DMEPOS Center – Older Spotlight Messages

Corrections Being Made to the 2022 DMEPOS Fee Schedule Amounts for Certain Items Furnished in Non-contiguous Areas (Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands)

CMS identified errors in the fee schedule amounts for certain items furnished in non-contiguous areas and has released revised public use fee schedule files. A list of 179 HCPCS code and modifier combinations affected by the revisions is included as a separate public use file under the link below. The revised 2022 public use files are now available: View the Revised DMEPOS Fee Schedule Files.

Most of the corrections to the fee schedule amounts were minor resulting in an estimated aggregate underpayment of about $3,200 dollars in 2022 with percentage fee adjustments ranging from 0.5% to 5.1% for the certain items.

Less than 3,000 claims are affected by these errors and will be automatically reprocessed by the DME MACs.

Information Regarding Implementation of Recent Rulemaking Addressing Classification of Adjunctive Continuous Glucose Monitors as Durable Medical Equipment (Revised)

The Centers for Medicare & Medicaid Services (CMS) recently issued a final rule that takes effect on February 28, 2022 and classifies non-implantable continuous glucose monitors (CGMs) as durable medical equipment (DME) regardless of whether the CGM has been approved or cleared by the Food and Drug Administration (FDA) to replace a blood glucose monitor for use in making diabetes treatment decisions. CGMs that do not replace a blood glucose monitor are referred to as adjunctive CGMs because they can be used as an adjunct to the blood glucose monitor by showing trends in glucose levels and alerting the patient about potentially dangerous levels, even while they sleep, that then must be verified by use of a separate blood glucose monitor. The final rule can be downloaded at: https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues

Non-adjunctive CGM receivers, which are DME that displays and monitors the continuous glucose readings and trends, replace a blood glucose monitor for use in making diabetes treatment decisions. Medicare claims for non-adjunctive CGM

receivers are submitted using code K0554 in the Healthcare Common Procedure Coding System (HCPCS). Medicare claims for the monthly supplies for non-adjunctive CGMs are submitted using HCPCS code K0553.

Effective for claims with dates of service from February 28, 2022 through March 31, 2022, suppliers should use HCPCS code E1399 (Durable medical equipment, miscellaneous) to submit claims for adjunctive CGM receivers and HCPCS code A9999 (Miscellaneous DME supply or accessory, not otherwise specified) to submit claims for the monthly supplies for adjunctive CGMs. Effective for claims with dates of service on or after April 1, 2022, suppliers should use new HCPCS codes E2102 (Adjunctive continuous glucose monitor or receiver) to submit claims for adjunctive CGM receivers and HCPCS code A4238 (Supply allowance for non-implantable adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service) to submit claims for the monthly supplies for adjunctive CGMs.

Beginning with claims with dates of service on or after February 28, 2022, local fee schedule amounts for the adjunctive CGM receiver and monthly supplies shall be gap-filled by the DME Medicare Administrative Contractors (DME MACs) as discussed in the final rule. Final HCPCS coding and national Medicare pricing for adjunctive CGMs will be part of an upcoming HCPCS public meeting, so the agency may consider public feedback. Details on this process will be provided in the near future.

CGM receivers can be rented or furnished on a lump sum purchase basis. HCPCS modifier RR should be used on any claims for rental of a CGM receiver, while HCPCS modifiers NU and UE should be used on any claims for the purchase of a new (NU) or used (UE) CGM receiver. Total payments for the CGM receiver (any combination of rental or purchase claims) cannot exceed the purchase fee schedule amount.

Special Instructions Regarding Insulin Pumps that Can Also be Used as CGM Receivers

The HCPCS code and modifier combination of E0784RR plus K0554RR are currently used by suppliers to bill for the rental of insulin pumps that also function as non-adjunctive CGM receivers. Effective for claims with dates of service February 28, 2022 through March 31, 2022, suppliers should use the HCPCS code and modifier combination of E1399RR plus E0784RR to bill for insulin pumps that also function as adjunctive CGM receivers. Effective for claims with dates of service on or after April 1, 2022, suppliers should use the HCPCS code and modifier combination of

