WILLOWWOOD®

Alpha Control® Liner System Reimbursement Manual

Medical Necessity Criteria, Documentation, Coding, and Claims Submission
Pattern Recognition Control

Phone:

(Toll free, U.S.) 1.800.848.4930
(Local, International) 740.869.3377

Address:

WillowWood Global LLC
15441 Scioto Darby Road, P.O. Box 130
Mt. Sterling, Ohio 43143, USA

How does Alpha Control Liner System Improve Myoelectric Control

The complex sets of Electromyography (EMG) or myoelectric signals need to be "decoded" in real time and matched to the corresponding motion of a prosthetic limb. To maintain robust myoelectric signals, the electrodes that capture and record the muscle signal information need to stay in contact with the skin. The Alpha Control Liner System, with built-in electrodes, is an elastic interface solution that ensures electrode contact and reliable myoelectric control for those with upper limb loss or difference.

Medical Necessity Criteria

Alpha Control Liner System for Myoelectric Prostheses

The Alpha Control Liner System includes electrodes embedded into the elastic interface material to capture the EMG signals and transfer them to a myoelectric prosthesis control system. This combined technology further enhances the functionality of a myoelectric-controlled upper limb prosthesis.

When evaluating patients for an Alpha Control Liner System, consider the following medical necessity criteria:

- Adequate cognitive and neurological ability to use a myoelectric prosthesis
- Adequate myocutaneous function to operate the prosthesis
- Traditional prosthetic socket materials are inadequate to maintain consistent electrode-to-skin contact
- Patient has challenges donning traditional prosthetic socket interfaces
- Patient has skin and/or limb co-morbidities (i.e grafted skin, adherent scar tissue, etc) that require an interface to be compliant and liner based
- Patient experiences significant volume fluctuations throughout wear periods, which may cause the patient to experience less control reliability

Alpha Control Liner System

Physician Documentation

A physician must evaluate the patient and provide comprehensive corroborating records.
The physician's documents could include the following:

- Diagnosis, date of amputation, side of amputation
- Previous prosthesis use
- History of clinical treatments, OT and/or PT, rehab
- Residual Limb Condition
- Cognitive, Musculoskeletal, and Neurological Exam
- Details of daily activities, work tasks, and how amputation impacts tasks
- Co-Morbidities that may impact the use of a myoelectric device
- Patient's desire to use a myoelectric prosthesis
- Current prosthesis control challenges and need for an electrode embedded liner for consistent electrode contact
    - Skin conditions
    - Prosthesis donning needs
    - Sensitivities and inapplicability of traditional socket technologies
    - Tasks requiring bimanual dexterity
        - Tying shoes
        - Perform daily hygiene, such as combing hair
        - Dress oneself/button/zip
        - Preparing/eating food
    - Holding something fragile (proportional control)
    - Operating small hand tools
    - Driving vehicles
    - Taking/placing something on a shelf at eye level or above – closet at home, shelf at work, or grocery store

Prosthetist Documentation

Adequate cognitive and neurological ability to use a myoelectric prosthesis.

Dr. Wood's notes, dated 10/15/2020, indicate that Ms. Willow has the cognitive ability to manage the technology in the prosthesis. She could comprehend myoelectric operation by manipulating a remote myoelectric hand with electrodes placed on her residual limb during myotesting.

Patient has trouble donning/doffing their prosthesis due to the need for a tight fit and dependence on donning aides.

Using the Alpha Control Liner System will reduce the time and difficulty required for Ms. Willow to don/doff her prosthesis, allowing her to dedicate more time to her vocational/advocational activities/caring for her children/pets.

Ms. Willow expresses the need to doff her traditional socket to dry off perspiration 5 times daily.
The Alpha Control Liner System locking suspension system will allow her to do this more efficiently
than commercially available systems.

The Alpha Control Liner System will allow for more consistent contact between the electrodes and the patient's skin, thereby enabling more reliable control of the prosthesis, which requires less concentration by the user. This enables the patient to focus on ADLs and job duties. The overall improved Functional Outcomes from using the Alpha Control Liner System mean an increased ability to manage ADLs, return to work activities, and enhanced mental attitudes.

