

AOPA In Advance SmartBrief November 28, 2023

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# CMS Publishes Final Rule that Defines Powered Orthoses and Exoskeletons as "Braces"

On November 1, 2023, the Centers for Medicare and Medicaid Services (CMS) released its annual final rule that established 2024 payment rates for the Medicare Home Health Prospective Payment System (PPS). As expected, the final rule carried forward several important, but unrelated provisions that are of significant interest to 0&P providers and the Medicare beneficiaries they serve. The DMEPOS provisions that were finalized in the rule include:

- The codification and expansion of the Medicare definition of the term "brace" to include powered orthoses and exoskeletons
- Creation of a new benefit category and payment for compression garments used to treat lymphedema
- Changes to the methodology used to calculate Medicare fee schedules based on rates established through competitive bidding
- Modifications to supplier enrollment processes designed to further control Medicare fraud and abuse

• Codification of existing policy regarding documentation requirements for DMEPOS refills The provision that will most likely have the greatest impact on the O&P profession is the inclusion of powered orthoses and exoskeletons in the brace benefit category for Medicare coverage and payment purposes. This represents a reversal of the long-standing CMS position that powered orthoses and exoskeletons should be classified as durable medical equipment (DME) as they generated motion across a joint without necessarily supporting a weakened joint or body member. AOPA and its O&P Alliance partners submitted detailed comments on this proposed provision and is pleased that CMS decided to include this provision in the final rule.

# DME MACs Validate AOPA LCD Reconsideration Request for Knee Orthoses Used to Treat Osteoarthritis

The DME MACs recently informed AOPA that its LCD Reconsideration Request for knee orthoses used to treat osteoarthritis without joint laxity was a valid request and will be considered for update. AOPA submitted its request on August 29<sup>th</sup>. The DME MACs have 60 days to notify requestors of the validity of the request but have no defined timeline to complete their review and propose any changes to the LCD. If the DME MACs propose changes to the LCD, they will publish them and schedule a public meeting to allow input from any interested parties. We have been in frequent communication with the DME MAC Medical Directors regarding this request and look forward to working with them to create a coverage pathway moving forward.

# Survey to help provide statistical data to quantify the provisions outlined in Medicare O&P Patient-Centered Care Act

Reagan Handley, a current master's student at the International Institute of Orthotics and Prosthetics (IIOP) in Tampa, FL, is conducting research to help provide statistical data to quantify the provisions outlined in <u>AOPA's Medicare Orthotics and Prosthetics Patient Centered Care Act</u> (<u>HR 4315</u>). This survey will focus on topics related to the prohibition of drop-shipping custom

orthotic and prosthetic devices, exemption for orthotics and prosthetics practitioners from requiring a competitive bidding license to provide off-the-shelf orthoses, and the removal of reasonable useful lifetime restrictions from custom orthoses. The goal of this survey is to determine where Medicare insurance coverage and policies are lacking, and to potentially highlight how to enact change in policy to better care for patients.

<u>This survey</u> is a total of 18 questions and should take approximately 5 minutes to complete. The data collected from this survey will be presented at the IIOP senior research symposium on December 6, 2023. Your responses will be anonymous when the results are presented. Please reach out to Reagan at <u>rhandley@iiofoandp.org</u> with any additional questions of comments regarding the survey

# New HCPCS Codes Introduced

The Centers for Medicare & Medicaid Services (CMS) have just released their final determinations from the First Biannual 2023 Healthcare Common Procedure Coding System (HCPCS) code application meetings.

The final determinations resulted in two new HCPCS codes which will be active and valid for claims with dates of service on or after October 1, 2023.

New Code as of 10/01/2023	Code Descriptor
L1681	Hip orthosis, bilateral hip joints and thigh cuffs, adjustable flexion, extension, abduction control of hip joint, postoperative hip abduction type, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L5991	Addition to lower extremity prostheses, osseointegrated external prosthetic connector

The final determinations also resulted in the creation of permanent "L" codes for the temporary "K" codes that have been introduced and active between January 1, 2020 through 2022. The new "L" codes will be active for claims with a date of service on or after January 1, 2024.

