank you for your time and consideration.*

*Sincerely,*

*[Physician Name and Credentials]*

***Enclosures***

*[List enclosures, which may include the letter of medical necessity, prescribing information, clinical notes/medical records, test results, executive summary/relevant peer-reviewed articles, and FDA-approved letter for the device.]*