noridian
Healthcare Solutions

900 42nd Street South
Fargo, ND 58103

December 21, 2015

THUASNE / TOWNSEND DESIGN
4615 SHEPARD ST
BAKERSFIELD CA 93313

Re: Reconsideration of Coding Verification Decision

Xref: 44751623

MANURHIZO FORM'IT	THUASNE / TOWNSEND DESIGN	7385 01	L3984

Dear William Cox:

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:

L3984 - UPPER EXTREMITY FRACTURE ORTHOSIS, WRIST, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

The Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Quality Standards define off-the-shelf (OTS), custom-fitted and custom fabricated as follows:

1. Custom Fabricated: A custom fabricated item is one that is individually made for a specific patient. No other patient would be able to use this item. A custom fabricated item is a device which is fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part. The fabrication may involve using calculations, templates, and components. This process requires the use of basic materials including, but not limited to, plastic, metal, leather,

or cloth in the form of uncut or unshaped sheets, bars, or other basic forms and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing prior to fitting on the patient.

a. Molded-to-Patient-Model: A particular type of custom fabricated device in which either:
   i. An impression (usually by means of a plaster or fiberglass cast) of the specific body part is made directly on the patient, and this impression is then used to make a positive model of the body part from which the final product is crafted; or
   ii. A digital image of the patient's body part is made using Computer-Aided Design-Computer-Aided Manufacturing (CAD-CAM) systems software. This technology includes specialized probes/digitizers and scanners that create a computerized positive model, and then direct milling equipment to carve a positive model. The device is then individually fabricated and molded over the positive model of the patient.

b. Positive Model of the Patient:
   i. Molded-to-patient-model is a negative impression taken of the patient's body member and a positive model rectification is constructed;

   ii. CAD-CAM system, by use of digitizers, transmits surface contour data to software that the practitioner uses to rectify or modify the model on the computer screen. The data depicting the modified shape is electronically transmitted to a commercial milling machine that carves the rectified model; or
   iii. Direct formed model is one in which the patient serves as the positive model. The device is constructed over the model of the patient and is then fabricated to the patient. The completed custom fabrication is checked and all necessary adjustments are made.

2. Custom Fitted: Custom fitted orthotics are defined as devices that are prefabricated. They may or may not be supplied as a kit that requires some assembly. They all require fitting and adjustment (for example, the item must be trimmed, bent, molded [with or without heat], or otherwise modified by an individual with expertise in customizing the fit in order for it to be used by a specific patient). Custom fitted requires modification of the item in order to provide an individualized fit. Modifications must result in alterations in the item beyond simple adjustments made by bending, trimming, and/or molding of the item, installation of add-on components or assembly of the item.

3. Off-The-Shelf: Off-the-shelf (OTS) orthotics are defined as those prefabricated items which require minimal self-adjustment for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit to the individual. Appendix C does not apply to OTS orthotics.

The Correct Coding Article titled Correct Coding - Definitions Used For Off-The-Shelf Versus Custom Fitted Prefabricated Orthotics (Braces) - Revised states:

Custom fitted orthotics are:

- Devices that are prefabricated
- They may or may not be supplied as a kit that requires some assembly. Assembly of the item and/or installation of add-on components and/or the use of some basic materials in preparation of the item does not change classification from OTS to custom fitted
- Classification as custom fitted requires substantial modification for fitting at the time of delivery in order to provide an individualized fit, i.e., the item must be trimmed, bent, molded (with or without heat), or otherwise modified resulting in alterations beyond minimal self-adjustment
- This fitting at delivery does require expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthosis to fit the item to the individual beneficiary

Substantial modification is defined as changes made to achieve an individualized fit of the item that requires the expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthotics such as a physician, treating practitioner, an occupational therapist, or physical therapist in compliance with all applicable Federal and State licensure and regulatory requirements. A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

Use of CAD/CAM or similar technology to create an orthosis without a positive model of the patient may be considered as custom fitted if the final fitting upon delivery to the patient requires substantial modification requiring expertise as described in this section.

A certified orthotist is defined as an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification.

Kits are:

- A collection of components, materials and parts that require further assembly before delivery of the final product
- The elements of a kit may be packaged and complete from a single source or may be an assemblage of separate components from multiple sources by the supplier

The product submitted for review does not meet the definition of custom fabricated as it is made of prefabricated parts included in a kit and not fabricated based on clinically derived and rectified castings, tracings, measurements, and/or other images (such as X-rays) of the body part. It also does not use molded-to-patient-Model or a Positive Model of the Patient. The device would be considered custom fitted as it would require a customized fit by an orthotist prior to use

and is also indicated for use with fractures. Therefore, HCPCS code L3984 is the most appropriate code.

This decision applies to the application we received on October 22, 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. 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