Current	New Permanent	Code Descriptor
Temporary	Code as of	
Code	1/01/2024	
K1014	L5615	Addition, endoskeletal knee-shin system, 4 bar
		linkage or multiaxial, fluid swing and stance phase
		control
K1015	L3161	Foot, adductus positioning device, adjustable
K1022	L5926	Addition to lower extremity prosthesis,
		endoskeletal, knee disarticulation, above knee, hip
		disarticulation, positional rotation unit, any type

Questions? Contact Joe McTernan at <u>jmcternan@AOPAnet.org</u> or Devon Bernard at <u>dbernard@AOPAnet.org</u>.

#### Limb Loss Survivor Advocates for Limb Loss and Preservation Registry

In the summer of 1974, two NY school teachers packed their children and grandparents into a station wagon hitched to a trailer and headed to Nova Scotia. Peter Thomas, age 10, his older sister and younger brother were thrilled to travel.

During the ride, a sudden swerve to avoid an oncoming car resulted in a collision with a stray snowplow, slicing the car's rear section and sending the two sleeping boys flying onto the road. Peter suddenly became aware that his legs were severed while his brother died upon impact.

So began the journey of a whole new life, including a chance meeting in the Canadian hospital ICU with a visitor who read about the accident and drove 200 miles to see him. The gentleman pulled the curtain around the bed, asked some questions and then dropped his trousers and jumped out of his artificial legs onto the next bed. A bilateral amputee above the knee with a wife, kids and job said, "Your life is not over. You're going to do just fine."

That conversation, now called *peer support* and practiced routinely by <u>Amputee Coalition</u> volunteers, materially impacted Peter's attitude and ability to adapt to his injury.

"Following more than two months of rehabilitation, I returned home with prosthetic limbs, walked into my 5<sup>th</sup> grade classroom and resumed a pretty normal existence," he shares.

By the time Peter graduated high school, he was walking all day, earning top grades and was elected president of the senior class. Peter focused on the positive, determined to get an education and office job.

With diplomas from Boston College and Georgetown Law School, he volunteered with a new, nonprofit group, the <u>NAAOP</u>, and worked to increase federal funding for O&P research and development. He was intimately involved in getting national O&P research legislation enacted in 1990, became involved with the <u>American Trauma Society</u> and served on its Board for 15+ years, helping to establish the <u>Trauma Survivors Network</u>.

He co-authored <u>a book</u> on the Americans with Disabilities Act of 1990, a time of increased emphasis on people with disabilities and non-discrimination. In 1997, President Clinton appointed him to the <u>President's Commission on Healthcare Quality and Patient Rights</u> that led to recognition of data collection, function measurement and outcomes as critical benchmarks for assessing what works and merits investments in the healthcare system.

He joined the Powers Law Firm which focuses on healthcare, rehabilitation law and disability advocacy work, married and raised three sons. 31 years later, he practices with the same firm as managing partner and credits a positive attitude as the foundation for overcoming any challenge or disadvantage.

Today, he continues to advocate, serving as a member of the External Collaborative Panel of the Limb Loss and Preservation Registry (LLPR) which moves the field toward evidence-based practice

to complement experience and expertise of the practitioner. LLPR follows, tracks and analyzes key data elements and functional outcomes to identify ways to improve care with a goal to collect as much data as possible from O&P practitioners, hospitals and hospital systems, therapists and therapy offices.

Utilizing numerous measurement tools and mechanisms to track this data in a given patient population, the LLPR aggregates, de-identifies and manipulates the data to analyze what will improve care for particular sub-populations of people with and facing limb loss. The LLPR was created through federal research funds from NIH and the Department of Defense, but will soon become an independent entity, relying on funding from the private sector and financial support from those who benefit from what the registry offers to advance care.

To learn more about the LLPR visit <a href="https://www.llpregistry.org/">https://www.llpregistry.org/</a>.

#### Help Gain Support for the Recently Introduced Medicare O&P Patient-Centered Care Act

Hopefully you saw that Friday of last week, <u>the Medicare O&P Patient-Centered Care Act (H.R.</u> <u>4315) was introduced</u> in the U.S. House of Representatives. This bipartisan legislation would improve access to, and quality of, orthotic and prosthetic care while simultaneously combating fraud and abuse from those outside the profession.