E2102RR plus E0784RR to bill for insulin pumps that also function as adjunctive CGM receivers. Once the 13-month rental cap period for code E0784 is reached, payments for both the rental of the insulin pump and the CGM receiver feature of the pump end. Also, if the beneficiary switches from an insulin pump without a CGM receiver feature to an insulin pump with a CGM feature, this does not result in the beginning of a new 13-month capped rental period for the pump. Payment for the monthly supplies for the CGM may continue for as long as medical necessity and coverage of the CGM continues. *Note: This paragraph was revised 2/22/22 to clarify the billing of E1399RR and E2102RR with E0784RR.*

If the beneficiary already owns a CGM receiver of any kind (adjunctive or non-adjunctive) and the receiver is less than five years old, or, if the beneficiary owns an insulin infusion pump that is less than five years old, then the billing instructions above do not apply. The beneficiary would not be eligible for coverage of a replacement CGM or insulin pump until the five-year reasonable useful lifetime for either or both items of beneficiary-owned equipment has expired. Payment for the monthly supplies for the CGM may continue for as long as medical necessity and coverage of the CGM continues. Further instructions regarding the submission and processing of adjunctive CGM claims for dates of service on or after February 28, 2022 will be provided by the DME MACs.

Special Note regarding Implantable CGMs

CMS has received questions regarding the appropriate use of HCPCS Level II codes for implantable CGMs. The Level II codes that have been issued were intended to describe non-implantable CGMs that fall under the Medicare benefit for durable medical equipment. Implantable CGMs have no durable component, cannot withstand repeated use because they are totally implanted, single patient use devices, and are paid for incident to the implantation procedure. Implantable CGMs therefore do not fall under the Medicare benefit for durable medical equipment and cannot be billed as such. CMS intends to clarify this further in an upcoming HCPCS Level II public meeting with revisions to the appropriate Level II code descriptors. We will seek public feedback during that meeting in regard to whether this change would impact other payers.

Information Regarding the DMEPOS Benefit Category Determination (BCD) Process Recently Established Through Rulemaking

On December 21, 2021, the Centers for Medicare & Medicaid Services (CMS) issued a final rule that establishes procedures for making benefit category determinations and payment determinations for new DMEPOS items and services under Medicare Part B. The final rule can be downloaded from CMS.gov at: https://www.cms.gov/medicare/durable-medical-equipment-prostheticsorthotics-and-supplies-fee-schedule/dmepos-federal-regulations-and-notices.

The process involves posting of preliminary benefit category and payment determinations for new DMEPOS items and services on CMS.gov as part of the agenda for the HCPCS Public Meeting and Consultation Process. This process is being used to address the benefit category status of codes added to the HCPCS from 2020 thru 2022 as well as new items in 2022 and future years. The agenda and timing for the public meetings will be posted at the following site: https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/HCPCSPublicMeetings.

The BCD process is separate and distinct from the HCPCS application, and an interested party can make a request for a BCD independent from any associated HCPCS code request. Accordingly, an interested party may request a BCD for an item or service without requesting a change to the HCPCS. Once the BCD request is received, CMS would follow the process discussed in the above-referenced rulemaking, which includes discussing the BCD at a public meeting. Requests for a DMEPOS BCD that do not involve an associated HCPCS coding request, should be submitted via email to DMEPOS@cms.hhs.gov.

Medicare Payment Rules for Items Described by Codes Recently Added to the Healthcare Common Procedure Coding System (HCPCS)

The following codes are added to the HCPCS effective October 1, 2021:

A4453 - Rectal catheter for use with the manual pump-operated enema system, replacement only

K1021 - Exsufflation belt, includes all supplies and accessories

For each code in HCPCS Level II, a pricing code is used to identify the appropriate methodology for developing payment allowances under Medicare Part B. The pricing code for both of the codes above is 00, indicating that the item or service is not separately priced or separately paid by Medicare under Part B.

In the case of code A4453, this code describes the replacement of an accessory used in conjunction with a manual pump-operated enema system (HCPCS code A4459), which does not fall under an existing Medicare benefit category that would result in separate payment or pricing for the device. As a result, there would be no payment or pricing for replacement of any components or accessories used in conjunction with this device.

Code K1021 describes an item that is used in conjunction with ventilators covered under the Medicare Part B benefit for durable medical equipment. The Medicare monthly rental payment amount for ventilators includes payment for all items and services furnished in conjunction with the ventilator. As a result, Medicare does not make a separate payment for any items used in conjunction with a ventilator.

