Office of Management & Budget
Executive Order 12866 Meeting
October 30, 2023 10:30am EST

Introduction:

USMCA companies including Essity, Juzo, Lohmann & Rauscher, mediUSA, and Sigvaris manufacture FDA registered, medical, gradient compression therapy garments in ready-to-wear and custom forms. They design, engineer, test, and manufacture ISO certified medical devices to ensure quality, safety, utility, and efficacy. The USMCA is committed to helping patients live more independent, healthy, and productive lives while ensuring access to medically necessary products to manage their chronic, lifelong symptoms they suffer due to lymphedema. The USMCA submitted comments to CMS proposed rule (CMS-1780) detailing our recommendations to ensure that Congress' intent of the Lymphedema Treatment Act is met to ensure access for Medicare beneficiaries. An executive summary of our comments is provided below.

I. **Healthcare Common Procedure Coding System (HCPCS) Codes**
   - **Challenges:** The proposed 48 HCPCS codes are insufficient to accurately differentiate the more than 25,000 available compression treatment items and accessories. CMS proposed to group Flat Knit and Circular Knit textiles under a single garment category. If existing codes are comingled with new codes, existing edits, coding articles, and coverage determinations will be impacted and will likely cause provider and MAC confusion and resource expenditures.
   - **Recommendation:** CMS should adopt the USMCA proposed 229 HCPCS codes to allow clinicians to prescribe medically necessary treatments and ensure patient access. The USMCA's proposed code set is not intended to be a universal listing of all items and services at a granular product-specific level, but is intended to describe the item or service in a way that is general enough so as not to be manufacturer specific. HCPCS codes need to differentiate between key categories including, textiles (circular knit, flat knit, inelastic adjustable wraps, nighttime, bandages, and accessories), compression dosage, anatomical location, and ready to wear and custom forms, as illustrated in the tables below. Comprehensive coding, coverage, and payment is necessary for all compression levels (low, medium, and high classes). Many lymphedema patients utilize lower compression classes to effectively manage their condition. Inadequate coding and coverage for all compression levels may result in patients foregoing or inadequately utilizing prescribed products leading to detrimental and costly health outcomes. Finally, CMS should establish a new set of HCPCS codes and not comingle existing codes into this new benefit.

mmHg			
Textile	I	II	III+
Circular Knit	18-30	30-40	40-50+
Flat Knit	15-21	22-32	33-46+
Nighttime	Any pressure		
Inelastic Adjustable Wraps	Any pressure		

Sizing - Bandages						
Length	½ meter	1 meter	2 meters	4 meters	5 meters	Linear yard
Width	< 6cm	6 to <12 cm	12 cm +			

Anatomical Location			
Upper Extremity	**Lower Extremity**	**Torso**	**Other**
Arm	Toe cap with individual digits	Abdomen	Head and Neck
Arm & Hand	Foot	Bra	Bodysuit
Gauntlet	Calf	Vest	
Glove	Below knee	Shorts	
	Knee & Thigh	Capri	
	Thigh Length	Long Sleeve Shirt	
	Full Length, chap style	Short Sleeve Shirt	
	Waist Length		

- **Stakeholder Alignment:** Organizations that support this recommendation include: AAHomecare, NLN, VGM, and AWCS

II. Payment Basis

- **Challenges:** CMS' proposed methodology provides insufficient payment and will limit patient access. Medicaid is an inappropriate and inconsistent data source; Tricare accounts for less than 3% of the US population; internet retail cash prices are not in line with payer rates and online searches are fraught with misinformation. Historically, nearly all lymphedema gradient compression products were described by miscellaneous or "not otherwise classified" codes without fee schedules, resulting in a highly variable mix of products and associated payment amounts all comingled into a few codes.
    1. Patient access challenges already exist today. Treatment of chronic illnesses now accounts for almost 93 % of Medicare spending.[1] Lymphedema, once acquired, is a lifelong progressing disease with no currently known cure. Chronic lymphedema places over 3 million Americans at risk of recurrent cellulitis. The quality of available treatment often does not meet the recommended standards of knowledgeable lymphedema specialty groups such as the International Society of Lymphology (ISL), the American Lymphedema Framework Project (ALFP), the American Cancer Society (ACS) and the National Lymphedema Network (NLN).[2]

[1] International Society of Lymphology Executive Committee. The diagnosis and treatment of peripheral lymphedema: 2013 consensus document of the international society of lymphology. Lymphology. 2013;46:51. Available from http://www.u.arizona.edu/~witte/2013consensus.pdf. Accessed 26 Aug 2016.

