



March 18, 2023

MATTHEW KYLE
 ONE LIFE SCIENCE - KURO
 4976 HIGHWAY 169 NORTH
 MINNEAPOLIS, MN 55428

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Manufacturer Name	Product Name	Model Number	Assigned HCPCS Code(s)
LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBBPV-XX	L3984
LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBBPV-XX	L3908
LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBBPV-XX	L3807
LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBBPV-XX	L3809
LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBBPZ-XX	L3984
LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBBPZ-XX	L3908
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LES CONCEPTS ORTHOPEDIQUES TURTLEBRACE	TURTLEBRACE WRIST	TBPPV-XX	L3984
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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:

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

L3908 WRIST HAND ORTHOSIS, WRIST EXTENSION CONTROL COCK-UP, NON MOLDED, PREFABRICATED, OFF-THE-SHELF

L3807 WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE

L3809 WRIST HAND FINGER ORTHOSIS, WITHOUT JOINT(S), PREFABRICATED, OFF-THE-SHELF, ANY TYPE

Based on the information in your application, the TURTLEBRACE WRIST is manufactured in multiple sizes. When a device is manufactured in multiple sizes, it is manufactured in quantity which is categorized by CMS as a prefabricated item. Therefore, your product cannot be described by a custom fabricated HCPCS code since it does not meet CMS's definition of custom fabrication DMEPOS quality standards, Appendix C, as 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