The following codes are added to the HCPCS effective January 1, 2022:

A4436 - Irrigation supply; sleeve, reusable, per month

A4437 - Irrigation supply; sleeve, disposable, per month

A4436 and A4437 describe subcategories of items currently described by HCPCS code A4397 (Irrigation supply; sleeve, each). HCPCS code A4397 is being discontinued effective December 31, 2021 and replaced by codes A4436 and A4437.

The pricing code for A4397 is 37, indicating that items described by these codes are subject to the Medicare Part B fee schedule payment methodology for ostomy, tracheostomy, or urological supplies at section 1834(h)(1)(E) of the Social Security Act, which mandates payment using fee schedule amounts based on average payments made for the items from July 1986 through June 1987, increased by annual update factors. A4436 and A4437 will continue to follow pricing code 37 for dates of service on or after January 1, 2022.

The fee schedule amounts for HCPCS code A4397 are based on average payments made for irrigation sleeves from July 1986 through June 1987, increased by annual update factors. Continuity of pricing regulations at 42 CFR § 414.236 indicate that when there is a single code that describes two or more distinct complete items and separate codes are subsequently established for each item, the fee schedule

amounts that applied to the single code continue to apply to each of the items described by the new codes. In this instance, the irrigation supply sleeve code A4397 is divided into separate reusable and disposable irrigation sleeve codes. The fee schedule amount for one month of the sleeves is equivalent to the A4397 fee schedule amount multiplied by the monthly utilization limit of four. Therefore, the current monthly fee schedule amounts will continue to apply to codes A4436 and A4437 effective January 1, 2022. Medicare payment is made in advance for the month's supply of irrigation sleeves and the supplier must ensure that the beneficiary has enough sleeves to last for the entire month. If replacement sleeves are needed before the end of the month, the supplier must deliver the additional sleeves to the beneficiary.

Respiratory Equipment Affected by Recent Phillips Respironics Recall

On June 14, 2021 Philips Respironics, a major manufacturer of respiratory equipment issued a recall for several of its models of continuous positive airway pressure (CPAP) devices, respiratory assist devices (RADs), and ventilators covered by Medicare under the durable medical equipment (DME) benefit due to possible health risks. See the Safety Communication issued by the FDA.

Philips Respironics will repair or replace devices affected by this recall; it could take up to a year to complete these remediation tasks.

Supplier Responsibility

You must help Medicare patients who rent or own devices affected by the recall and explain which items and services are covered and paid for related to this recall. You and your staff must understand the requirements if you furnished certain respiratory equipment subject to the recent recall under the Medicare Part B benefit for DME, including:

- Ventilators
- CPAP devices
- RADs

Ventilators:

If you are renting ventilators affected by this recall to patients enrolled under Medicare Part B, work with the patients and their physicians to identify and furnish appropriate alternative devices to use during the remediation period.

CPAP Devices and RADs:

If you rented CPAP devices or RADs affected by this recall to patients enrolled under Medicare Part B for less than 13 months of continuous use, work with the patients and their physicians to identify and furnish appropriate alternative devices for the remainder of the 13-month period of continuous use.

If you transferred title to CPAP devices or RADs affected by this recall to patients enrolled under Medicare Part B after 13-months of continuous use, and:

- **They used it for the 5-year reasonable useful lifetime** of the device, tell the patient they can get a replacement device if they haven't already and if it's still medically necessary.
- **They used it for less than the 5-year reasonable useful lifetime** of the device, help them register the device with Philips Respironics for repair or replacement. Furnish a replacement device as it may take Philips Respironics up to a year to repair or replace the device. Under federal regulations, you must replace the equipment at no charge to the Medicare Program or patient if the equipment doesn't last for the entire 5-year reasonable useful lifetime.

If it's difficult to get replacement CPAP devices or RADs for all of your patients, another supplier can furnish replacement devices while the Medicare patients wait for their devices to be repaired or replaced by the manufacturer if the new supplier does not charge your patients or the Medicare Program for the replacement devices. The supplier furnishing the substitute devices at no additional cost can bill and get paid for accessories used with the replacement devices.

FY 2022 Final Rule

CMS issued an FY 2022 final rule that includes a DMEPOS payment provision. See a summary of key provisions in the rule, effective October 1.

