

USMCA companies including Essity, Juzo, Lohmann & Rauscher, mediUSA, and Sigvaris manufacture FDA registered, medical, gradient compression treatments 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. Our comments provide support for specific CMS proposals and recommend changes to ensure that Congress' intent of the LTA is met to ensure access for Medicare beneficiaries. A summary of our primary recommendations follows:

- **Healthcare Common Procedure Coding System (HCPCS) Codes**
  - **Challenges:** The proposed 48 HCPCS codes are insufficient to accurately differentiate amongst the more than 25,000 available compression treatment items and accessories. CMS proposes 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.
  - **Recommendation:** CMS should adopt the USMCA proposed ~229 HCPCS codes to allow clinicians to prescribe medically necessary treatments and ensure patient access. HCPCS codes need to differentiate between textiles and technologies (circular knit, flat knit, inelastic adjustable wraps, nighttime, bandages, and accessories), compression dosage, anatomical location, and ready to wear and custom forms. CMS should establish a fresh new set of HCPCS codes and not comingle existing codes into this new benefit.
- **Payment Basis**
  - **Challenges:** The proposed payment methodology will lead to insufficient 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. Nearly all 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.
  - **Recommendation:** 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.
- **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 are required for chronic disease management, improved patient quality of life, and reduced healthcare costs related to infections, cellulitis, hospitalizations, and disease progression.
- **The Fitting Process**
  - **Challenges:** The process requires clarity to prevent fraud and abuse 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 the inclusion of qualified, non-clinician fitters to allow for multiple fitter options and to not delay access to care, consistent with today’s market.

**HCPCS cont.** The construct for creation of the ~229 proposed HCPCS codes is in the charts below. HCPCS codes must differentiate ready to wear vs custom, type of textile or technology, anatomical location, dosage (mmHg), and sizing of bandages. It is important to note that a ready-to-wear version does not exist for all products, so the recommended HCPCS code list to CMS is not symmetrical.

Type of Textile or Technology	Anatomical Locations			
Description	Upper Extremity	Lower Extremity	Torso	Other
Circular Knit	Arm	Toe cap with individual digits	Abdomen	Head and Neck
Flat Knit	Arm & Hand	Foot	Bra	Bodysuit
Inelastic Adjustable Wraps	Gauntlet	Calf	Vest	
Nighttime	Glove	Below Knee	Shorts	
Bandages		Knee and Thigh	Capri	
Accessories		Thigh Length	Long Sleeve Shirt	
<ul style="list-style-type: none"> <li>• Efficacy Aids</li> <li>• Modifications</li> </ul>		Full Length, chap style	Short Sleeve Shirt	
		Waist Length		

Compression Dosage (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			

<b>Sizing of Bandages</b>	<b>Bandages</b>						
	Length	½ meter	1 meter	2 meter	4 meter	5 meter	Linear yard
	Width	<6 cm	6 to less than 12 cm	=> 12 cm			

**Additional Recommendations:**

Topic	CMS Proposal	Challenges	Recommendation
HCPCS codes	CMS proposes to modify and add to the existing HCPCS codes for surgical dressings and lymphedema compression treatment items as explained in section VII.B.4. of this rule.	<ul style="list-style-type: none"> <li>Proposed codes lack appropriate textile and technology specifications.</li> <li>Without specificity, versions of products provided vary greatly.</li> </ul>	<ul style="list-style-type: none"> <li>CMS should adopt the USMCA proposed HCPCS code set.                             <ul style="list-style-type: none"> <li>Including specifically differentiating between circular and flat knit garments</li> </ul> </li> <li>New HCPCS codes will allow more accurate descriptions of the numerous lymphedema compression treatment items currently in therapeutic use.</li> <li>More specific HCPCS codes facilitate the ability of clinicians to order medically necessary item(s) accurately and appropriately.</li> <li>Support HCPCS application process for future technology.</li> </ul>
	CMS proposes to add three new HCPCS codes for use when billing for A6531, A6532, and A6545 items used as surgical dressings.	<ul style="list-style-type: none"> <li>Modifying these widely understood and utilized codes would require administratively burdensome change to existing wound care guidance, national and local coverage determinations, and related documents.</li> </ul>	<ul style="list-style-type: none"> <li>Maintain the existing A6531, A6532, and A6545 codes for use as surgical dressings.</li> </ul>

