



Centers for Medicare & Medicaid Services' (CMS') Healthcare Common Procedure Coding System (HCPCS) Level II Final Coding, Benefit Category and Payment Determinations

First Biannual (B1), 2024 HCPCS Coding Cycle

This document presents a summary of each HCPCS Level II code application and CMS' coding decision for each application processed in CMS' First Biannual 2024 Non-Drug and Non-Biological Items and Services HCPCS Level II code application review cycle. Each summary includes the Medicare Electronic Application Request Information System™ (MEARIS™) identification number; topic; a summary of the applicant's request as written by the applicant with occasional non-substantive editorial changes made by CMS; CMS' preliminary HCPCS Level II coding recommendation; a summary of public feedback from or following the HCPCS Level II public meeting; CMS' final HCPCS Level II coding decision, as well as CMS' preliminary and final benefit category and payment determination, if applicable.

In accordance with the procedures at 42 CFR §414.240 and §414.114, final Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) benefit category and payment determinations are listed below, if applicable. These procedures follow HCPCS Level II determinations and payment determinations for new DME under Medicare Part B following public consultation held through public meetings in accordance with section 531(b) of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub L. 106-554). CMS started using these public meetings and procedures for HCPCS Level II code requests for items and services other than DME in 2005. The procedures for making Medicare benefit category and payment determinations for new DMEPOS items and services using the BIPA 531(b) public meeting process were promulgated through regulations. The final rule (86 FR 73860) is available at <https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues>.

Whether or not an item or service falls under a Medicare benefit category, such as the Medicare Part B benefit category for DME, is a necessary step in determining whether an item may be covered under the Medicare program and, if applicable, what statutory and regulatory payment rules apply to the items and services. If the item is excluded from coverage by the Social Security Act or does not fall within the scope of a defined benefit category, the item cannot be covered under Medicare Part B. When the item is not excluded from coverage by statute and is found to fall within a benefit category, CMS needs to determine what payment rules apply to the item if other statutory criteria for coverage of the item are met. DMEPOS payment categories with corresponding HCPCS pricing indicator codes are included in the Appendix.

All new coding actions will be effective October 1, 2024, unless otherwise indicated.

The HCPCS Level II coding decisions below will also be included in the October 2024 HCPCS Quarterly Update, pending publication by CMS in the coming weeks at: <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>. For inquiries regarding coverage, please contact the insurer(s) in whose jurisdiction(s) claim(s) would be filed. Specifically, contact the Medicaid agency in the state in which a Medicaid claim is filed, the individual private insurance entity, the Department of Veterans Affairs, or, for local Medicare coverage determinations, contact the Medicare contractor in the jurisdiction the claim would be filed. For detailed information describing CMS' national coverage determination process, refer to information published at <https://www.cms.gov/Medicare/Coverage/DeterminationProcess> and <https://www.cms.gov/Center/Special-Topic/Medicare-Coverage-Center>.

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Volara™ System - HCP231218VF0N3

Topic/Issue

Request to establish a new HCPCS Level II code to identify the Volara™ System.

Applicant's suggested language: XXXXX, “Multi-function oscillation and lung expansion airway clearance device, performs functions of continuous positive expiratory pressure, continuous high frequency oscillation, and nebulization, and supports delivery of supplemental oxygen”

