noridian
Healthcare Solutions

900 42nd Street South
Fargo, ND 58103

December 5, 2014

DICARRE LLC
500 N RAINBOW BLVD SUITE 300
LAS VEGAS NV 89107

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

**Xref: 35959200**

| | | | |
|---|---|---|---|
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT BLUE SMALL | DICARRE LLC | DA13-BU-SM | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT BLUE MEDIUM | DICARRE LLC | DA13-BU-MD | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT BLUE LARGE | DICARRE LLC | DA13-BU-LG | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT GREY SMALL | DICARRE LLC | DA13-GY-SM | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT GREY MEDIUM | DICARRE LLC | DA13-GY-MD | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT GREY LARGE | DICARRE LLC | DA13-GY-LG | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT BLACK SMALL | DICARRE LLC | DA13-BK-SM | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT BLACK MEDIUM | DICARRE LLC | DA13-BK-MD | L4398 |
| DICARRE PLANTAR FASCIITIS NIGHT SPLINT BLACK LARGE | DICARRE LLC | DA13-BK-LG | L4398 |

Dear Humberto Fong:

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). The above listed product(s) has been reviewed. 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°; 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. In order to be assigned L4396, 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 there is a foam wedge included, this does not provide adequate dorsiflexion required for the product to be considered in HCPCS code L4396. Therefore, HCPCS code L4398 has been assigned.

In addition, the product submitted for reviewed does not require the expertise of a trained individual for significant modification as defined by customization.

Certain HCPCS codes were updated/added effective January 1, 2014 to include verbiage of products that could be either "PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE" or "OFF-THE-SHELF". Codes L4396 and L4397 are examples of those codes.

Off-the-Shelf orthotics under Medicare are statutorily defined by law in Title 18 of the Social Security Act [section 1847(a)(2)(C)], and also in Federal Regulations at 42 CFR §414.402 as follows: *Off-the-shelf orthotics, which are orthotics described in section 1861(s)(9) of the Act that require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling or customizing to fit a beneficiary.* Products provided

off-the-shelf are prefabricated and may require minimal self-adjustment or modifications for appropriate use.

Minimal Self-Adjustment is defined at 42 CFR §414.402 Subpart F as follows: *Minimal self-adjustment means an adjustment that the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and does not require the services of a certified orthotist (that is, an individual certified by either the American Board for Certification in Orthotics and Prosthetics, Inc., or the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training.*

Items that are considered custom-fitted are prefabricated products requiring significant modifications beyond simple bending, trimming or cutting in order to fit an individual. Custom fitted modifications may include using tools to apply high heat for bending or molding, or to modify the product. These modifications need to be performed by a person of expertise such as a certified orthotist.

This decision applies to the application we received on September 29, 2014. 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. 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