900 42nd Street South
Fargo, ND 58103

August 22, 2014

HELY & WEBER
1185 EAST MAIN STREET
SANTA PAULA CA 93060

Re: Assigned HCPCS Codes for DME Billing

Xref: 33549418

CONTROLLER PLUS	HELY & WEBER	2804-RT	L3924
CONTROLLER PLUS	HELY & WEBER	2804-LT	L3924

Dear Jim Weber:

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:

L3924 - HAND FINGER ORTHOSIS, WITHOUT JOINTS, MAY INCLUDE SOFT INTERFACE, STRAPS, PREFABRICATED, OFF-THE-SHELF

The description of the requested HCPCS code indicates that L3923 requires the orthosis to be customized to fit a specific patient by an individual with expertise. The product submitted for review may be trimmed and the stay molded to the patient, however these modifications do not require the skill of an individual of expertise. This is considered off-the-shelf and meets code description for code L3924. Therefore, HCPCS code L3923 is not assigned.

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 L3923 and L3924 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 June 03, 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