PROPOSED RULE SUMMARY

AAHOMECARE
American Association for Homecare

MEMORANDUM

Date: July 10, 2023

Subject: Medicare Program; Calendar Year (CY) 2024 Home Health (HH) Prospective Payment System Rate Update; HH Quality Reporting Program Requirements; HH Value-Based Purchasing Expanded Model Requirements; Home Intravenous Immune Globulin Items and Services; Hospice Informal Dispute Resolution and Special Focus Program Requirements, Certain Requirements for Durable Medical Equipment Prosthetics and Orthotics Supplies; and Provider and Supplier Enrollment Requirements (CMS–1780–P)

Overview

On July 10, 2023, the Centers for Medicare and Medicaid Services published the above captioned proposed rule on Calendar Year 2024 Home Health Payment Proposed Rule (CMS-1780-P). The proposed rule includes Durable Medical Equipment Prosthetics and Orthotics Supplies (DMEPOS) provisions that address the non-rural, non-competitive bidding area payments starting in 2024, coverage of lymphedema compression treatment items, provider enrollment provisions, and refill policy.

CMS is accepting comments on the proposed rule until August 29, 2023. This summary refers only to the DMEPOS proposals.

Non-Rural Area Payment

CMS is proposing to update the DMEPOS payment regulation to conform with the provisions passed in the Consolidated Appropriations Act of 2023, which extended the 75/25 blended rates for non-rural areas until December 31, 2023, or end of PHE, whichever is later. The regulation will state non-rural, non-CBAs will have the 75% adjusted and 25% unadjusted rates from March 6, 2020, until the duration of the PHE period or December 31, 2023, whichever is later.

Scope of the Benefit and Payment for Lymphedema Compression Treatment Items

The Consolidated Appropriations Act of 2023 (CCA) requires coverage of lymphedema compression treatment items to be covered under a new Part B benefit category.

Currently, CMS does not cover lymphedema compression treatment items under Part B other than compression pumps and accessories that meet the definition of DME. In this rule, CMS is proposes that for items to be covered under the new benefit category, the compression treatment items must be used in treating lymphedema and will not include professional treatment services that are not directly related to supplying lymphedema compression treatment items. Professional services related to the treatment of lymphedema will be covered under the Medicare Physician Fee Schedule.

HCPCS Codes for Lymphedema Compression Treatment Items

There are HCPCS codes for compression treatment items for gradient compression stockings, wraps, sleeves, gloves, and gauntlets (26 HCPCS listed in the rule).

Proposed Changes to Existing HCPCS codes: **A6531, A6532, A6545**

The following gradient compression HCPCS codes are covered under Part B for surgical dressings when they are used to treat open venous stasis ulcer.

- **A6531** Gradient compression stocking, below knee, 30-40 mmhg, each
- **A6532** Gradient compression stocking, below knee, 40-50 mmhg, each
- **A6545** Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, each

CMS proposes to distinguish the three codes when used for lymphedema v open venous stasis ulcer. Therefore, CMS proposes to add three new HCPCS codes for use when billing for A6531, A6532, and A6545 items when used as surgical dressings:

- AXXX-- *Gradient compression stocking, below knee, 30-40 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each*
- AXXX—*Gradient compression stocking, below knee, 40-50 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each*
- AXXX—*Gradient compression wrap with adjustable straps, non-elastic, below knee, 30- 50 mmhg, used as surgical dressing in treatment of open venous stasis ulcer, each*

Proposed Changes to Existing HCPCS codes: **A6530-A6541**

For HCPCS codes **A6530-A6541** (gradient compression stockings), CMS is soliciting comments on whether the pressure level differentiations in the codes should be changed other than 18-30, 30-40, and 40-50 mmHg and whether the body area descriptions should be changed other than the current: *"below knee," "thigh-length," "full-length/chap style," and "waist-length."* In addition, , CMS proposes to create a corresponding custom version of the garment for each code.

Proposed Changes to Existing HCPCS codes: **A6549**, and **S8420-S8428**

CMS proposes to modify the current HCPCS codes **A6549, and S8420-S8428** for gradient compression garments for upper body/extremities. CMS also proposes to:

- change the S codes to A codes;
- remove "ready-made" in the descriptions;
- revise "custom made" to "custom" in the descriptions;
- where relevant, add "arm" in front of the word "sleeve"; and
- add the word "each" at the end of each description.