Payment for Certain Manual Wheelchair Accessories on July 1, 2021

CMS is continuing the same payment rates for DMEPOS items and services under the DMEPOS fee schedules as were in effect on April 1, 2021, through the quarter beginning July 1, 2021. This includes wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs (HCPCS codes E1161, E1231, E1232, E1233, E1234 and K0005) and certain manual wheelchairs currently described by HCPCS codes E1235, E1236, E1237, E1238, and K0008, as specified in section 106 of the Further Consolidated Appropriations Act, 2020. CMS will not apply fee schedule adjustments based on information from competitive bidding programs for these wheelchair accessories. Suppliers should continue using the KU modifier on claims for accessories and seat and back cushions furnished in connection with the wheelchair base codes above.

CMS is continuing these payment rates based on several factors. Beneficiaries with disabilities such as amyotrophic lateral sclerosis, cerebral palsy, multiple sclerosis, muscular dystrophy, spinal cord injury, and traumatic brain injury often rely on complex rehabilitative wheelchairs and accessories to maximize their function and independence. It is important to avoid any potential operational difficulties for suppliers, our partners in the Medicaid program, or private payers that have elected to rely on the DMEPOS fee schedule that could result from frequent updates to the Medicare fee schedules. Finally, this action is consistent with prior Medicare program policy actions related to similar accessories for complex power rehabilitative wheelchairs as described in section 2 of the Patient Access and Medicare Protection Act of 2015. CMS is actively reviewing public comments submitted to the agency on related rulemakings, including engaging in future rulemaking, and will update interested stakeholders and suppliers when more information is available.

Corrections Being Made to the 2021 April DMEPOS Fee Schedule Amounts for Certain Items

On March 11, 2021, CMS released the 2021 April Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule amounts. The DMEPOS public use file contains fee schedules for certain items that were adjusted based on information from the DMEPOS Competitive Bidding Program in accordance with Section 1834(a)(1)(F) of the Act. CMS identified errors in the fee schedule amounts for some items and has therefore released a revised April DMEPOS fee schedule file on March 30, 2021. The April fee schedule files are effective for claims with dates of service on or after April 1, 2021. The revised fee schedule amounts will be used to pay claims received on or after April 1, 2021. No re-processing of claims will be required as a result of these corrections.

Corrections to the 2021 DMEPOS Fee Schedule Amounts

On December 11, 2020, CMS released the 2021 Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) fee schedule amounts. The DMEPOS and Parenteral and Enteral Nutrition (PEN) public use files contain fee schedules for certain items that were adjusted based on information from the Medicare DMEPOS Competitive Bidding Program in accordance with Sections 1834(a)(1)(F) and 1842(s)(3)(B) of the Act. CMS identified errors in the fee schedule amounts for some items and has released revised public use fee schedule files. A list of 919 HCPCS code and modifier combinations affected by the revisions is included as a separate public use file under the link below. The revised January 2021 public use files are now available: View the January 2021 Public Use Files

Claims submitted before January 26, 2021, with dates of service on or after January 1, 2021 may have been processed and paid using the incorrect fee schedule amounts. Most of the corrections to the fee schedule amounts were minor, resulting in the application of a missing update factor and increase in the 2021 fee schedule amount of less than 1 percent. However, in approximately 8 percent of the cases, the corrections were significant. CMS identified multiple calculation errors, and correction of those errors has resulted in changes that range from a 2021 fee schedule amount decrease of 30 percent to a 2021 fee schedule amount increase of 57 percent. Most of these significant fee schedule corrections are for

claims that included a KE modifier, with the greatest fee schedule amount increases in the non-contiguous areas of the country.

Suppliers may request that the DME MAC reprocess and adjust incorrectly paid claims for these HCPCS code/modifier combinations by providing their PTAN to the DME MAC. If the supplier makes this request, then all of the supplier's claims affected by the erroneous fee schedule amounts (both overpayments and underpayments) will be reprocessed and adjusted. Please contact the DME MAC(s) for additional information about reprocessing.

