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October 10, 2019

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The Honorable Frank Pallone, Jr.
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Committee on Energy and Commerce
House of Representatives

The Honorable Richard Neal
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The Honorable Kevin Brady
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Committee on Ways and Means
House of Representatives

Medicare: Spending on Certain Disposable Wound Care Devices in Home Health

Medicare fee-for-service’s durable medical equipment (DME) benefit covers medical devices that are appropriate for use in the home and have an expected lifetime of at least 3 years, among other criteria. While new medical technology that is disposable may potentially substitute for DME in certain circumstances, disposable devices generally have not been covered by Medicare as DME because they are not considered durable.¹ The Consolidated Appropriations Act, 2016, provided for a separate payment for disposable negative pressure wound therapy (NPWT) devices under Medicare’s home health benefit as of January 1, 2017.²

Under the Medicare home health benefit, home health agencies provide services to Medicare beneficiaries that are homebound and need skilled nursing or therapy services, with all services

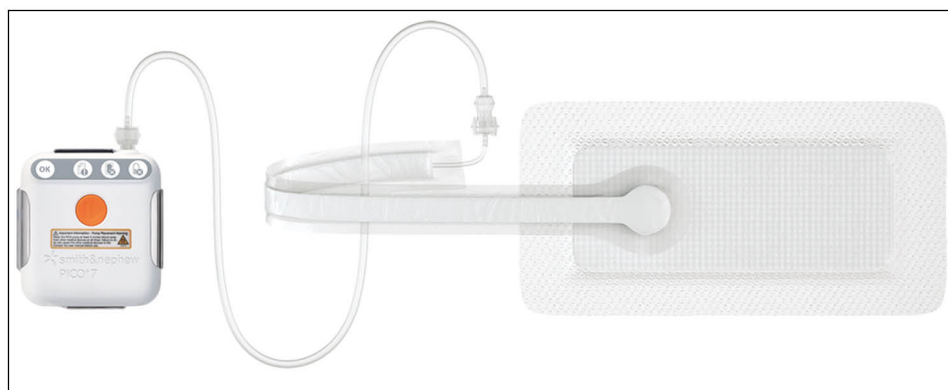
¹The Centers for Medicare & Medicaid Services has defined DME as equipment that (1) can withstand repeated use; (2) has an expected lifetime of at least 3 years; (3) is used primarily to serve a medical purpose; (4) is not generally useful in the absence of an illness or injury; and (5) is appropriate for use in the home. See 42 C.F.R. § 414.202 (2018). The 3-year minimum lifetime requirement is effective for items classified as DME after January 1, 2012. We previously reported on issues for consideration related to the potential Medicare coverage of disposable medical devices. See GAO, *Medicare: CMS Should Evaluate Providing Coverage for Disposable Medical Devices That Could Substitute for Durable Medical Equipment*, [GAO-17-600](#) (Washington, D.C.; Jul 17, 2017).

²Pub. L. No. 114-113 § 504(a), (b), 129 Stat. 2242, 3021 (2015)(codified at 42 U.S.C. §§ 1395l(a)(1), 1395m(s) and 1395x(m)(5)). The act covers disposable negative pressure wound therapy devices only for beneficiaries who are receiving home health services.

generally covered under a bundled payment for an episode of care.³ The act provides for a separate payment, in addition to the episode payment, for furnishing disposable NPWT devices. The act also sets the payment rate equal to the rate for their use in the hospital outpatient setting, with beneficiaries responsible for paying 20 percent in coinsurance.⁴ The payment covers both the device itself and the provision of associated medical services, such as wound care and dressing changes.⁵ Prior to January 1, 2017, disposable NPWT devices were considered supplies that home health agencies could use when providing care, but they were not reimbursed separately from the episode payment.

Medicare covers NPWT devices to treat a number of specific conditions, including pressure and diabetic ulcers, and certain wounds initially treated in an inpatient setting.⁶ NPWT devices involve the application of an airtight dressing on the wound, which is then connected through tubing to a NPWT device that applies negative pressure, or suction, to remove fluid and debris from the wound and promote healing. Disposable NPWT devices are designed for single use over a period of days or weeks, and more than one disposable device may be needed during the course of wound healing treatment (see fig. 1). The disposable devices are designed to provide patient mobility and are generally small, all-in-one devices that include dressings that collect and store fluid. They are typically more appropriate for smaller wounds that do not require the removal of large amounts of fluid.

Figure 1: Example of a Disposable Negative Pressure Wound Therapy Device



Source: Smith & Nephew. | GAO-20-42R

³Home health bundled payments cover 60-day episodes of care and are based on beneficiaries' conditions and service use.

⁴Medicare beneficiaries are generally responsible for paying a portion of costs for covered services when they receive care—referred to as beneficiary cost-sharing. Cost-sharing includes payments toward program deductibles—costs that beneficiaries are responsible for before Medicare pays any costs—and coinsurance or copayments. Coinsurance payments are specified as a percentage of the service cost, while copayments are a fixed dollar amount.

⁵81 Fed. Reg. 76702, 76730 (Nov. 3, 2016) (preamble, III.E.).