CMS also proposes to create a new code for custom gauntlet. CMS is also soliciting comments on whether mastectomy sleeves could be grouped with the proposed arm sleeves (**S8422-S8484**) or if it would be more appropriate to have separate mastectomy sleeve codes.

CMS is soliciting comments on whether **S8420-S8428** should be retained for other payers. If codes are retained, Medicare will only accept the new A codes, but the retained S codes may be used by other payers. they will not be valid for Medicare.

CMS also solicits comments on replacing the words 'medium' and 'heavy weight' in the descriptions.

New Proposed HCPCS Codes

In addition, CMS proposes adding the following new codes for upper body areas:

- AXXX—Gradient compression garment, neck/head, each
- AXXX—Gradient compression garment, neck/head, custom, each
- AXXX—Gradient compression garment, torso and shoulder, each
- AXXX—Gradient compression garment, torso/shoulder, custom, each
- AXXX—Gradient compression garment, genital region, each
- AXXX—Gradient compression garment, genital region, custom, each

CMS solicits comments on whether additional codes are needed and if the pressure levels should be differentiated to mirror A6530-A6541 HCPCS code descriptions.

CMS is proposing new nighttime garment codes:

- AXXX—Gradient compression garment, glove, padded, for nighttime use, each
- AXXX—Gradient compression garment, arm, padded, for nighttime use, each
- AXXX—Gradient compression garment, lower leg and foot, padded, for nighttime use, each
- AXXX—Gradient compression garment, full leg and foot, padded, for nighttime use, each

Proposed Changes to Existing HCPCS codes: **A6545**

CMS proposes to use the **A6545** HCPCS code (Gradient compression wrap, non-elastic, below knee, 30-50 mmHg, each) for below knee wraps. CMS is requesting comments on whether coding revision or additional codes are needed for gradient compression wraps with adjustable straps.

New Codes for Compression Bandaging Systems

Currently, there are two compression bandaging codes: **S8430** and **S8431**. CMS is soliciting comments on codes needed to cover the different compression bandaging systems used for lymphedema treatment. CMS is also soliciting comments on codes needed for accessories to be used with gradient compression garments or wraps with adjustable straps.

Benefit Category Determinations and Payment Determinations for New Lymphedema Compression Items

CMS proposes to create a new Part B benefit for lymphedema compression treatment items starting on January 1, 2024. CMS proposes to use the current benefit category and payment determinations for new lymphedema compression treatment items. Under the current process, new code requests are reviewed by a public consultation on preliminary coding, benefit category, and payment determinations.

CMS also proposes to revise the regulations to include lymphedema treatment items in the competitive bidding program.

Payment Basis and Frequency Limitations

CMS proposes to set payment amounts to the average payment amounts for lymphedema compression treatment items at 120% of the average Medicaid payment amounts. Where Medicaid payment amount is not available for an item, CMS proposes to set the payment rate at 100% of the average internet retail price and payment rate from TRICARE. When payment for TRICARE is not available, the Medicare payment will be based on 100% of the average retail price. CMS seeks comments on this proposed payment methodology.

The Medicare payment rate will include fitting and other needed services. Suppliers are liable for fitting services.

Below are the preliminary prices shared in the proposed rule:

TABLE FF-A 2: EXAMPLE PAYMENT AMOUNTS FOR LYMPHEDEMA COMPRESSION TREATMENT ITEMS

Code	Description	Example Payment Amount
A6530	Gradient compression stocking, below knee, 18-30 mmhg, each	$37.95
A6531	Gradient compression stocking, below knee, 30-40 mmhg, each	$54.92
A6532	Gradient compression stocking, below knee, 40-50 mmhg, each	$73.49
A6533	Gradient compression stocking, thigh length, 18-30 mmhg, each	$50.24
A6534	Gradient compression stocking, thigh length, 30-40 mmhg, each	$60.32
A6535	Gradient compression stocking, thigh length, 40-50 mmhg, each	$68.45
A6536	Gradient compression stocking, full length/chap style, 18-30 mmhg, each	$70.12
A6537	Gradient compression stocking, full length/chap style, 30-40 mmhg, each	$83.26
A6538	Gradient compression stocking, full length/chap style, 40-50 mmhg, each	$97.81
A6539	Gradient compression stocking, waist length, 18-30 mmhg, each	$92.01
A6540	Gradient compression stocking, waist length, 30-40 mmhg, each	$110.04
A6541	Gradient compression stocking, waist length, 40-50 mmhg, each	$128.85
A6545	Gradient compression wrap, non-elastic, below knee, 30-50 mmhg, each	$110.95
Axxxx	Gradient compression arm sleeve and glove combination, custom, each	$369.90
Axxxx	Gradient compression arm sleeve and glove combination, each	$94.55
Axxxx	Gradient compression arm sleeve, custom, medium weight, each	$172.29
Axxxx	Gradient compression arm sleeve, custom, heavy weight, each	$177.98
Axxxx	Gradient compression arm sleeve, each	$58.10
Axxxx	Gradient compression glove, custom, medium weight, each	$283.50
Axxxx	Gradient compression glove, custom, heavy weight, each	$349.33
Axxxx	Gradient compression glove, each	$92.24
Axxxx	Gradient compression gauntlet, each	$42.85