		<ul style="list-style-type: none"> <li>• Modifications would cause disruption in wound care setting and increase administrative burden with regards to claim reviews and audits, which would need to account for modified codes.</li> </ul>	
	<p>We are soliciting comment on whether separate codes are needed for mastectomy sleeves or whether these items can be grouped together under the same codes used for other arm sleeves (S8422 thru S8424).</p>	<ul style="list-style-type: none"> <li>• Not all patients with breast cancer have a mastectomy.</li> <li>• Products do not change based on whether or not a patient had a mastectomy, prescriptions are based on symptoms and severity.</li> </ul>	<ul style="list-style-type: none"> <li>• Do not separate the codes. Base provision of products on a diagnosis of lymphedema (including all four the recommended ICD-10 codes).</li> </ul>
<p>Payment</p>	<p>CMS proposes to pay for lymphedema items based on Medicaid payment rates plus 20%. Where Medicaid rates are unavailable, CMS proposes to use the average of internet retail prices and payment amounts established by TRICARE (or, where there is no TRICARE fee schedule rate, the average of internet retail prices alone).</p>	<ul style="list-style-type: none"> <li>• Medicaid is an inappropriate data sources because they pay for less than 21% of proposed codes and have inconsistent data. <ul style="list-style-type: none"> <li>○ Medicaid data is inconsistent with many states not reporting or only a handful reporting fee schedules. Only 5 codes have more than half the states reporting. The payment amount variance within a code is as high as 8x</li> </ul> </li> <li>• Tricare makes up less than 3% of the US population. If used by CMS, its fee schedule should be weighted much less than MAP.</li> <li>• Internet retail cash prices are not in line with payer rates and do not include the additional costs of doing business with Medicare.</li> </ul>	<ul style="list-style-type: none"> <li>• Establish Bundled Single Payment Basis= <ul style="list-style-type: none"> <li>○ 120% of MAP for low pressure standard item</li> <li>x Pressure x Custom Conversion Factors</li> <li>+ Fitting Fee</li> <li>○ 120% of MAP for accessories</li> </ul> </li> <li>• MAP= Manufacturer’s Minimum Advertised Price. The actual cash pay rate published across qualified internet suppliers (less than MSRP).</li> </ul>

		<ul style="list-style-type: none"> <li>• Internet searches are fraught with misinformation.</li> </ul>	
Frequency Limits & Replacements	<p>CMS proposes to add § 414.1680 and the following frequency limitations for lymphedema compression treatment items established in accordance with section 1834(z)(2) of the Act under new subpart Q:</p> <ul style="list-style-type: none"> <li>• Two daytime garments or wraps with adjustable straps for each affected limb or area of the body, replaced every 6 months.</li> <li>• One nighttime garment for each affected limb or area of the body, replaced once a year.</li> </ul> <p>CMS is soliciting comments on whether two nighttime garments should be allowed, with both garments being replaced once every 2 years, to allow for more than 1 day for washing and drying of the garment(s).</p> <p>CMS proposes to cover replacements of garments or wraps that are lost, stolen, irreparably damaged, or when needed due to a change in the patient’s medical or physical condition.</p>	<ul style="list-style-type: none"> <li>• Compression products are intimate apparel. Most individuals have more than two pairs of socks or under garments. Due to constant skin contact and laundering needs, additional pairs are necessary for compliance and effective use.</li> </ul>	<ul style="list-style-type: none"> <li>• Recommend three sets of daytime products replaced every 6 months, and two sets of nighttime products replaced every year. Additional frequencies should be allowed with documentation of need.</li> <li>• Recommend that Medicare cover replacements of garments or wraps that are lost, stolen, irreparably damaged, or when needed due to a change in the patient’s medical or physical condition, including significant change in body weight and/or size.</li> </ul>
Coverage of Professional Services (i.e., The Fitting Process)	<p>Custom fit garment must be properly evaluated and fitted by qualified practitioner with appropriate training and specialized skills of gradient compression such as PT, OT, or physician.</p>	<ul style="list-style-type: none"> <li>• Only paying for fitting services provided by clinicians will limit access and likely delay care due to wait times.</li> </ul>	<ul style="list-style-type: none"> <li>• Require and pay for fitting for standard and custom garments.</li> <li>• Allow qualified non-clinicians to provide fitting services, consistent with today’s market.</li> </ul>

		<ul style="list-style-type: none"> <li>• Paying for fitting services only for custom will result in ineffective care.</li> </ul>	
	<p>CMS recognizes that there is not necessarily a standard industry practice for the fitting and training components for furnishing lymphedema compression garments and seeks comment on whether there are best practices in this space that CMS should consider further in the future.</p>	<ul style="list-style-type: none"> <li>• Need to protect standard of care provided to patients.</li> </ul>	<ul style="list-style-type: none"> <li>• While manufacturer certification exists today, we propose Medicare qualification standards for non-clinician fitters, similar to Certified Mastectomy Fitters.</li> <li>• Allow for 18–24-month phase-in period.</li> </ul>
	<p>Therefore, the Medicare payments would likewise include payment for all services necessary for furnishing the gradient compression garment; this is consistent with how Medicare payment is made for DMEPOS. We understand that in many cases a therapist may take measurements and provide other fitting services necessary for furnishing a gradient compression garment that is then furnished by a separate supplier. Under this scenario, the supplier receiving payment for the garment would be responsible for paying the therapist for the fitting component that is an integral part of furnishing the item.</p> <p>An alternative option, which we are not proposing but are seeking comment on, would be to pay separately for the fitting component furnished by the therapist and then back this payment out of the payment for the garment.</p>	<ul style="list-style-type: none"> <li>• Payment for fitting services must be separately identified, regardless of how that payment is administered.</li> <li>• Medicare payment policies should align with current market where fitting services may be provided by a clinician, employees of the DME supplier, or both; otherwise access to care issues will arise.</li> </ul>	<ul style="list-style-type: none"> <li>• Recommend CMS provide transparency regarding payment amount for item and for related fitting fee.</li> <li>• CMS payment policies need to recognize and accommodate the various ways the fitting process occurs, whether that is with a clinician, a DMEPOS provider, or a combination of the two.</li> </ul>