Section 3712 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act

Section 3712 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), signed into law on March 27, 2020, revises the fee schedule amounts for certain durable medical equipment and enteral nutrition HCPCS codes whose fees are adjusted using competitive bidding information during the COVID-19 Public Health Emergency (PHE). Section 3712(a) of the CARES Act extends the current adjusted fee schedule methodology that pays for certain items furnished in rural and non-contiguous non-CBAs based on a 50/50 blend of adjusted and unadjusted fee schedule amounts through December 31, 2020 or through the duration of the PHE, whichever is later. Section 3712(b) of the Act requires the calculation of new, higher fee schedule amounts for certain items furnished in non-rural contiguous non-CBAs based on a blend of 75 percent of the adjusted fee schedule amount and 25 percent of the unadjusted fee schedule amount for the duration of the PHE.

On April 30, 2020, CMS published an interim final rule with comment period (CMS-5531-IFC) that includes these changes and clarifies that the effective date for the revised 75/25 fees of section 3712(b) applies to items furnished in non-rural contiguous non-CBAs on or after March 6, 2020 through the duration of the PHE. Because the new 75/25 fee schedule amounts are based in part on unadjusted fee schedule amounts, CMS is also adding KE fee schedule amounts for certain codes for items furnished in non-rural areas to the files implementing the CARES Act. Background information and a list of the applicable KE HCPCS codes was issued in Appendix B (ZIP) of Transmittal 1630, Change Request (CR) 6270, dated November 7, 2008. In cases where accessories included in the 2008 Original Round One Competitive Bidding Program (CBP) are furnished for use with base equipment that was not included in the 2008 CBP or in the Further Consolidated Appropriation Act of 2020 (i.e., K0005, E1161, E1231-E1238), suppliers should

append the KE modifier to the applicable HCPCS code for the accessory to avoid a 9.5% reduction in the unadjusted portion of the blended 75/25 non-rural fees.

The revised fee schedule public use files for payment of claims beginning March 6, 2020 in accordance with section 3712(b) of the CARES Act are now available. The Medicare Claims Processing Contractors will begin applying the new 75/25 blended fee schedule amounts in non-rural areas immediately after the fee schedule file update is complete. CMS is currently working to implement the retroactive payments required by section 3712(b) of CARES for dates of service back to March 6, 2020. We will be providing instructions for reprocessing the applicable claims in the near future. There is no action required by suppliers at this time. Please note that the fee schedule changes made in relation to section 3712(b) of the CARES Act have no impact on the wheelchair accessory KU fee schedule amounts that are calculated based on unadjusted fee schedule amounts.

Update regarding Implementation of Section 106 of the Further Consolidated Appropriations Act, 2020

The Further Consolidated Appropriations Act, 2020 (Pub.L. 116-94) was signed into law on December 20, 2019. Section 106 of the Further Consolidated Appropriations Act, 2020 mandates the non-application of fee schedule adjustments based on information from competitive bidding programs for wheelchair accessories (including seating systems) and seat and back cushions furnished in connection with complex rehabilitative manual wheelchairs (HCPCS codes E1161, E1231, E1232, E1233, E1234 and K0005) and certain manual wheelchairs currently described by HCPCS codes E1235, E1236, E1237, E1238, and K0008 during the period beginning on January 1, 2020 and ending June 30, 2021.

The Centers for Medicare & Medicaid Services (CMS) has released instructions (PDF) that include the list of HCPCS codes for wheelchair accessories impacted by section 106 of the Further Consolidated Appropriations Act, 2020 (Attachment A). CMS is on track to modify its Medicare claims processing system to begin paying claims for the impacted HCPCS codes at the unadjusted rates beginning on July 1, 2020. Until these changes to the Medicare claims processing system are implemented, payment for claims submitted for these items is based on the adjusted fee schedule amounts.

Claims for these accessories submitted prior to July 1, 2020, with dates of service from January 1, 2020 through June 30, 2020, will need to be reprocessed to ensure that CMS pays the unadjusted fee schedule amounts, as required by section 106 of the Further Consolidated Appropriations Act, 2020. To support suppliers with their reprocessing requests, the DME MACs have implemented a streamlined approach to adjust previously processed claims with dates of service from January 1, 2020 through June 30, 2020 for the manual wheelchair accessories referenced in Attachment A. When completing the DME MAC Reopening Request Form on or after July 1, 2020, suppliers should:

1. For "Supplier Information" - Complete all fields
    - **Important** - list all PTANs for which you request these reopenings
2. For "Beneficiary Information" – Complete only as follows:
    - Reason for Adjustment: Check "Other"
    - Comments: State "Please adjust my previously processed claims for the PTAN(s) listed above for the HCPCS covered in CR 11635"

On the DME MAC Reopening Request Form, suppliers do not need to complete the fields associated with the beneficiary (i.e., beneficiary name, Medicare number, address, etc.), Date of Service, HCPCS, or Claim Control Number.

