

February 2, 2015

DJO GLOBAL INC  
1430 DECISION STREET  
VISTA CA 92081-8553

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

**Xref: 36894789**

XCELTRAX AIR X-SMALL	DJO GLOBAL INC	79-95512	L4361
XCELTRAX AIR SMALL	DJO GLOBAL INC	79-95513	L4361
XCELTRAX AIR MEDIUM	DJO GLOBAL INC	79-95515	L4361
XCELTRAX AIR LARGE	DJO GLOBAL INC	79-95517	L4361
XCELTRAX AIR X-LARGE	DJO GLOBAL INC	79-95518	L4361

Dear Dale Hammer:

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:

**L4361** - Walking Boot, Pneumatic And/Or Vacuum, With Or Without Joints, With Or Without Interface Material, Prefabricated, Off-The-Shelf

Local Coverage Article for Ankle-Foot/Knee-Ankle-Foot Orthoses - Policy Article - Effective January 2014:

Off-the-shelf (OTS) orthotics are:

- Items 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.
- OTS items require minimal self-adjustment for fitting at the time of delivery for appropriate use and do not require expertise in trimming, bending, molding, assembling, or customizing to fit an individual.
- This fitting does not require expertise of a certified orthotist or an individual who has equivalent specialized training in the provision of orthoses to fit the item to the individual beneficiary.

The term “minimal self-adjustment” is defined at 42 CFR §414.402 as an adjustment the beneficiary, caretaker for the beneficiary, or supplier of the device can perform and that does not require the services of a certified orthotist (that is, an individual who is certified by the American Board for Certification in Orthotics and Prosthetics, Inc., or by the Board for Orthotist/Prosthetist Certification) or an individual who has specialized training. For example, adjustment of straps and closures, bending or trimming for final fit or comfort (not all-inclusive) fall into this category.

Fabrication of an orthosis using CAD/CAM or similar technology without the creation of a positive model with minimal self-adjustment at delivery is considered as OTS.

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.

Fitting and adjustment is included in the allowance for the orthosis. This includes molding, trimming, bending and assembly to fit and deliver to the beneficiary. The PDAC has determined the design of this product does not allow for substantial modifications at the time of delivery to the beneficiary requiring the expertise of a certified orthotist or specially trained individual.

This decision applies to the application we received on November 18, 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](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)