[2] Weiss, R. Cost of a lymphedema treatment mandate 10 years of experience in the Commonwealth of Virginia Health Economics Review (2016) 6:42 DOI 10.1186/s13561-016-0117-3

2. The Congressional Budget Office (CBO) estimated a reduction in Medicare fee for service (FFS) spending on other health care services because of the new benefit for compression garments. CBO estimated that use of compression garments would reduce those hospitalizations for beneficiaries with lymphedema by about 30 percent.[3]
3. Medicaid and Tricare fee schedules are either non-existent or highly variable, and low reimbursement rates cause suppliers to stop taking assignment.[4]
4. A high number of DMEPOS suppliers taking non-assignment could produce similar challenges to those seen in competitive bidding. Beneficiaries self-reported intentionally bypassing the Medicare HME system and paying for equipment/supplies out-of-pocket to avoid delays and inaccessible equipment, which was corroborated by case managers' reports on beneficiary complaints.[5]
5. Internet cash pay prices do not reflect the cost of doing business with payers (i.e., accreditation, documentation collection, claim submission, compliance, audits, accounts receivable, etc.)
6. Online retailers are challenging to navigate as many overseas companies sell inferior imposter products, and retailers that do sell quality products may not have accurate descriptions or inventory for the item being advertised.

- **Recommendations:** CMS should adopt the USMCA proposed bundled single payment basis, which is a formula based on 120% of manufacturer's Minimum Advertised Price (MAP), pressure and custom conversion factors, as well as an additional fee to cover the necessary fitting services.
    1. The only common denominator that exists across all proposed codes is Minimum Advertised Price (MAP): The actual advertised cash-pay rate published across qualified internet suppliers (less than MSRP).
    2. Increase the MAP by 120% to account for the cost of doing business with health insurance payers.
    3. Utilized proposed rule "Table FF-A 2: Example Payment Amounts" to determine price percentage differences from low to high pressure items and from standard to custom.

Average low to medium pressure =	125.8%
Average low to high pressure =	152.4%
Assume medium to low pressure=	80.1%
Average standard to custom items=	241.7%

        These cost variances by pressure are also supported by the resources required to treat patients. There are a few key factors which increase the required resources for higher pressure items. First, higher pressure garments have significantly lower demand and volume manufactured. This low volume reduces the economies of

[3] hr3630.pdf (cbo.gov)
[4] Dobson DaVanzo & Associates, Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences, (2017).
[5] Dobson DaVanzo & Associates, Access to Home Medical Equipment: Survey of Beneficiary, Case Manager, and Supplier Experiences, (2017).

scale and increase the average unit costs. Second, higher pressure, Class II garments, require more testing, factory processes, training, and audit paperwork management. Finally, higher compression levels typically have a return and/or remake rate that is two times more than lower compression levels indicative of more complex tissue morphology, higher acuity disease, and more challenging fitting processes.

The cost variances by pressure are also supported by the existing gradient compression HCPCS and accompanying DMEPOS fee schedule demonstrate a price increase from lower to higher pressure levels:

HCPCS	Long Description	Short Description	Ceiling	Floor
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each	Compression stocking bk 30-40	57.53	48.90
A6532	Gradient compression stocking, below knee, 40-50 mmhg, each	Compression stocking bk 40-50	81.07	68.91

This is also demonstrated in existing state fee schedules (i.e., Maine, Minnesota, Virginia, Rhode Island)

4. Add a fitting fee for a set of garments to establish a single payment amount.
5. Below is an example that uses $100 to illustrate the math of how the conversion factor methodology is used to establish the single payment amounts for each code (note, this is not the actual average internet minimum advertised price).

