PO BOX 100320 | COLUMBIA, SC 29202-3320 | DMEPDAC.COM | ISO 9001

PRICING DATA ANALYSIS AND CODING (PDAC)

PALMETTO GBA®
A CELERIAN GROUP COMPANY

October 21, 2022

MATTHEW KYLE
TURTLEBRACE
4976 HIGHWAY 169 N
MINNEAPOLIS, MN 55428

Document Control Number (DCN): 22224003000004

Manufacturer Name	Product Name	Model Number	Assigned HCPCS Code(s)
TURTLEBRACE	TURTLEBRACE FOR THE ANKLE	TBBC-XX	L2116
TURTLEBRACE	TURTLEBRACE FOR THE ANKLE	TBCP-XX	L2116
TURTLEBRACE	TURTLEBRACE FOR THE ANKLE	TBCPR-XX	L2116
TURTLEBRACE	TURTLEBRACE FOR THE ANKLE	TBCA-XX	L2116
TURTLEBRACE	TURTLEBRACE FOR THE ANKLE	TBCAR-XX	L2116

Dear MATTHEW KYLE,

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.

Based on this review and application of DME MAC policy, the HCPCS code(s) listed below should be used when billing the DME MACs:

L2116 ANKLE FOOT ORTHOSIS, FRACTURE ORTHOSIS, TIBIAL FRACTURE ORTHOSIS, RIGID, PREFABRICATED, INCLUDES FITTING AND ADJUSTMENT

This product is manufactured in multiple sizes which describes a prefabricated orthosis which is manufactured in quantity without a specific beneficiary in mind and does not meet the DMEPOS quality standards of a custom fabricated device described below.

Custom-fabricated items are individually made for a specific patient. No other patient can use them. A custom-fabricated device is fabricated on clinically derived and rectified castings, tracings, measurements, and or other body part images, like X-rays. Fabricating may involve calculations, templates, and components. This process uses basic materials including, but not limited to, plastic, metal, leather, or uncut or unshaped cloth sheets, bars, or other basic forms, and involves substantial work such as vacuum forming, cutting, bending, molding, sewing, drilling, and finishing before a patient fitting.

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 www.dmepdac.com. 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 Product Classification List (PCL) on the Durable Medical Equipment Coding System (DMECS). Further information for requesting updates to the PCL can be found on the PDAC website at www.dmepdac.com. 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 Palmetto GBA; nor does it imply or guarantee claim reimbursement or coverage.

If you have questions, please contact the PDAC HCPCS Helpline at (877) 735-1326 during the

hours of 9:30 a.m. to 5:00 p.m. ET, Monday through Friday. You may also visit our website to chat with one of our representatives or select the Contact Us button at the top of the page for email, FAX or postal mail information.

Sincerely,

Pricing, Data Analysis, and Coding (PDAC)
Palmetto GBA, LLC
www.dmepdac.com