**Additional Recommendations**

Topic	CMS Proposal	Challenges	Recommendation
Benefit Category	The statute limits the benefit to items used for the treatment of lymphedema as determined by the Secretary, and we are proposing that this includes items used to treat all types or diagnoses of lymphedema, but does not include the same items when used to treat injuries or illnesses other than lymphedema. In other words, if a gradient compression garment or other lymphedema compression treatment item is furnished to treat an injury or illness other than lymphedema, those items would not be classified under the Medicare benefit category for lymphedema compression treatment items.	<ul style="list-style-type: none"> <li>Concern for comorbidities resulting in denied coverage (i.e., chronic venous insufficiency, wounds).</li> </ul>	<ul style="list-style-type: none"> <li>Allow coverage for the following ICD-10 codes.               <ul style="list-style-type: none"> <li>Q82.0</li> <li>I89.0</li> <li>I97.2</li> <li>I97.89</li> </ul> </li> </ul>
Definitions	Gradient compression means the ability to apply a higher level of compression or pressure to the distal (farther) end of the limb or body part affected by lymphedema with lower, decreasing compression or pressure at the proximal (closer) end of the limb or body part affected by lymphedema.	<ul style="list-style-type: none"> <li>Distal to proximal is specific to limbs, and does not account for applications for head, neck, chest, and trunk.</li> </ul>	<ul style="list-style-type: none"> <li>The ability to apply a higher level of compression or pressure at one end point and a lower level of compression or pressure at an opposite end point or the ability to apply an appropriate level of compression dosage or pressure to a specific anatomical location affected by lymphedema.</li> </ul>
Competitive Bidding	As previously discussed, section 4133(a)(3) of the CAA, 2023 adds subparagraph D to section 1847(a)(2) of the Act to add lymphedema compression treatment items to the DMEPOS competitive bidding program.	<ul style="list-style-type: none"> <li>Concern for limiting patient access to a new benefit.</li> <li>CMS will not have sufficient utilization and payment data to properly consider</li> </ul>	<ul style="list-style-type: none"> <li>Oppose</li> <li>The competitive bidding law provides CMS the authority to not include in the competitive bidding program items for which there will be no expectation of significant savings. There will be no expectation of significant savings</li> </ul>

		<p>whether substantial savings would occur.</p> <ul style="list-style-type: none"> <li>• Many suppliers have yet to enroll, implementing competitive bidding too early will artificially limit the number of suppliers.</li> </ul>	<p>for lymphedema compression garments because CMS is already required to establish payment rates that are competitive in today's market.</p>
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**Supported Language**

<b>Topic</b>	<b>CMS Proposal</b>	<b>Comment</b>
<b>HCPCS</b>	CMS is proposing that compression bandaging systems applied in a clinical setting as part of phase one decongestive therapy would also be items covered under the new benefit category for lymphedema compression treatment items if this rule is finalized.	Support
	CMS is not proposing specific replacement frequencies for compression bandaging systems or supplies. We are proposing that determinations regarding the quantity of compression bandaging supplies covered for each beneficiary during phase one of decongestive therapy would be made by the DME MAC that processes the claims for the supplies.	Support
	CMS is soliciting comments on whether there is a need to retain codes S8420 through S8428, in addition to the renumbered A code versions, for use by other payers other than Medicare. If these codes are retained, they would be invalid for Medicare use, but could be used by other payers in lieu of the new A codes.	Support
	CMS proposes that future changes to the HCPCS codes for these items based on external requests for changes to the HCPCS or internal CMS changes would be made through the HCPCS public meeting process described at: <a href="https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings">https://www.cms.gov/medicare/coding/medhcpcsgeninfo/hcpcspublicmeetings</a>	Support
<b>Payment</b>	In order to maintain mobility, patients may require separate garments or wraps above and below the joint of the affected extremity or part of the body, and we are proposing that payment may be made in these circumstances.	Support



	<p>CMS proposes that payment may be made for multiple garments used on different parts of the body when the multiple garments are determined to be reasonable and necessary for the treatment of lymphedema. For example, if it is determined that a beneficiary needs three daytime garments to cover one affected area for the treatment of lymphedema, Medicare would pay for two sets of those three garments for that specific affected area, as well as any other areas of the body affected by lymphedema.</p>	<p>Support</p>
	<p>CMS proposes under § 414.1650(c) that, beginning January 1, 2025, and on January 1 of each subsequent year, the Medicare payment rates established for these items in accordance with section 1834(z)(1) of the Act and § 414.1650(b) would be increased by the percentage change in the Consumer Price Index for All Urban Consumers (CPI-U) for the 12-month period ending June of the preceding year. For example, beginning January 1, 2025, the payment rates that were in effect on January 1, 2024, would be increased by the percentage change in the CPI-U from June 2023 to June 2024.</p>	<p>Support</p>