

March 13, 2015

COMFORTLAND MEDICAL INC  
709 A O SMITH ROAD  
MEBANE NC 27302

**Re: Assigned HCPCS Codes for DME Billing**

**Xref: 37825930**

PADDED NIGHT SPLINT	COMFORTLAND MEDICAL INC	63-105-2	L4398
PADDED NIGHT SPLINT	COMFORTLAND MEDICAL INC	63-105-3	L4398
PADDED NIGHT SPLINT	COMFORTLAND MEDICAL INC	63-105-4	L4398

Dear Lois Tsui:

The Pricing, Data Analysis, and Coding (PDAC) Contractor has reviewed the product(s) listed above and has approved the listed Healthcare Common Procedure Coding System (HCPCS) code(s) for billing the four Durable Medical Equipment Medicare Administrative Contractors (DME MACs).

The PDAC Contractor provides coding assistance to manufacturers to ensure proper coding of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS). The PDAC publishes coding decisions based on the coding guidelines established by the Local Coverage Determinations (LCDs) and associated Policy Articles and any related Advisory Articles established by the DME MACs. All products submitted to the PDAC for a coding verification review are examined by coders and professionals following a formal, standardized process.

The PDAC has reviewed the above listed product(s). Based on this review and application of DME MAC policy, the HCPCS code(s) listed below should be used when billing the DME MACs:

**L4398 - Foot Drop Splint, Recumbent Positioning Device, Prefabricated, Off-The-Shelf**

The Local Coverage Article for Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article - Effective January 2014 states, a static or dynamic positioning ankle-foot orthosis (L4396, L4397) is a prefabricated ankle-foot orthosis which has all of the following characteristics:

1. Designed to accommodate either plantar fasciitis or an ankle with a plantar flexion contracture up to 45 degrees; and
2. Applies a dorsiflexion force to the ankle; and
3. Used by a beneficiary who is minimally ambulatory, or nonambulatory; and

4. Has a soft interface.

The product submitted for review does not provide for safe, minimal ambulation or dorsiflexion. In order to be assigned L4396/L4397, the product must provide dorsiflexion to the ankle, which is usually achieved through straps or turnbuckles extending from the toe of the footplate to the upper portion of the calf shell or some other similar mechanism. Although a foam wedge is included, this does not provide adequate dorsiflexion required for the product to be considered in HCPCS code L4396/L4397. Therefore, HCPCS code L4398 has been assigned.

This decision applies to the application we received on January 02, 2015. If information submitted in that application has changed or were to change, it could impact our decision. Therefore, a new application would need to be submitted for HCPCS coding verification review. The coding assigned in this decision letter will be available on the Product Classification List (PCL) on the Durable Medical Equipment Coding System (DMECS) within ten (10) working days from the letter's date. The DMECS can be accessed on the PDAC website, [www.dmepdac.com](http://www.dmepdac.com). Please take the time to verify that this coding decision is correctly reflected in DMECS.

If you disagree with this decision, you may request a reconsideration within 45 days of the letter's date and provide evidence to substantiate a reconsideration of PDAC's original coding determination. To request a reconsideration, complete the Reconsideration Request form located on the PDAC website at <https://www.dmepdac.com/review/requesting.html>. If your request for a reconsideration is made after the 45-day time frame, it will require a new application and documentation to support the request.

It is the responsibility of manufacturers and distributors to notify the PDAC immediately of any changes involving their products, as listed on the PCL on DMECS. Further information for requesting updates to the PCL can be found on the PDAC website at <https://www.dmepdac.com/review/notifying.html>. It is also the responsibility of manufacturers and distributors to assure their websites and product marketing materials accurately reflect the product reviewed by the PDAC and the coding decision assigned.

An assignment of the HCPCS code(s) to product(s) is not an approval or endorsement of the product(s) by Medicare or Noridian Healthcare Solutions; nor does it imply or guarantee claim reimbursement or coverage.

If you have questions about policy, claim coverage or reimbursement, please contact the DME MAC for your jurisdiction. For other questions, contact the PDAC Contact Center at the address listed above or by telephone at (877) 735-1326. The Contact Center is open Monday through Friday from 8:30 a.m. to 4 p.m. CT.

Sincerely,

PDAC  
Noridian Healthcare Solutions, LLC  
[www.dmepdac.com](http://www.dmepdac.com)