Until the payment amounts are published by CMS, the DME MACs will have the authority to determine the appropriate payment amount on a claim-by-claim basis based on established payment for similar items.

CMS also proposes that when reasonable and necessary, Medicare will cover multiple garments or wraps that are used on different parts of the body. CMS explained that when a patient needs three different garments for daytime and needs separate nighttime garments, Medicare would cover two sets of the three garments.

Enrollment and Accreditation Requirements

The CAA 2023 applies lymphedema compression items to follow the medical equipment and supplies requirement. CMS proposes to add lymphedema compression items to fall under the DMEPOS items.

Changes to the Provider and Supplier Enrollment Requirements

CMS has previously formed regulations, requiring providers and suppliers to meet necessary requirements and submit the CMS-855 enrollment form. The CMS-855 form is submitted for the following situations:

- Initial enrollment
- Change of Ownership
- Revalidation
- Reactivation
- Change of Information

In this rule, CMS proposes requirements for a provisional period of enhanced oversight (PPEO) to last between 30 days to 1 year for certain new providers and suppliers. The provision has already implemented similar procedures for new home health agencies through sub-regulatory guidance that went into effect in 2022.

CMS proposes to clarify “new” provider or supplier as:

- A new enrollee as a Medicare provider or supplier
- Certified provider or supplier undertaking a change of ownership
- Provider or supplier doing a 100% change of ownership through a change of information request

CMS also proposes the effective date of the provision to be the first claim submission date. The date of service or effective date of the ownership change does not activate the effective date of the PPEO. Having the effective date of the PPEO to be the first claim submission date ensures providers or suppliers cannot delay billing until the PPEO’s expiration.

CMS notes that while the proposed changes are made through the formal rule-making process, they have the authority to make changes via sub-regulatory guidance.

Under existing regulations, Medicare providers are authorized to voluntarily terminate their agreement and participation in the Medicare program. Medicare providers may request a retroactive termination date only if the provider has not served any Medicare beneficiaries on or after the requested termination date. This safeguard ensures financial protection for beneficiaries and that Medicare can cover the services provided prior to the final stages of the provider’s operations.

Changes to the Refill Policy

CMS proposes to update the refill policy by extending the 14-day timeframe to contact the beneficiary to a 30-day timeframe. The extended timeframe is intended to alleviate possible burdens. In addition, CMS proposes to require suppliers to confirm the need for a refill before delivery. CMS is not requiring specific quantities remaining to be verified, just their need for a refill. To eliminate subjective interpretation, CMS also proposes to remove the term, "pending exhaustion" to "the expected end of the current supply." CMS proposes to codify the requirement for DMEPOS suppliers to deliver no earlier than 10 days before the end of the current supply in the patient's hands. CMS proposes that the delivery date or the date the shipping label is created or the date the shipment is retrieved by the delivering party as the date of service.

CMS proposes the following for refill documentation:

- Evidence of the need for a refill by either the beneficiary or their representative.
- Affirmation of a refill to be retrieved within 30 calendar days from the expected end of the current supply.
- For items acquired in person, a signed delivery slip by the beneficiary or representative or a copy of an itemized sales receipt
- For shipped items, the following is needed:
  - Beneficiary name
  - Date of contact
  - Item
  - Affirmative response from the beneficiary or beneficiary's representative of a refill

CMS is seeking comments on:

- Whether there is a better way to balance the beneficiary burden of responding to supplier outreach while protecting program integrity. (ex/ text message v phone calls)
- Are there diagnoses/conditions that do not require confirmation prior to refill?