MyoPro Executive Summary

Introduction

The MyoPro[i] is a myoelectric orthosis that provides active movement to the hand and elbow to restore function to the wearer's paralyzed or weakened upper extremity, most commonly due to diagnoses such as stroke, brachial plexus injury, and traumatic brain injury.[1-10] The device is designed for use at home to support a weak upper extremity and assist movement, thereby promoting functional activities of daily living (ADLs). In the past, the term "orthoses" primarily described splints or braces.[ii] This framework has been expanded to include technologies which support and assist movement to promote functional ADLs, including the MyoPro.[11,12]

Product Information

The Technology

The underlying technology and function of a myoelectric orthosis is similar to that of a myoelectric prosthesis (Table 1). Both use electromyographic (EMG) technology to detect residual nervous system activity in the remnant muscles of the upper extremity, a microprocessor which amplifies the detected signal, and electric motors to output the desired movement in the elbow and/or hand. The parameters of the MyoPro settings can be adjusted for each patient based on their level of impairment through a custom software interface to support and assist movement, thereby promoting functional ADLs.

Table 1. Myoelectric Prostheses & Myoelectric Orthoses Comparison Chart

	MYOELECTRIC PROSTHESES	MYOELECTRIC ORTHOSES	SIMILARITIES
EMG Technology	✓	✓	Electromyographic (EMG) technology detects residual nervous system activity in the remnant muscles of the arm
Microprocessor	✓	✓	A microprocessor amplifies the detected signal
Electric Motors	✓	✓	Electric motors recreate desired movement
Support & Assist Movement	✓	✓	". . . powered exoskeleton devices that support a patient's weak arms . . . are classified as braces due to their use in stabilizing, positioning, supporting, and restoring functions of the patient's weak limb."[11]
Promote Activities of Daily Living (ADLs)	✓	✓	Controlled clinical trials are neither necessary nor feasible; the literature has focused on case series where patients serve as their own controls
Presence of a Limb		✓	The only appreciable difference between a myoelectric prosthesis and a myoelectric orthosis is the presence or absence of a limb

[i] The MyoPro 2x and MyoPro 2+ are the current commercially available version of the device. Previous versions now out of production include the MyoPro, MyoPro 2, mPower 1000, and E100. Throughout this document, we will simplify and refer to the device as the "MyoPro."

[ii] The terms orthosis and brace are overlapping. Throughout this document, the word "orthosis" will be used to describe the overall category of orthoses and braces.

A key difference between a myoelectric prosthesis versus orthosis is that the technology underlying a myoelectric prosthesis is located within the device itself, while the technology for a myoelectric orthosis is located on the outside of device. A myoelectric orthosis is analogous to an "inside out" myoelectric prosthesis in which the orthotic/bracing component functions as an exterior delivery system. It is important to note that from a functional point of view, the patient selection criteria for the two groups are similar. Regardless of whether the arm is present or absent, both patient groups are unable to perform bimanual ADLs without the device, which significantly impacts their quality of life.

FDA Registration & Listing

Myomo Inc. is an FDA-registered medical device company with its MyoPro family of products, which includes the current MyoPro 2x/MyoPro 2+ as a listed FDA Class-2, 510-K exempt device. Our medical devices are produced under the Medical Device Single Audit Program (**MDSAP**)—a Quality Management System (QMS) certification to which FDA subscribes. Myomo's FDA registration can be found on the Department of Health & Human Services Us Food and Drive Administration (FDA) Establishment Registration and Device Listing Database for each of the four device components: a) orthosis, limb brace b) joint, elbow, external limb component, powered c) hand, external limb component, powered and d) device, biofeedback.[13-16]

Reimbursement information

Coding

HCPCs Level II codes are developed and maintained by the Centers for Medicare & Medicaid Services (CMS). CMS established two HCPCS codes effective January 1, 2019, to report the MyoPro devices:

- HCPCS code L8701 describes the MyoPro Motion W (elbow-wrist-hand orthosis that has one degree of freedom and a multi-articulating wrist joint) and MyoPro Motion E (elbow wrist-hand orthosis that has one degree of freedom and a fixed wrist joint).[iii]
- HCPCS code L8702 describes the MyoPro Motion G (elbow-wrist-hand-finger orthosis that has two degrees of freedom and a multi-articulating wrist joint).