Suppliers must fax the completed DME MAC Reopening Request Form to the appropriate DME MAC fax number located at the bottom of the form. The DME MACs will identify and adjust the claims to ensure appropriate payment at the unadjusted fee schedule amount.

Link to JA and JD Reopening Request Form: https://protect2.fireeye.com/url?k=9c38cccc-c06dc51c-9c38fdf3-0cc47a6a52de-a333b2b0726c3520&u=https://med.noridianmedicare.com/documents/2230703/6501021/Reopening+Request

Link to JB Reopening Request Form: https://protect2.fireeye.com/url?k=81ac222f-ddf92bff-81ac1310-0cc47a6a52de-4bcb538bf030571d&u=https://www.cgsmedicare.com/jb/forms/pdf/jb_reopenings_form.pdf

Link to JC Reopening Request Form: https://protect2.fireeye.com/url?k=e291d2e7-bec4db37-e291e3d8-0cc47a6a52de-32f7383359783c04&u=https://www.cgsmedicare.com/jc/forms/pdf/jc_reopenings_form.pdf

On or after July 1, 2020, suppliers should use the KU modifier when submitting claims for the accessories listed in Attachment A with dates of service from January 1, 2020 through June 30, 2020; payment based on the unadjusted fee schedule amounts will be made for these items. As the KU modifier is currently only associated when billing for wheelchair accessories and seat and back cushions furnished in connection with Group 3 complex rehabilitative power wheelchairs, the Medicare claims processing system is currently programmed to reject the KU modifier when associated with claims for accessories furnished in conjunction with complex rehabilitative manual wheelchairs. However, the changes that CMS is making to the Medicare claims processing system will facilitate the use of the KU modifier with claims for accessories furnished in conjunction with complex rehabilitative manual wheelchairs. As aforementioned, these system changes will be implemented on July 1, 2020. Suppliers should use the KU modifier for claims with dates of service on or after July 1, 2020 through June 30, 2021 for Attachment A codes that are furnished in conjunction with complex rehabilitative manual wheelchairs or certain manual wheelchairs.

Coverage and Payment for New, Innovative Tumor Treatment Field Technology (TTFT)

The Durable Medical Equipment Medicare Administrative Contractors (DME MACs) recently revised the Tumor Treatment Field Therapy (TTFT) Local Coverage Determination (LCD L34823) to extend coverage for the use of TTFT as a treatment option for Medicare beneficiaries with newly diagnosed glioblastoma multiforme (GBM) when certain criteria are met. More information on this important milestone in cancer treatment can be found at the DME MAC websites:

https://med.noridianmedicare.com/web/jddme

https://www.cgsmedicare.com/jc/

Access to the specific policy is available under the "Future Effective" pages of the DME MACs:

Noridian: https://med.noridianmedicare.com/web/jadme/policies/lcd/active

CGS: https://www.cgsmedicare.com/jc/coverage/lcdinfo.html (then click on Future LCD - Future Effective Date)

TTFT is a system consisting of an electromagnetic field generator and transducer arrays and will be covered under the Medicare Part B benefit for durable medical equipment (DME) for items and services furnished on or after September 1, 2019. Payment for the TTFT system will be made using monthly rental fee schedule amounts that include payment for the entire system (electromagnetic field generator, transducer arrays, and all related accessories) as well as all services furnished in providing the TTFT system, including frequent and substantial servicing of the device.

On June 11, 2018, CMS announced a change to the way that fee schedule amounts for DME are established, indicating that prices paid by other payers may be used to establish the Medicare fee schedule amounts for new technology items and services. The innovative aspects of this change in the pricing methodology for DME are intended to ensure that Medicare is expeditious and responsive to providing reimbursement and access to new technology and devices for beneficiaries.

This innovative pricing methodology was used to establish the Medicare monthly rental fee schedule amounts for the TTFT system. Based on the median of 2018 prices paid by other payers, CMS has established a 2019 monthly fee schedule amount of $13,237.