⁶The Consolidated Appropriations Act, 2016 provided for a separate payment under the home health benefit for disposable devices that, among other things, must be used “in lieu” of durable devices. As coverage for durable NPWT devices is limited to the treatment of specific conditions, coverage for disposable devices is accordingly limited to those conditions as well.

In contrast, durable NPWT devices are generally larger, more stationary devices designed for use by numerous patients over a period of several years. The devices are used in conjunction with disposable dressings and fluid-collection canisters, which are also covered under Medicare's DME benefit as supplies that are necessary for the effective use of the devices (see fig. 2).⁷ The devices are usually obtained as monthly rentals and, in 2017, Medicare paid for nearly 103,000 monthly rentals. In the same year, Medicare DME spending for the device rentals and associated supplies, including beneficiary cost sharing, totaled more than \$102 million.

Figure 2: Example of a Durable Negative Pressure Wound Therapy Device



Source: KCI, an Acelyty Company. © 2019 KCI. Licensing, Inc. | GAO-20-42R

The Consolidated Appropriations Act, 2016, included a provision for GAO to report to Congress on the effect of paying for disposable NPWT devices under the Medicare home health benefit and provide information on state Medicaid agency and commercial insurer coverage of disposable NPWT devices.⁸ This report describes Medicare home health utilization and spending for disposable NPWT devices and other payer coverage of disposable NPWT devices.

To address our objective, we analyzed Medicare home health claims data for the period of January 1, 2017 through June 30, 2018—the most recent data available at the time of our review. To contextualize Medicare spending on disposable NPWT devices, we also obtained

⁷When Medicare beneficiaries use durable NPWT devices in conjunction with home health services, payments are made separately to DME suppliers under the DME benefit.

⁸Pub. L. No. 114-113 § 504(c), 129 Stat. 3022.

Medicare data on durable NPWT device utilization and spending for calendar year 2017. However, we did not directly compare spending on disposable NPWT devices to durable devices because, among other reasons, durable NPWT devices are appropriate for treating a wider range of wounds than disposable devices.⁹ To ensure the reliability of the data, we reviewed related documentation, interviewed Centers for Medicare & Medicaid Services (CMS) officials, reviewed the data for obvious errors, and removed claims in which Medicare did not make a payment. We found these data to be sufficiently reliable for the purposes of our review. We also interviewed CMS officials and stakeholders, including home health and DME associations and device manufacturers, to obtain perspectives on NPWT devices and Medicare home health utilization of disposable NPWT devices.¹⁰ We also reviewed federal laws and regulations, including stakeholder comments on regulations implementing payments for disposable NPWT devices under the home health benefit.

To describe other payer coverage of disposable NPWT devices, we reviewed publicly available medical policies and coverage information for five state Medicaid programs, five large national commercial insurers, and three regional and state-level commercial insurers.¹¹ We selected the state Medicaid programs and commercial insurers based on the programs and insurers being among the largest in terms of beneficiary enrollment, as well as information on disposable NPWT device coverage provided by stakeholders.¹² Information about state Medicaid program and commercial insurer coverage of disposable NPWT devices cannot be generalized.

We conducted this performance audit from March 2019 to September 2019 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Medicare Home Health Spending and Other Payer Coverage for Disposable Negative Pressure Wound Therapy Devices

From January 1, 2017 to June 30, 2018, Medicare covered 3,978 disposable NPWT devices furnished by home health agencies, with spending, including beneficiary coinsurance, totaling \$923,340. Of this total amount, Medicare paid \$735,490, and the average Medicare payment

⁹Additionally, Medicare payments for disposable NPWT devices cover both the disposable NPWT device itself and the provision of associated medical services, while payments for durable NPWT devices only cover the device. The measure of utilization also differs between durable and disposable devices. Durable NPWT device utilization is based on monthly rentals, while disposable NPWT device utilization is based on the number of devices used, with beneficiaries potentially using several devices in a single month.

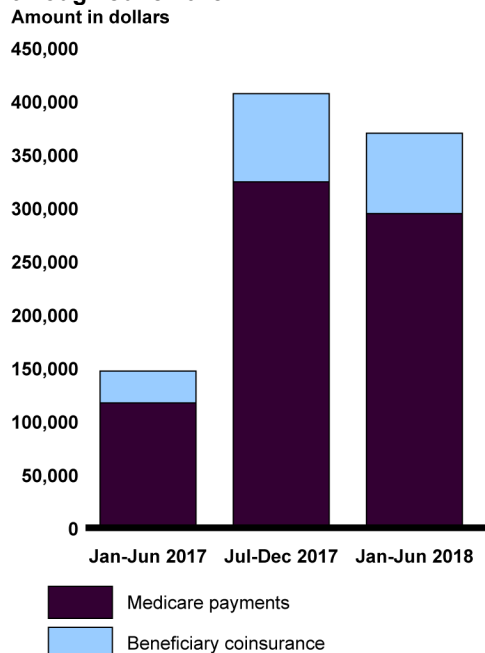
¹⁰We interviewed officials representing the following associations and manufacturers: Acelity; Advanced Medical Technology Association; American Association for Homecare; Apria Healthcare; Cardinal Health; ConvaTec; Lincare; National Association for Home Care and Hospice; Smith & Nephew; and Wound, Ostomy, and Continence Nurses Society.