The descriptors for HCPCS codes L8701 and L8702 are listed below (Table 2).

Table 3. HCPCS Codes

HCPCS CODE	DESCRIPTOR
L8701	MyoPro Motion W: Powered upper extremity range of motion assist device, elbow, wrist, hand with single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated
L8702	MyoPro Motion G: Powered upper extremity range of motion assist device, elbow, wrist, hand, finger, single or double upright(s), includes microprocessor, sensors, all components and accessories, custom fabricated

Medicare Benefit Category

On November 13, 2023, CMS issued the calendar year (CY) 2024 Home Health (HH) Prospective Payment System (PPS) Rate Update final rule.[11,12] The rule is effective for services performed on or after January 1, 2024. In the Final Rule, CMS codified its definition of a brace and specified that the MyoPro, described by HCPCS codes L8701 and L8702, fits within the Medicare brace benefit category. Specifically, CMS determined that powered orthotic devices, such as the MyoPro myoelectric orthosis, are included in the brace definition as they perform the key bracing functions of stabilizing, positioning, supporting, and restoring the functions of the patient's weak limbs.

[iii] Please note the Motion E was discontinued as it was determined that patients referred for a MyoPro without a grasp function still benefited from the availability of the multi-articulating wrist on the Motion W.

Patient Pathway

Patient Selection Criteria

Candidates for a myoelectric orthosis used in the home are adolescents and adults with chronic muscle weakness or partial paralysis. Common diagnoses include, but are not limited to, stroke, brachial plexus injury, and traumatic brain injury. Careful selection criteria are used to identify the subset who will benefit and routinely use the orthosis in the home setting to support and assist movement, thereby promoting ADLs. Patients must meet all of the following criteria:

- Failure to recover meaningful use of their upper limb for performance of daily activities after conventional therapies;
- Sufficient neurological, musculoskeletal, and cognitive function (or caregiver support) including myoelectric signal output to meet the minimum microvolt threshold required to operate the device;
- Absence of contraindications that would interfere with routine use of the MyoPro (e.g., severe/unmanaged spasticity, subluxation, or contracture);
- Reasonable expectation of a predicted improved functional state per clinical judgement of the prescriber (with the use of the prescribed orthosis and necessary training with a trained occupational or physical therapist); and
- Standard static orthotic/brace or a related rehabilitation modality cannot be used or is insufficient to meet the member's functional needs in performing ADLs.

Pre-Delivery

If the physician deems there is a reasonable expectation that the patient would benefit from use of the device to support and assist movement for ADLs, they write a prescription for the device. The patient next enters medical records review, and the Myomo clinical team performs an additional evaluation process to ensure the patient meets criteria for clinical candidacy and medical necessity.

After confirmation of medical necessity, the patient information is submitted to the insurer for authorization. Once authorization is received, a sequence of events takes place prior to delivery to optimize the success of the MyoPro which includes electromyographic sensor confirmation, shape capture, and custom fabrication.

Post-Delivery

Upon device delivery, Myomo offers MyoCare - a post-delivery support system to the patient and their healthcare team - throughout device adoption to maximize functional benefits. The MyoCare team consists of licensed physical and occupational therapists who provide virtual or in-person visits with patients and their local healthcare professionals to optimize early adoption and functional outcomes. In particular, the MyoCare program ensures the user benefits from the multiple elbow and hand positions produced by the microprocessor and motors.

Clinical Evidence

Clinical studies demonstrate statistically significant outcomes, indicating the use of the MyoPro use restores the ability to perform functional tasks required for activities of daily living.[1-10] Additionally, several studies include secondary outcome measures which show improvements in range of motion and strength, as well as a decrease in spasticity.[5,17-19]

Summary

The MyoPro has demonstrated in multiple peer-reviewed journals the ability to assist a weak arm and improve functional outcomes when evaluated with standard outcome measures.[1-5] MyoPro patients are selected based on criteria to ensure the likelihood of success with the orthosis. Myomo offers MyoCare, a post-delivery support system, to the patient and their healthcare team throughout device adoption to maximize functional benefits. We hope you find this information useful in understanding the immense clinical value of the MyoPro for appropriately indicated patients.

Sincerely,

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