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

PRICING DATA ANALYSIS AND CODING (PDAC)

PALMETTO GBA®
A CELERIAN GROUP COMPANY

April 14, 2023

KIMBERLY HANSON
OTTOBOCK
11809 DOMAIN DR UNIT 400
AUSTIN, TX 78758

Document Control Number (DCN): 23039C25100004

Manufacturer Name	Product Name	Model Number	Assigned HCPCS Code(s)
OTTO BOCK HEALTHCARE	AGILIUM FORTE KNEE BRACE	50K305	L1843
OTTO BOCK HEALTHCARE	AGILIUM FORTE KNEE BRACE	50K305	L1851

Dear KIMBERLY HANSON,

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:

L1843 KNEE ORTHOSIS, SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED ITEM THAT HAS BEEN TRIMMED, BENT, MOLDED, ASSEMBLED, OR OTHERWISE CUSTOMIZED TO FIT A SPECIFIC PATIENT BY AN INDIVIDUAL WITH EXPERTISE

L1851 KNEE ORTHOSIS (KO), SINGLE UPRIGHT, THIGH AND CALF, WITH ADJUSTABLE FLEXION AND EXTENSION JOINT (UNICENTRIC OR POLYCENTRIC), MEDIAL-LATERAL AND ROTATION CONTROL, WITH OR WITHOUT VARUS/VALGUS ADJUSTMENT, PREFABRICATED, OFF-THE-SHELF

Please note that you wrote in your additional information request that your item is 510(k) exempt. In future submissions, please provide the FDA Exemption Regulation Number if your product is 510(k) exempt as indicated in application instructions. Also note that individual application submission require all documentation to be included and cannot be combined. Pages 1 and 2 of the application were missing in this submission. If this information is not provided, your application will be considered incomplete and will not be processed.

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