

Summary Literature Review on Powered Orthoses for Arm Weakness

The following is a narrative summary of just some of the best contemporary studies on the efficacy of powered orthoses as applied in the rehabilitation and restoration of upper extremity function in patients with arm weakness following neurological insult. There is a widespread misconception among health insurance payers that this technology is *experimental/investigational*, and should not be a covered benefit. But the body of evidence clearly demonstrates otherwise. Therefore, this summary is by a rehab clinician for rehab clinicians in talking to their colleagues in the health insurance field about why this technology is well proven and medically necessary. Please share widely for the good of our patients.

- 1) There is a significant, historically-unmet need for restorative, powered bracing in the patient population suffering from upper extremity weakness secondary to neurological injury (e.g. stroke, brachial plexus injury, ALS, head / spinal cord injury, cerebral palsy, etc.). These patients often spend years fully exploring the potential benefits of traditional rehabilitation and less sophisticated medical devices, before reaching a point where no further progress can be made because of time constraints, limited insurance resources, as well as limits inherent to traditional technology. Traditional, static upper extremity braces in particular have been shown to provide no functional benefit¹.
- 2) Powered, myoelectric technology has been used to restore function in patients with paresis and amputations since the 1950s². It is not a new technology.
- 3) Since then numerous clinical trials have repeatedly demonstrated that powered orthotic devices are in fact highly effective for improving function, motor control, ROM, and bimanual dexterity on several validated measures^{3,4,5,6} as well as widening patients' working envelopes, all while even decreasing spasticity^{9,10, 11, 12}.
- 4) This technology has been shown to be *superior to conventional therapy* as well as even some newer therapies involving non-assisted electrical stimulation^{8, 11, 12, 13, 14}.
- 5) Economic analyses show that even with the initially higher upfront costs, using powered orthoses results in long term cost savings to payers given more effective, less labor intensive rehab and lower healthcare utilization that comes from improved function^{15, 16}.
- 6) Therefore, FDA-approved, myoelectrically powered orthoses, commercially available today have in fact been thoroughly vetted by the scientific and clinical communities since emerging from their experimental phase in the last century. This technology is now normative and becoming the standard of care for patients with upper extremity weakness. Meanwhile, other newer, even more sophisticated, devices, still in the experimental phase, continue to build on the progress established by other devices already vetted by the FDA^{16, 17}.

- 7) A growing number of specialized treatment centers (e.g. Mayo Clinic, Cleveland Clinic, Massachusetts General Hospital, the Veterans Administration health system) are including myoelectric orthotic restoration in their rehab protocols for patients with arm paresis from neurological injury. And insurance payers, recognizing the medical necessity and clinical benefit of this technology, are increasingly providing coverage for these devices. Several hundred myoelectric upper extremity orthoses have been approved for permanent, daily use to restore paretic arms since 2006 by numerous payers (e.g. various policies available from Aetna, Anthem, BCBS, Cigna, Harvard Pilgrim, Humana, Kaiser Permanente, Neighborhood Health, Tufts, United Healthcare, the VA, various state Medicaid plans, et al).
- 8) Given the lack of viable alternatives, no other less costly treatment options exist for this patient population.

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