Summary of Applicant's Submission

Baxter submitted a request to establish a new HCPCS Level II code to identify the Volara™ System. The Volara™ System received the Food and Drug Administration’s (FDA’s) 510(k) clearance for home use on January 20, 2020. The Volara™ System is a multi-function airway clearance device that provides oscillation and lung expansion (OLE) therapy, delivering three therapies, continuous positive expiratory pressure (CPEP), continuous high frequency oscillation (CHFO) and nebulization, in one integrated product. The CPEP function treats and helps prevent pulmonary atelectasis by delivering continuous positive pressure to help expand and hold the airways open. When delivering CPEP therapy, the device provides continuous positive pressure to the patient’s airway opening regions of the lung that are otherwise closed off during tidal volume breathing. In addition, CPEP helps mobilize peripheral lung secretions into the larger airways and contributes to resolving atelectasis by preventing airway collapse during expiration. The CHFO function delivers continuous pulses of positive pressure. These pulsations shear or break down the mucus, loosen the mucus from the walls of the peripheral airways, and use the airflow to mobilize the mucus toward the central airways. CHFO is a form of chest physiotherapy that provides oscillating airflow to the airways by mouthpiece or mask. Nebulizer function allows for delivery of medication and/or delivery of saline to provide humidification and facilitate airway clearance. The aerosol and nebulizer function can be delivered concurrently with CPEP and CHFO for treatment efficiency or deliver nebulized medication as a stand-alone function. The supplemental oxygen capability supports delivery of oxygen during OLE therapy for patients who dependent on the oxygen. The Volara™ System utilizes a platform from which both CPEP and CHFO can be administered during alternating periods in a single treatment session. The treatments are provided in cycles with alternating intervals of 2.5 minutes of CPEP to open the airways and 2.5 minutes of CHFO to create airflow within the lungs to move retained secretions. Caregivers have the option of adjusting the duration of each interval based on physician’s order.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code XXXXX, “Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device” to describe the Volara™ System.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

DME is defined in Medicare regulations at title 42 Code of Federal Regulations (CFR) 414.202 as equipment furnished by a supplier or a home health agency that meets all of the following conditions:

1. Can withstand repeated use.
2. Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
3. Is primarily and customarily used to serve a medical purpose.
4. Generally is not useful to an individual in the absence of an illness or injury.
5. Is appropriate for use in the home.

All five of these conditions must be met in order for equipment to be classified as DME.

The Volara™ device meets the requirements to be classified as DME.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. As a result, the preliminary pricing methodology for new HCPCS Level II code EXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code E0483 (“High frequency chest wall oscillation system, with full anterior and/or posterior thoracic region receiving simultaneous external oscillation, includes all accessories and supplies, each”) for the continuous high frequency oscillation function, with additional amounts based on HCPCS Level II code E0482 (“Cough stimulating device, alternating positive and negative airway pressure”) and HCPCS Level II code E0570 (“Nebulizer, with compressor”) to account for the continuous positive expiratory pressure and nebulizer functions of the device.

CMS has compared the three HCPCS Level II codes to Volara™ as shown in the below comparability table. Volara™ provides three functions in one integrated device: continuous positive expiratory pressure, continuous high frequency oscillation, and nebulization. HCPCS Level II codes E0482, E0483, and E0570 describing the three separate functions of the integrated device are found to be comparable to the Volara™ with respect to physical, mechanical, and electrical components, and function and intended use.

| | Volara™ | E0482 | E0483 | E0570 |
|----------------------------|--|--|---|---|
| Physical Components | Control Unit Three Therapy ports (Continuous Positive Expiratory Pressure (CPEP), | Control Unit One therapy port: Continuous Positive Expiratory Pressure (CPEP) | Control Unit One therapy port: High Frequency Chest Wall | Control Unit One therapy port: Nebulizer |

| | Volara™ | E0482 | E0483 | E0570 |
|--|--|---|---|--|
| | Continuous High Frequency Oscillation (CHFO), and Nebulizer Air Filter, Breathing Tube, Nebulizer kit, Mouthpiece, Face Mask | Air Filter, Breathing Tube | Oscillation (HFCWO) Valves, Pistons, Pads | Air Filter, Tubing + Mouthpiece, Nebulizer Chamber |
| Mechanical Components | Utilizes Automatic Program | Utilizes Automatic and Manual Program | Utilizes Manual Program | Utilizes Automatic Program |
| Electrical Components | Replaceable Battery | AC Adapter | Rechargeable Battery | AC Adapter |
| Function and Intended Use | Triple therapy in one: secretion clearance, lung expansion, and nebulizer treatment. It benefits cystic fibrosis, neuromuscular, and bronchiectasis patients. | Lung expansion Treatment It benefits patients with muscle weakness in neurological conditions such as muscular dystrophies and spinal cord lesions | Secretion Clearance therapy It benefits patients having difficulty with secretion clearance, or the presence of atelectasis caused by mucus plugging | Breaking the liquid medication into breathable mist or aerosol It benefits patients where inhaled medicines are indicated such as asthma and Chronic Obstructive Pulmonary Disease (COPD) |
| Additional Aspects and Features | Single Patient Use 10 min therapy Maximum of 90 treatment sessions Features a WiFi module to export | Multiple Patient Use Ranging from 6 to 1200 breaths per minute. | Multiple Patient Use Connected through Mobile App as an option | Multiple Patient Use Can be Ultrasonic or Electronic |

| | | | | |
|--|-------------------------|--------------|--------------|--------------|
| | Volara™ | E0482 | E0483 | E0570 |
| | system and therapy data | | | |