HCPCS Description	Custom or Ready to Wear (RTW)	Example* Minimum Advertised Price	Conversion Factor Formula	Item Payment Amount	Fitting Fee	Final Bundled Single Payment Amount
Gradient compression flat knit garment, Arm, 18-30, each	RTW	$100.00	$100*1.20	$120.00	$58.45	$178.45
Gradient compression flat knit garment, Arm, 30-40, each	RTW		$120*1.258	$150.96	$58.45	$209.41
Gradient compression flat knit garment, Arm, 40+, each	RTW		$120*1.524	$182.88	$58.45	$241.33
Gradient compression flat knit garment, Arm, 18-30, each, custom	Custom		$120 *2.417	$290.04	$73.07	$363.11
Gradient compression flat knit garment, Arm, 30-40, each, custom	Custom		$150.96*2.417	$364.87	$73.07	$437.94
Gradient compression flat knit garment, Arm, 40+, each, custom	Custom		$182.88*2.417	$442.02	$73.07	$515.09

- **Stakeholder Alignment:** Organizations that support this recommendation:
  - AAHomecare, VGM

III. **Frequency Limits & Replacements**

- **Challenges:** The proposed frequency limits would impose onerous, daily laundry requirements on patients and require patients to wear compression garments past the garment's warranty period.
- **Recommendation:** CMS should cover at least 3 sets of daytime products every 6 months and 2 sets of nighttime per year. Additional quantities should be allowed based on medical need. Compliant utilization of clean products is required for chronic disease management, improved patient quality of life, and reduced healthcare costs related to infections, cellulitis, hospitalizations, and disease progression.
- **Stakeholder Alignment:** Organizations that support this recommendation:
  - AAHomecare, LAG, NLN, VGM, WOCN (nighttime support)

IV. **The Fitting Process**

- **Challenges:** The process requires clarity to prevent fraud, waste and protect quality patient care. CMS stated custom fit garments must be properly evaluated and fitted by qualified practitioner with appropriate training and specialized skills of gradient compression such as PT, OT, or physician.
- **Recommendation:** CMS should clarify the fitting process is essential for both ready to wear and custom products. USMCA supports clinician provision of these services, but also recognizes not all have the bandwidth or business model to support being the sole providers of all elements of the fitting process. USMCA recommends that qualified, non-clinician fitters to be included so, multiple fitter options are available to patients depending on the healthcare systema and available resources in that system. USMCA recommends an 18-24 month phase-in for qualification requirements of non-clinician fitters to allow for continued patient access and adequate time for individuals to complete necessary steps.
- **Stakeholder Alignment:** Organizations that support this recommendation:
  - AAHomecare, Klose Training, NLN, VGM

V. **Access Monitoring**:

CMS should monitor implementation of the benefit to ensure patient access is not limited by these policies by measuring key metrics. For example, the baseline supplier population may be identified by DMEPOS Suppliers who have submitted claims for existing compression HCPCS codes for venous insufficiency and/or wound indications in 2023. Of this baseline, identify % enrolled as participating and non-participating suppliers.

- In 2024 measure changes between new and existing enrolled suppliers as well as participation status to determine if there have been suppliers not willing to accept assignment of fee schedules as payment in full.
- Assess utilization by comparing claims from 2022-2023 to 2024 for the "enrolled population" (all people enrolled in Medicare), "utilizer groups" (original Medicare beneficiaries who have a claim for a lymphedema product), and "access groups" (original Medicare beneficiaries who are likely to use a lymphedema product on the basis of diagnosis or related health condition, for example beneficiaries with lymphedema or cellulitis).

We appreciate the agencies work to collect information prior to making policies that effect stakeholder's lives and the health of patients living with lymphedema. The USMCA looks forward to continuing our mission and helping Medicare beneficiaries obtain appropriate access to gradient compression therapies and fitting services.

Sincerely,

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