The Alpha Control Liner System is necessary for Ms. Willow as her current socket system allows the electrodes to lift off her skin when reaching above her head to perform the XYZ task. The Alpha Control Liner System electrodes maintain contact with her skin, allowing her to consistently activate her elbow unit/terminal device with her hand overhead to perform XYZ; expanding her functional envelope.

The Alpha Control Liner Systems incorporates a distal locking suspension, allowing increased flexibility in socket design and trim line location.

With the use of the Alpha Control Liner System with locking suspension, the trim lines of Ms. Willow's socket can be lowered, allowing her greater elbow ROM, which is not possible with her current socket system with suction suspension.

Coding

There is no existing HCPCS code to describe the Alpha Control Liner System. The option is to use a Not Otherwise Specified code (NOS), more commonly known as a miscellaneous code. There are specific requirements to include in your claim when using a miscellaneous code.

Payment Methodology

Miscellaneous codes do not have defined reimbursement amounts. Payers have various methods for determining the payment amount when processing a miscellaneous code. Commercial payer contracts usually specify how miscellaneous codes are processed, and they typically use one of the following methods:

1. __% of Billed Charges
2. MSRP minus __%
3. Invoice plus __%

Percent of Billed Charges

The contract may state, "Payment will be X% of billed charges." The payer will discount the amount you submit on the claim by the percentage indicated in the contract. In this case, you must know the rate to understand possible reimbursement. If your contract is unclear, contact the Provider Relations department at the payer.

MSRP Minus

The contract may state, "Payment will be MSRP minus X%." The payer may ask for official documentation to substantiate the MSRP. Please use the attached MSRP letter.

Invoice Plus

The contract may state, "payment will be the invoice amount plus X%." In this case, the payer will ask for a complete invoice and increase it by the amount specified in the contract. The invoice includes time and materials. We encourage you to create an invoice that includes your time, materials, and other costs for providing the prosthesis to your patient.

NOTE: Check your payer contract for payment terms/fee schedules. The fee schedule amount may be referenced in an attachment and should include information about how reimbursement for miscellaneous codes is paid. If the contract is not readily available or the fee schedule information needs to be listed, call the Provider Relations team at the insurer.

Claim

When billing a product using a miscellaneous code, there are specific requirements for the claim form.

HCFA 1500 INSTRUCTIONS

In addition to the standard information, provide these details:

Box 17B: Enter NPI of referring/ordering physician
Box 19: Enter a product description within the 71-character limit, including the manufacturer's name
Box 19: Include the MSRP of the product
Box 19: Include product model number
Box 21: The appropriate ICD-10 diagnosis code
Box 24D: L7499

ELECTRONIC CLAIMS

SV101-7 segment for HIPAA 5010A1 claims Loop 2400 (line note), segment NTE02 (NTE01=ADD) of the ANSI X12N, version 5010A1 professional electronic claim format:

- Enter a description of the product within 71 characters
- Model Number
- MSRP

*The description box size is limited, so abbreviations must be used. We have provided recommended descriptions in this guide. Please use these descriptions for all claims.

Alpha Control Liner System Coding: L7499

L7499
The Alpha Control Liner System combines an instrumented interface locking liner and locking mechanism.
The interface liner includes embedded electrode leads and metal dome electrodes.
The EMG signals are collected and conditioned within the electronics module contained in the distal liner locking umbrella. EMG signals can then be transferred from the liner via the spring-loaded contacts in the socket-mounted locking mechanism. The instrumented lock transfers power to the liner electronics module while also transferring the conditioned EMG signals to myoelectric prosthesis control system. This combined technology further enhances the functionality and usability of a myoelectrically-controlled upper limb prosthesis. The Alpha Control Liner System will provide for more consistent contact between the electrode and the patient's skin, thereby enabling more reliable control of the prosthesis, which requires less concentration by the user and enables the patient to more intuitively complete ADLs and job duties.

Suggested MSRP for the Alpha Control Liner System is $19,500

Short Description: Instrumented UE prosthetic liner and Lock Mechanism

WILLOWWOOD

WillowWood Global LLC
15441 Scioto Darby Road
Mt. Sterling, OH 43143
phone 740.869.3377 / 800.848.4930
fax 740.869.4374 www.willowwood.com

Ohio Willow Wood Company B.V
Keizersgracht 62/64
1015 CS Amsterdam
The Netherlands
Patent www.willowwood.com/education-and-resources/patents

PN-2704-B 30 OCT 2023