As described above, the preliminary payment determination is to use the pricing for HCPCS Level II code E0483 to account for the continuous high frequency oscillation function and additional amounts to recognize the device's continuous positive expiratory pressure and nebulizer functions using HCPCS Level II codes E0482 and E0570 respectively. We believe the additional cost of the continuous positive expiratory pressure function can be accounted for by dividing the rental fee of HCPCS Level II code E0482 ("Cough stimulating device, alternating positive and negative airway pressure") by two to recognize only the positive pressure since HCPCS Level II code E0482 devices provide both positive and negative pressure. Secondly, we would compute the purchase price of HCPCS Level II code E0482 by multiplying the rental amount by 10 and then dividing that amount by 60 in order to get the cost of the continuous positive expiratory pressure feature added to the device over the course of the five-year reasonable useful lifetime. Similarly, we believe the additional cost of the nebulizer function can be accounted for by calculating the purchase price of HCPCS Level II code E0570 ("Nebulizer, with compressor") by multiplying the rental amount by 10 and then dividing that amount by 60 to obtain the cost of the added function over the device's five-year reasonable useful lifetime.

Therefore, the preliminary payment determination for HCPCS Level II code EXXXX using comparable items is calculated using the following formula: $EXXXX = E0483 + ((E0482/2) * 10/60) + (E0570 * 10/60)$. The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code EXXXX would be approximately \$1,505.16 for months 1 through 3 and approximately \$1,128.90 for months 4 through 13.

Pricing Indicator = 36

Summary of Public Feedback

Baxter agreed with CMS' published preliminary HCPCS Level II coding, Medicare benefit category, and Medicare payment recommendations.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code E0469, "Lung expansion airway clearance, continuous high frequency oscillation, and nebulization device" to describe the Volara™ System.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We are finalizing our preliminary payment determination to establish the Medicare payment amount using fee schedule amounts for comparable items in accordance with regulations at 42 CFR 414.238. The fee schedule amount will be established as discussed in the preliminary determination. The final payment determination for HCPCS Level II code E0469 is calculated using the following formula: $E0469 = E0483 + ((E0482/2) * 10/60) + (E0570 * 10/60)$.

The 2024 average non-rural capped rental fee schedule amount for HCPCS Level II code E0469 will be approximately \$1,505.16 for months 1 through 3 and approximately \$1,128.90 for months 4 through 13.

Pricing Indicator = 36

Volara™ System Supply Kit - HCP231218VBVAD

Topic/Issue

Request to establish a new HCPCS Level II code to identify disposable supply kit for the Volara™ System.

Applicant's suggested language: XXXXX, “Disposable supply kit for multi-function oscillation and lung expansion airway clearance device, includes but not limited to handset, nebulizer kit, biofilter, adapters, and hose”

Summary of Applicant's Submission

Baxter submitted a request to establish a new HCPCS Level II code to identify disposable supply kit used with the Volara™ System. Volara™ System received the Food and Drug Administration’s (FDA’s) 510(k) clearance for home use on January 20, 2020. The supply kit is an integral part of the system, required for the patient to receive the therapy. The components in the supply kit connect to the Volara™ System to deliver the oscillation and lung expansion therapy. It has the following components: biofilter, nebulizer kit, handset, hose, and adapters. Biofilter is used as a barrier between patient and device to reduce chance for bioburden contamination. This filter is used for 90 therapy sessions and automatically alerts the patient when a new filter and supply kit are required. Nebulizer kit including nebulizer cup and tubing, transfers pressurized air from device nebulizer port to the nebulizer cup for the nebulization process to occur. Handset serves as the central connection point for the supply kit components and is the ergonomic means for the patient or caregiver to administer therapy. Hose is conduit for therapy air from device therapy port to the patient handset. Adapters allow for different configurations or setups of the supply kit based on the individual patient’s clinical needs. The Volara™ System supply kit is configurable via various adapters to adjust to the patient’s clinical needs.