¹¹We reviewed publicly available medical and coverage policies for the following commercial insurers: Aetna, Anthem Blue Cross, Blue Cross Blue Shield of Alabama, Cigna, Health Care Service Corporation, Highmark, Humana, and UnitedHealthcare. The medical policies of commercial insurers generally guide overarching coverage policies, though specific plan coverage and individual coverage determinations may vary.

¹²We reviewed publicly available coverage policies for the following state Medicaid programs: California, Illinois, Michigan, New York, and North Carolina. We selected the state Medicaid programs based on fee-for-service program enrollment.

per furnished device was \$185. Medicare spending increased during the first year of this benefit, but did not continue to grow in the first half of 2018. (See fig. 3).

Figure 3: Medicare Home Health Spending for Disposable Negative Pressure Wound Therapy, January 2017 through June 2018



Source: GAO analysis of Medicare claims data. | GAO-20-42R

From January 1, 2017 to June 30, 2018, 340 unique Medicare beneficiaries received disposable NPWT devices furnished by home health agencies. Around 85 percent of beneficiaries receiving disposable NPWT devices during the period we examined received more than one device, with beneficiaries receiving an average of 12 devices. Beneficiaries are responsible for a 20 percent coinsurance payment for the devices and collectively paid \$187,850 in coinsurance for the 3,978 disposable NPWT devices they received during the period we examined.¹³ The average total coinsurance amount beneficiaries paid for the disposable NPWT devices they received was \$553, with an average payment amount of \$47 per furnished device.¹⁴

Medicare paid 170 unique home health agencies for furnishing disposable NPWT devices from January 1, 2017 to June 30, 2018. Ninety percent of the 170 agencies furnished more than one

¹³Beneficiaries may have additional health care coverage, such as a Medicare supplemental health insurance policy, to help pay these costs.

¹⁴The average payment amount per disposable NPWT device furnished, including beneficiary coinsurance, was lower than the outpatient fee schedule amount for the service—\$293 in 2017, and \$311 in 2018—as numerous home health agencies billed for the devices in a way that subjected the service to a multiple procedure payment reduction. In June 2019, CMS issued clarification regarding appropriate billing practices for the devices. See CMS, “Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy (NPWT) Using a Disposable Device,” June 11, 2019, <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17027.pdf> (accessed June 27, 2019). Further, CMS officials told us that they are updating Medicare’s claims processing systems to prevent the service from being subject to the payment reduction.

disposable NPWT device, with agencies furnishing an average of 23 disposable NPWT devices during the period we examined. Seventeen agencies furnished more than 50 disposable NPWT devices.

Utilization of disposable NPWT devices has been low compared to durable NPWT devices covered under Medicare's DME benefit. Our analysis showed that Medicare home health spending for disposable NPWT devices in 2017 amounted to less than 1 percent of the program's spending for durable NPWT devices and supplies that year. CMS officials told us that the relatively low utilization of disposable NPWT devices was likely due to their more limited clinical application, as the disposable devices are typically more appropriate for small wounds that do not require the removal of large amounts of fluid. Further, the officials noted that in many cases traditional topical wound treatments may be just as effective at treating small wounds as disposable NPWT devices. CMS officials and stakeholders also told us that, since referring physicians generally decide whether to use a disposable or durable NPWT device, physicians likely determine the extent of disposable NPWT device utilization under the home health benefit.

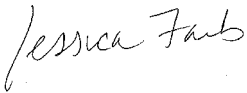
Stakeholders we interviewed mentioned several administrative barriers associated with furnishing disposable NPWT services faced by home health agencies. They explained that many home health agencies generally only submit claims for episode payments and are not experienced with, or face difficulties submitting, claims for separately payable outpatient services. The stakeholders also mentioned that certain home health agencies may face challenges billing and collecting beneficiary coinsurance amounts for furnishing disposable NPWT devices because home health services generally are not subject to beneficiary coinsurance. Additionally, agencies are required to track the time spent furnishing disposable NPWT devices during a home visit separately from other care that is billed under the episode payment, which stakeholders said is burdensome.

Outside of Medicare, we found limited coverage for disposable NPWT devices for use in the home, based on our review of publicly available medical policies and coverage information. For the five selected state Medicaid programs that we reviewed, the publicly available information we reviewed did not explicitly establish coverage for disposable NPWT devices. Most of the eight selected commercial insurers we reviewed do not currently cover home use of disposable NPWT devices because they consider the disposable devices investigational or experimental treatments.

Agency Comments

We provided a draft of this correspondence to the Department of Health and Human Services for review and comment, and it did not have any comments. We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-7114 or farbj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. Key contributors to this report included Leslie V. Gordon (Assistant Director), Michael Erhardt (Analyst-in-Charge), Sam Amrhein, George Bogart, Rich Lipinski, Vikki Porter, and Chris Zakroff.

A handwritten signature in cursive script that reads "Jessica Farb".

Jessica Farb
Director, Health Care

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