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| CMS Manual System | Department of Health & Human Services (DHHS) |
| Pub 100-20 One-Time Notification | Centers for Medicare & Medicaid Services (CMS) |
| Transmittal 2206 | Date: November 21, 2018 |
| | Change Request 10854 |

Transmittal 2121, dated August 10, 2018, is being rescinded and replaced by Transmittal 2206, dated, November 21, 2018, to revise the background section, policy section, revise business requirements 10854.2,10854.2.2,10854.3,10854.3.1, and 10854.4.1, and to add one new business requirement (10854.3.2). This Transmittal is no longer sensitive. All other information remains the same.

SUBJECT: Implementation of a Bundled Payment for Multi-Component Durable Medical Equipment (DME)

I. SUMMARY OF CHANGES: This Change Request (CR) implements new multi-function ventilator HCPCS code E0467 with a single payment amount that would include payment for Multi-Component DME.

EFFECTIVE DATE: January 1, 2019

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: January 7, 2019

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

| R/N/D | CHAPTER / SECTION / SUBSECTION / TITLE |
|--------------|---|
| N/A | N/A |

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

One Time Notification

Attachment - One-Time Notification

| | | | |
|-------------|-------------------|-------------------------|-----------------------|
| Pub. 100-20 | Transmittal: 2206 | Date: November 21, 2018 | Change Request: 10854 |
|-------------|-------------------|-------------------------|-----------------------|

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SUBJECT: Implementation of a Bundled Payment for Multi-Component Durable Medical Equipment (DME)

EFFECTIVE DATE: January 1, 2019

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IMPLEMENTATION DATE: January 7, 2019

I. GENERAL INFORMATION

A. Background: Under Medicare, ventilators fall under the frequent and substantial servicing DME payment category described in section 1834(a)(3) of the Act. Payment for items falling under the frequent and substantial servicing payment category is made on a monthly rental basis until medical necessity ends, and includes payment for all related accessories necessary for the effective use of the equipment. Recently, a new type of ventilator was cleared by the Food & Drug Administration (FDA) that integrates multiple therapies into a single device for ventilator-dependent patients. This new multi-function ventilator can also function as an oxygen concentrator, cough stimulator, aspirator and nebulizer. The multi-function ventilator replaces the multiple stand-alone devices (e.g., a separate ventilator, oxygen concentrator, etc.) that beneficiaries may need over time. A special payment rule was added to the regulations at 42 CFR §414.222 for 2019 to address payment for this new type of multi-function ventilator.

This Change Request (CR) instructs contractors to deny claims that are submitted on the same claim or that overlap any dates of service for the new multi-function ventilator for same or similar items (e.g., oxygen and oxygen equipment, nebulizers and related accessories, aspirators and related accessories, or cough stimulators and related accessories) if furnished on or after the date that the multi-function ventilator is furnished. This CR also instructs contractors to deny claims for the new multi-function ventilator when the beneficiary owns any of the same or similar equipment, or has reached the 36-month cap for oxygen equipment, for equipment that has not reached the end of its reasonable useful lifetime.

B. Policy: To implement this special payment rule, a new Healthcare Common Procedure Coding System (HCPCS) code will be established describing the multi-function ventilator along with a single fee schedule amount under the frequent and substantial servicing payment category. The new multi-function ventilator policy and HCPCS code applies to beneficiaries who are prescribed and meet the medical necessity coverage criteria for a ventilator and at least one of the four additional functions (i.e., oxygen concentrator, cough stimulator, suction pump and nebulizer). When a claim is received for the rental of a multi-function ventilator under the new HCPCS code, claims for the rental of separate stand-alone devices and related accessories would be denied, if the claim for the separate stand-alone devices overlaps a rental month for the paid multi-function ventilator and the date of service is on or after that of the multi-function ventilator. The new multi-function ventilator will be denied if it is billed during a rental month of a paid separate stand-alone rental device and the date of service is on or after that of the separate stand-alone rental device. Only one item may be paid during a rental month and payment will be made for the earliest dated item billed. The separate stand-alone rental devices and accessories that are integrated into the multi-function ventilator or which represent similar equipment used for the same purpose that should be denied if billed in conjunction with the new multi-function ventilator code are:

- Oxygen and oxygen equipment (HCPCS codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E1390, E1391, E1392, E1405, E1406 and K0738)
- Nebulizers and related accessories (HCPCS codes E0565, E0570, E0572, E0585, A4619, A7003, A7004, A7005, A7006, A7007, A7012, A7013, A7014, A7015, A7017, A7525, and E1372)
- Aspirator and related accessories (HCPCS codes E0600, A4216, A4217, A4605, A4624, A4628, A7000, A7001, A7002, and A7047)
- Cough Stimulator, High Frequency Chest Wall Oscillation, Oscillatory Positive Expiratory Pressure and related accessories (HCPCS codes E0482,A7020, E0483, A7025, A7026 and E0484)
- CPAP/RAD and related accessories (HCPCS codes E0601, E0470, E0471, E0472, A4604, A7027, A7028, A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, E0561, and E0562)
- Oral appliance (HCPCS code E0486)
- Ventilators (HCPCS codes E0465 and E0466)

In addition, any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement parts) of beneficiary-owned equipment identified by HCPCS codes E0482, E0565, E0570, E0572, E0585, or E0600 should be denied if the dates of service for the repair service overlaps any dates of service for the multi-function ventilator.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

| Number | Requirement | Responsibility | | | | | | | | | |
|-----------|---|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|------|
| | | A/B MAC | | | D M E M A C | Shared- System Maintainers | | | | Other | |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | | |
| 10854.1 | Contractors shall accept the new HCPCS code E0467 multi-function ventilator NOTE: The short descriptor will be provided in the January 2019 HCPCS Update. The Common Working File (CWF) may use short descriptor –Multi-function ventilator. | | | X | X | X | | X | X | | IOCE |
| 10854.1.1 | Contractors shall add categories 02 and 60 to the new HCPCS code E0467 -Multi-function ventilator. | | | | X | | | | | X | |
| 10854.1.2 | Contractors shall use Type of Service (TOS) Code R for HCPCS code E0467. | | | | X | | | X | X | | |

| Number | Requirement | Responsibility | | | | | | | | | |
|-----------|---|----------------|---|-------------|-------------|---------------------------|------------------|-------------|-------------|-------|-------------|
| | | A/B MAC | | | D M E | Shared-System Maintainers | | | | Other | |
| | | A | B | H H H | | M A C | F I S S | M C S | V M S | | C W F |
| 10854.2 | <p>Effective for dates of service on and after January 1, 2019, when multi-function ventilator HCPCS E0467 is billed on the same claim and the line item date of service is within the same rental month with any of the individual DME items listed below, contractors shall pay the multi-function ventilator HCPCS E0467 and deny the line item with the any of the following HCPCS codes</p> <ul style="list-style-type: none"> E0465, E0466, A4216, A4217, A4605, A4624, A4628, A4619, A7000, A7001, A7002, A7003, A7004, A7005, A7006, A7007, A7012, A7013, A7014, A7015, A7017, A7020, A7025, A7026A7047, A7525, E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E0482, E0483, E0484 E0565, E0570, E0572, E0585, E0600, E1372, E1390, E1391, E1392,K0738,E0470, E0471, E0472, E0601, A4604, A7027, A7028,A7029, A7030, A7031, A7032, A7033, A7034, A7035, A7036, A7037, A7038, A7039, A7044, A7045, A7046, E0561,E0562, E1405,E1406 and E0486 <p>For example, a paid claim for HCPCS code E0467 with a date of service of June 8 includes payment for rental of the ventilator through July 7, since July 8 would be the anniversary date or the date that the next rental month would begin. If the date of service for any claim lines for any of the individual DME items listed above falls within that paid rental month for code E0467 of June 8 through July 7, then the claims line(s) should be denied.</p> | | | X | X | X | | X | | | |
| 10854.2.1 | Contractors shall review and ensure that the earliest line item date in the rental month is payable and the DME item overlapping the rental month is denied. | | | | X | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | | |
|-----------|--|----------------|---|-------------|----------------------------|----------------------------------|-------------|-------------|-------------|-------|--|
| | | A/B MAC | | | D M E M A C | Shared- System Maintainers | | | | Other | |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | | |
| 10854.3 | CWF shall reject the incoming claim line when HCPCS E0467 is billed and any of the individual DME items in requirement 2 is found in the paid claim history in the same rental month or the incoming claim line has any of the HCPCS in requirement 2 and HCPCS E0467 is found in the paid claim history in the same rental month.” Note: See example in BR 10854.2 | | | | | | | | | X | |
| 10854.3.1 | Contractors shall suspend the claim for review when the line item is rejected by CWF. | | | | | X | | X | | | |
| 10854.3.2 | Contractors shall review suspended claims and ensure that the earliest line item date in the rental month is payable and the DME item overlapping the rental month is denied | | | X | X | | | | | | |
| 10854.4 | CWF reject edits associated with this Change Request shall be overridable. | | | | | | | | | X | |
| 10854.4.1 | Contractors shall override the CWF reject edits only when instructed to do so by CMS or determined necessary through claim review to ensure the earliest dated line item DME in a rental month is payable and any subsequent overlapping DME item in the rental month is denied. | | | X | X | | | | | | |
| 10854.5 | When the multi-function ventilator HCPCS E0467 is billed and a claim for any of the HCPCS codes below is found in paid claim history and for any rental claim past the rental period, contractors shall deny the incoming claim with multi-function ventilator HCPCS E0467 if the 5-year reasonable useful lifetime for the equipment below has not expired. E0424, E0431, E0433, E0434, E0439, E0470, E0471, E0472, E0482, E0483,E0484 E0565, E0570, E0572, E0585, E0600, E0601, E1390, E1391, E1392, or K0738 | | | | X | | | | | | |