Its three major provisions include: prohibiting "drop shipping" of custom orthoses and prostheses to Medicare beneficiaries; ensuring Medicare beneficiaries can access the full range of orthotic care from one O&P practitioner rather than requiring patients to visit multiple providers when the treating orthotist or prosthetist does not have a competitive bidding contract and; ensuring Medicare beneficiaries can access replacement custom-fitted and custom-fabricated orthoses when a change in their condition or clinical needs occurs.

To move this legislation forward, we need to garner as much support as possible for it. Please write your Representative and urge them to support this important legislation - simply enter your information on the AOPAvotes platform, be sure to personalize it to tell YOUR story - and click send.

Finally, as you are using the AOPAvotes platform to send letters to your Representatives, be sure to utilize the automated Twitter campaign. Every Member of Congress has a Twitter account making it a great way to ask for their support.

#### ACT NOW

These actions just a few minutes and go a long way. If Members of Congress do not hear from you, they will not know how important this legislation is to your business and more importantly, your patients.

If you have any questions, contact Sam Miller, AOPA's State and Federal Advocacy Manager at <u>smiller@AOPAnet.org</u>.

Thank you for your efforts, they make an impact!

# Competitive Bidding: Round 2021 Coming to an End

The Competitive Bidding Program (CBP) Round 2021, which included 16 off-the-shelf (OTS) spinal orthoses and 7 OTS knee orthoses, contracts will expire on December 31, 2023. Beginning on January 1, 2024 there will be a temporary gap period for the CBP. During this gap period all enrolled Medicare DMEPOS suppliers may once again provide the OTS orthoses previously subject to the CBP. Please review the 2024 DMEPOS Fee Schedule for the updated fees for these 23 OTS orthoses.

The next round of the CBP for orthotics and prosthetics, has not been announced. However, CMS has stated that the next round will not begin until they:

- Complete the formal public notice and comment rulemaking process
- Implement necessary DMEPOS CBP changes to:
- Establish sustainable prices
- $\circ$  Save money for Medicare patients and taxpayers
- $\circ$  Help limit fraud, waste, and abuse in the Medicare Program
- Ensure patient access to quality items and services During the temporary gap period.

AOPA will notify all members when CMS releases new regulations related to the next round of the CBP and will continue to seek a legislative exemption for O&P providers.

Questions? Joe McTernan at <u>imcternan@AOPAnet.org</u> or Devon Bernard at <u>dbernard@AOPAnet.org</u>.

# AOPA Has MUE Updated

AOPA was made aware that the Medically Unlikely Edit (MUE), the total number of units of a service/item you may bill for a single beneficiary on any date of service, for the K1014 (Addition, endoskeletal knee-shin system, 4 bar linkage or multiaxial, fluid swing and stance phase control) was set at one. This MUE did not allow suppliers to bill for bi-lateral patients, without having to appeal the claim. AOPA contacted CMS and convinced them to update and change the MUE of the K1014 to two. The revised MUE will be published in future quarterly MUE updates.

Questions? Contact Joe McTernan at <u>jmcternan@AOPAnet.org</u> or Devon Bernard at <u>dbernard@AOPAnet.org</u>

#### **Renewed ABN Form Released**

The Advance Beneficiary Notice of Noncoverage (ABN) form is subject to re-approval and renewal every three years, and the current version of the ABN was approved in 2020 and expires on June 30, 2023. The new ABN, form CMS-R-131, was approved by the Office of Management and Budget (OMB) and released on April 4, 2023.

There were no substantial changes made to the content or to the directions for use of the ABN. The only change was to update the expiration date. The use of the revised ABN will be mandatory on June 30, 2023. To verify if you are using the most recent version of the ABN, on/after June 30, 2023, be sure to check the expiration date on the bottom left corner of the form; it should be 01/31/2026.

The new ABN form with instructions may be found here.

Questions? Contact Joe McTernan at <u>imcternan@AOPAnet.org</u> or Devon Bernard at <u>dbernard@AOPAnet.org</u>

#### Survey Socket Guidance Workgroup Publishes White Paper

Currently, no guidelines exist to test the mechanical strength of prosthetic sockets. To address this, AOPA established the Socket Guidance Workgroup which consists of multidisciplinary experts from various countries and backgrounds.