CMS Preliminary HCPCS Coding Recommendation

Establish a new HCPCS Level II code XXXXX, “Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)” to describe the disposable supply kit for the Volara™ System.

Preliminary Medicare Benefit Category Determination

Durable Medical Equipment.

The Volara™ supply kit serves as a DME accessory to the durable Volara™ device. The single patient use supply kit is intended for 30 days of treatment or a maximum of 90 treatment session. Section 110.3 of the Medical Benefit Policy Manual (CMS Pub. 100-03) indicates that payment may be made for supplies and accessories that are necessary for the effective use of durable medical equipment. Because the Volara™ supply kit is an accessory to an item of DME, the supply kit falls under the DME benefit category.

Preliminary Medicare Payment Determination

In accordance with Medicare regulations at 42 CFR § 414.238, fee schedule amounts for new HCPCS Level II codes for items and services without a fee schedule pricing history are established using existing fee schedule amounts for comparable items when items with existing fee schedule amounts are determined to be comparable to the new items and services based on a comparison of: physical components, mechanical components, electrical components, function and intended use, and additional attributes and features. As a result, the preliminary pricing methodology for new HCPCS Level II code AXXXX is to use the existing fee schedule amounts for comparable items described by HCPCS Level II code A7030 ("Full face mask used with positive airway pressure device, each"), HCPCS Level II code A7003 ("Administration set, with small volume nonfiltered pneumatic nebulizer, disposable"), HCPCS Level II code A7004 ("Small volume nonfiltered pneumatic nebulizer, disposable"), HCPCS Level II code A7037 ("Tubing used with positive airway pressure device") and HCPCS Level II code A7039 ("Filter, non disposable, used with positive airway pressure device") to describe the components of the Volara™ supply kit.

CMS has compared the five HCPCS Level II codes to the components of the Volara™ supply kit as shown in the below comparability tables. HCPCS Level II code A7030 describes the Volara™ mask and HCPCS Level II codes A7003 and A7004 recognize the Volara™ handset, mouthpiece, nebulizer cup and tubing. The Volara™ breathing tube and tracheostomy adaptor is described by comparable HCPCS Level II code A7037 and the Volara™ biofilter by HCPCS Level II code A7039. We believe HCPCS Level II codes A7030, A7003, A7004, A7037 and A7039 describe the components of the Volara™ supply kit and are comparable with respect to the physical and mechanical components, function and in the additional aspects and features.

| | Volara™ Face Mask | A7030 |
|--|--|---|
| Physical Components | Mask | Mask |
| Mechanical Components | Contains Silicone | Contains Silicone |
| Electrical Components | NA | NA |
| Function and Intended Use | It covers the mouth and nose of the patient tightly. Use is Optional in the Volara™ system | It covers the mouth and nose of the patient tightly. It is used with CPAP ventilation system |
| Additional Aspects and Features | The narrow end of the mask is over the patient's nose 15mm Outer Diameter (OD) (infant) or 22mm of Internal Diameter (ID) (Adult) Comes in regular or inflatable Single Patient Use | The narrow end of the mask is over the patient's nose 15mm Outer Diameter (OD) (infant) or 22mm of Internal Diameter (ID) (Adult) Comes in small, medium, and large Reusable or Single Patient use |