| Number | Requirement | Responsibility | | | | | | | | |
|---------|--|----------------|---|-------------|----------------------------|---------------------------|-------------|-------------|-------------|-------|
| | | A/B MAC | | | D M E M A C | Shared-System Maintainers | | | | Other |
| | | A | B | H H H | | F I S S | M C S | V M S | C W F | |
| 10854.6 | When any of the individual DME items listed above in Business Requirement 5 are billed and the multi-function ventilator HCPCS E0467 is found in history in the preceding five years, contractors shall deny the incoming claim with the individual DME item. | | | | X | | | | | |
| 10854.7 | Contractors shall deny claim line for labor (code K0739) and/or replacement parts (HCPCS with RB modifier) associated with the repair of HCPCS codes E0482, E0565, E0570, E0572, E0585, or E0600 if the dates of service overlap any dates of service for a paid rental month for the multi-function ventilator E0467. | | | X | X | | | | | |
| 10854.8 | <p>Contractors shall use the following messages when denying claims submitted with same or similar HCPCS as the HCPCS E0467 multi-function ventilator</p> <p>Claim Adjustment Reason Code (CARC) 151: Payment adjusted because the payer deems the information submitted does not support this many/frequency of services.</p> <p>Remittance Advice Remark Code (RARC) M3: Equipment is the same or similar to equipment already being used.</p> <p>Medicare Summary Notice (MSN) 8.04: Payment can't be made for equipment that's the same or similar to equipment already being used.</p> <p>Claim Adjustment Group Code - CO (Contractual Obligation)</p> | | | X | X | | | | | |

III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility | | | | |
|---------|---|----------------|---|-------------|-----------------------|-----------------------|
| | | A/B MAC | | | D M E D I | C M E D I |
| | | A | B | H H H | | |
| 10854.9 | MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter. | | | X | X | |

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

"Should" denotes a recommendation.

| X-Ref Requirement Number | Recommendations or other supporting information: |
|--------------------------|--|
| 10854.2 | Please see 100-4, Chapter 20, section 210 for additional information pertaining to the anniversary date. |

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Teira Canty, teira.canty@cms.hhs.gov (Billing Requirements) , Karen Jacobs, karen.jacobs@cms.hhs.gov (Policy Contact)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0