To address the knowledge gaps, the Workgroup undertook a critical analysis regarding the requirements for mechanical testing of lower limb prosthetic sockets and developed recommended potential solutions for each gap. The identified gaps were: i) the shape and composition of a mock residual limb, to support and generate realistic stresses within the socket; ii) alignment of the socket; iii) selection and requirements of accessory components; and iv) test conditions and acceptance criteria.

The intent is for the recommendations to support established researchers, PhD students, and Master's students in addressing these knowledge gaps and reporting back to the Workgroup. With AOPA's support, the Workgroup is building and maintaining a database to house the findings.

A full-length white paper and introductory editorial detailing the gaps and recommendations were recently published in Prosthetics and Orthotics International.

# Full-length white paper

# <u>Editorial</u>

Project authors: Francesca Gariboldi, Andrea Cutti, Jeff Erenstone, Stefania Fatone, Eric Nickel, Saeed Zahedi, Joshua Steer, Alex Dickinson.

# CMS Expands its List of Codes Subject to Face to Face Encounters and Written Orders Prior to Delivery

On January 17, 2023, the Centers for Medicare and Medicaid Services (CMS) added the following ten O&P HCPCS codes to the list of codes which require a written order prior to delivery (WOPD) and a face-to-face encounter (F2F) as a condition of payment for claims with a date of service on or after April 17, 2023:

- L0631- Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise
- L0637-Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panels, Posterior Extends From Sacrococcygeal Junction To T-9

Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panels, Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise

- 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
- L1932-Ankle Foot Orthosis, Rigid Anterior Tibial Section, Total Carbon Fiber Or Equal Material, Prefabricated, Includes Fitting And Adjustment
- L1940-Ankle Foot Orthosis, Plastic Or Other Material, Custom-Fabricated.L1951Ankle Foot Orthosis, Spiral, (Institute Of Rehabilitative Medicine Type), Plastic Or Other Material, Prefabricated, Includes Fitting And Adjustment
- L1960-Ankle Foot Orthosis, Posterior Solid Ankle, Plastic, Custom-Fabricated.L1970Ankle Foot Orthosis, Plastic With Ankle Joint, Custom-Fabricated
- L2005-Knee Ankle Foot Orthosis, Any Material, Single Or Double Upright, Stance Control, Automatic Lock And Swing Phase Release, Any Type Activation, Includes Ankle Joint, Any Type, Custom Fabricated
- L2036-Knee Ankle Foot Orthosis, Full Plastic, Double Upright, With Or Without Free Motion Knee, With Or Without Free Motion Ankle, Custom Fabricated.

Questions regarding this list may be directed to Joe McTernan at jmcternan@aopanet.org or Devon Bernard at dbernard@aopanet.org .

# Medicare DMEPOS Fee Schedule Will See its Largest Annual Increase in 2023

The Centers for Medicare and Medicaid Services (CMS) has officially released the 2023 DMEPOS Medicare fee schedule and it has increased by 8.7%, this is larger than any annual Medicare increase in the last several decades.

The annual increase to the Medicare O&P fee schedule is based on the annual change to the Consumer Pricing Index for all urban areas (CPI-U) from June to June of the previous year adjusted by an annual productivity adjustment (MFPA) or Total Factor Productivity (TFP). The CPI-U from June 2021 to June 2022 was 9.1%. The MFPA or TFP for the 2023 DMEPOS Medicare fee schedule was 0.4%. So, when the 9.1% increase in the CPI-U is reduced by the 0.4% increase in the MFPA or TFP the results are a total net increase of 8.7% in the DMEPOS fee schedule for 2023.

Questions regarding the 2023 Medicare DMEPOS Fee Schedule may be directed to Joe McTernan at <u>jmcternan@AOPAnet.org</u> or Devon Bernard at <u>dbernard@AOPAnet.org</u>.