Establishment of Medicare Fees for Newly Covered Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)

For newly covered items of DMEPOS paid on a fee schedule basis where a Medicare fee does not exist, the Centers for Medicare & Medicaid Services (CMS) uses a process to establish fees called gap-filling. This allows Medicare to establish a price that aligns with the statutory requirements for the DMEPOS fee schedule.

Sections 1834(a), (h), and (i) of the Social Security Act mandate that the fee schedule amounts for durable medical equipment (DME), prosthetic devices, prosthetics and orthotics, and surgical dressings, respectively, be calculated based on average reasonable charges paid for the item or device under Medicare from a past period ("the base year"). For example, the exclusive payment rule for DME items requiring frequent and substantial servicing indicates that the fee schedule amounts must be based on the average reasonable charge in the state for the rental of the item or device for the 12-month period ending with June 1987.

Under current gap filling guidelines outlined in Chapter 60.3 of the Medicare Claims Processing Manual, Medicare establishes a new fee schedule amount based on (1) the fee schedule amount for a comparable item in the DMEPOS fee schedule, or (2) supplier price lists or retail price lists, such as mail order catalogs, with prices in effect during the base year. In establishing fees for newly covered DMEPOS, Medicare first looks to identify a comparable DMEPOS item for which a fee schedule amount already exists, as existing fee schedule amounts are based on average reasonable charges for items paid during the base year. CMS determines whether a comparable item exists based on the purpose and features of the device, nature of the technology, and other factors, and then applies that fee to the new item.

Supplier price lists include catalogues and other retail price lists (such as internet retail prices) that provide information on commercial pricing for the item. Going forward, potential appropriate sources for such commercial pricing information can also include verifiable information from supplier invoices and non-Medicare payer data (e.g., fee schedule amounts comprised of the median of the commercial pricing information adjusted as described below).

If the only available commercial pricing is from a period other than the base year, CMS first deflates pricing data to the mid-point of the base year (e.g., December 1986) using the percentage change in the Consumer Price Index for All Urban Consumers from the mid-point of the pricing year to the mid-point of the base year. CMS then inflates that amount to the payment year using the update factors required by law. This allows Medicare to establish a fee for the newly covered item consistent with the law.

CMS expects to update the Medicare Claims Processing Manual to reflect the gap-filling method described above.

Replacement of Accessories used with a Beneficiary-Owned Continuous Positive Airway Pressure (CPAP) Device or a Respiratory Assist Device (RAD) Purchased by Medicare

This message applies to the replacement of essential accessories used with a beneficiary-owned CPAP device or RAD purchased by Medicare following 13 months of continuous use. For the purpose of processing claims for replacement of essential accessories for this equipment, the medical necessity for the beneficiary-owned base CPAP device or RAD is assumed to have been established. This does not mean that the Centers for Medicare & Medicaid Services (CMS) or its contractors cannot determine that the payments for the equipment were inappropriate based on additional information or investigations related to auditing previously processed Medicare claims. This assumption is merely made so that initial claims for essential accessories used with a beneficiary-owned CPAP device or RAD purchased by Medicare following 13 months of continuous use can be processed timely to ensure beneficiary access to these items.

In accordance with this assumption, all of the documentation needed to establish medical necessity for the equipment (e.g., sleep tests) are not needed for the purpose of establishing medical need for replacement accessories alone. As long as no other information is uncovered or reviewed that would result in a determination that the equipment furnished and paid for by Medicare was not medically necessary, then all that is necessary for the purpose of processing claims for replacement of essential accessories used with a beneficiary-owned CPAP device or RAD purchased by Medicare following 13 months of continuous use is a determination that the medical need for the equipment continues, and that the claims for the accessories themselves are reasonable and necessary. In that regard, CMS will ensure that the supplier's documentation records support the need to replace the accessory to maintain the equipment's functionality and meet the beneficiary's medical need. In the event that certain accessories are furnished for the first time, such as a heated humidifier or heated tubing, CMS will ensure that the accessories are medically necessary.

This policy DOES NOT apply to replacement of accessories for a CPAP device or RAD that has been used for less than 13 months of continuous use or for replacement of accessories for a CPAP device or RAD that is owned by the beneficiary but was not purchased by Medicare. In these cases, all medical necessity documentation needed for the initial use of the CPAP device or RAD must be furnished, but the 120

day grace period above would apply for transitions to contract suppliers at the start of the Round 2 Recompete.