| | Volara™ Nebulizer Kit | A7003 | A7004 |
|--|---|---|---|
| Physical Components | Nebulizer Cup Nebulizer Tube | Nebulizer Cup Nebulizer Tube | Nebulizer Cup |
| Mechanical Components | Capacity: 2-10 ml | Capacity: 0.2 ml | Capacity: 0.2 ml |
| Electrical Components | NA | NA | NA |
| Function and Intended Use | It is designed to aerosolize medication approved for nebulization and prescribed by a physician. A fill volume of 2.5 ml of medication is expected to last 10 minutes of nebulization. | It is intended for use in the treatment of upper and lower respiratory tract illnesses where aerosolized medication is required. A fill volume of 0.2 ml of medication is expected to last 1 minute of nebulization. | It is intended for use in the treatment of upper and lower respiratory tract illnesses where aerosolized medication is required. A fill volume of 10 ml of medication is expected to last 6-8 minutes of nebulization. |
| Additional Aspects and Features | Single Use Includes connection for in-line nebulization filter | Single Use (disposable) | Single Use (disposable) |

| | Volara™ Tubing | A7037 |
|--|---|---|
| Physical Components | Endotracheal tube or tracheostomy tube. | Endotracheal tube or tracheostomy tube. |
| Mechanical Components | 22 mm x 20 mm adapter | 22mm male fitting connectors |
| Electrical Components | NA | NA |
| Function and Intended Use | Used in Volara™ System | Used in CPAP system |
| Additional Aspects and Features | | |

| | Volara™ Bio-Filter | A7039 |
|------------------------------|---------------------------------|--|
| Physical Components | Connector, Filter, Port | Connector, Filter, Port |
| Mechanical Components | Poly Propylene Housing Material | Poly Propylene Housing Material Contains Foam |
| Electrical Components | NA | NA |

| | Volara™ Bio-Filter | A7039 |
|--|--|--|
| Function and Intended Use | Used in Volara™ System Attached to the breathing hose | Used in CPAP or BIPAP system Attached to the breathing hose |
| Additional Aspects and Features | The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1% | The biofilter has a filtration efficiency of greater than 99% or penetration of less than 1% |

As described above, the preliminary payment determination is to use the pricing for HCPCS Level II codes A7030, A7003, A7004, A7037 and A7039 to describe the various components of the Volara™ supply kit. We believe that these codes represent the characteristics of the Volara™ supply kit and when the comparable code fees are summed, can be used to establish the fee schedule amounts for new supply HCPCS Level II code AXXXX. Payment for the supply kit would be established by summing the individual fee schedules for the following HCPCS Level II codes: A7030, A7003, A7004, A7037 and A7039.

Therefore, the preliminary payment determination for HCPCS Level II code AXXXX using comparable items is calculated using the following formula: $AXXXX = A7030 + A7003 + A7004 + A7037 + A7039$. The average 2024 non-rural fee schedule amount for code AXXXX would be approximately \$137.34.

Pricing Indicator = 34

Summary of Public Feedback

Baxter agreed with CMS' published preliminary HCPCS Level II coding, Medicare benefit category, and Medicare payment recommendations.

CMS Final HCPCS Coding Decision

We appreciate the comments provided in response to CMS' published preliminary recommendations. Based on the information provided in the application and after consideration of the comments we received, CMS is finalizing its preliminary recommendation to:

Establish a new HCPCS Level II code A7021, "Supplies and accessories for lung expansion airway clearance, continuous high frequency oscillation, and nebulization device (e.g., handset, nebulizer kit, biofilter)" to describe the disposable supply kit for the Volara™ System.

Final Medicare Benefit Category Determination

Durable Medical Equipment.

Final Medicare Payment Determination

We are finalizing our preliminary payment determination with the fee schedule amounts established as discussed in the preliminary determination. Existing HCPCS level II codes

A7030, A7003, A7004, A7037 and A7039 describe the various components of the Volara™ supply kit and when the fees are summed, are used to establish the fee schedule amounts for new supply HCPCS Level II code A7021. The final payment determination for HCPCS Level II code A7021 is calculated using the following formula: $A7021 = A7030 + A7003 + A7004 + A7037 + A7039$. The average 2024 non-rural purchase fee schedule amount for new code A7021 will be approximately \$137.34.

The preliminary determination incorrectly classified this accessory to an item of DME as a supply under pricing indicator 34. In the final determination we are revising the payment class to inexpensive and other routinely purchased items for this accessory, reflected by a pricing indicator of 32. Payment will be made on a purchase basis in accordance with section 1834(a)(2)(A) of the Social Security Act.

Pricing Indicator = 32