### New National Provider Enrollment Contractors

Prior to November 6, 2022, there was only one contractor handling all enrollments and revalidations for durable, medical equipment, prosthetic, orthotic and supplies (DMEPOS) suppliers; and that was the National Supplier Clearinghouse (NSC). Palmetto GBA had the contract to be the NSC contractor. As of November 7, 2022 there are now two National Provider Enrollment (NPE) contractors handling enrollment and revalidation activities for DMEPOS suppliers, and each contractor is handling a different region.

Novitas Solutions will handle all suppliers in the eastern part of the United States including Alabama, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Kentucky, Maine, Maryland, Massachusetts, Michigan, Mississippi, New Hampshire, New Jersey, New York, North Carolina, Ohio, Pennsylvania, Rhode Island, South Carolina, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, District of Columbia, Puerto Rico, US Virgin Islands; and will be referred to as National Provider Enrollment (NPE) East. Novitas Solutions website for NPE East is: www.novitas-solutions.com/webcenter/portal/DMEPOS.

Palmetto GBA will continue to handle all suppliers in the western part of the United States including Alaska, Arizona, Arkansas, California, Colorado, Hawaii, Idaho, Iowa, Kansas, Louisiana, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Texas, Utah, Washington, Wyoming, American Samoa, Guam, Northern Mariana Islands; and will be referred to as National Provider Enrollment (NPE) West. You may still use the old National Supplier Clearinghouse website for Palmetto GBA to access information about NPE West or you may use the new site www.palmettogba.com/palmetto/npewest.nsf.

Questions? Contact Joe McTernan at jmcternan@AOPAnet.org or Devon Bernard at dbernard@AOPAnet.org.

# Final Phase of Prior Authorization for Select Orthoses Begins October 10

As a reminder Phase III, the final phase, of Prior Authorization for the following five orthoses:

- L0648 Lumbar-Sacral Orthosis, Sagittal Control, With Rigid Anterior And Posterior Panels, Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Produces Intracavitary Pressure To Reduce Load On The Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf
- L0650 Lumbar-Sacral Orthosis, Sagittal-Coronal Control, With Rigid Anterior And Posterior Frame/Panel(S), Posterior Extends From Sacrococcygeal Junction To T-9 Vertebra, Lateral Strength Provided By Rigid Lateral Frame/Panel(S), Produces Intracavitary Pressure To Reduce Load On Intervertebral Discs, Includes Straps, Closures, May Include Padding, Shoulder Straps, Pendulous Abdomen Design, Prefabricated, Off-The-Shelf
- L1832 Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated Item That Has Been Trimmed, Bent, Molded, Assembled, Or Otherwise Customized To Fit A Specific Patient By An Individual With Expertise

- L1833 Knee Orthosis, Adjustable Knee Joints (Unicentric Or Polycentric), Positional Orthosis, Rigid Support, Prefabricated, Off-The Shelf
- 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

Will begin in all remaining states and territories for all claims with a date of service on or after October 10, 2022.

Questions? Contact Joe McTernan at <u>imcternan@AOPAnet.org</u> or Devon Bernard at <u>dbernard@AOPAnet.org</u>.

#### CO-261 Claim Rejections Resolved

Several AOPA members had reported having an issue with select lower limb prosthetic claims being rejected with the remark code CO-261 (The procedure or service is inconsistent with the patient's history). Since the claims were rejected and not denied the claim could not be appealed; it could only be fixed and resubmitted. However, there was no information or directions provided as to what was "inconsistent", and how it could be fixed. This inability to fix/appeal the claims was also causing some members to miss their timely filing window.

AOPA, over the last several months, has been working diligently with key staff members at the DME MACs, the DME MAC Medical Directors and high-ranking CMS officials to find a reasonable solution and provide a pathway for suppliers to appeal these rejections; especially for those who may have missed their timely filing windows. The DME MAC Medical Directors recently informed AOPA that the issue has been resolved, and that they will be contacting the affected suppliers and provide them with directions on how to resubmit and/or appeal their claims.

Questions? Contact Joe McTernan at <u>imcternan@AOPAnet.org</u> or Devon Bernard <u>dbernard@AOPAnet.org</u>.

# **Upcoming Events**

**November 16** AOPA Advocacy in Action **<u>Register</u>** 

See AOPA's Education Calendar