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Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year

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Why OIG Did This Review

A 2018 report by the Medicare Payment Advisory Commission found that Medicare paid substantially more than commercial payers for certain items, including intermittent urinary catheters. The report recommended that Medicare incorporate such items into its competitive bidding program, thereby reducing the rates that Medicare allows. However, Medicare has not done so. In fiscal year (FY) 2020, Medicare Part B and its beneficiaries paid \$407 million for all intermittent urinary catheters. OIG evaluated whether Medicare's payment amounts for these catheters may offer the potential for savings.

How OIG Did This Review

We sampled 600 Medicare claims from FY 2020, for the three billing categories of intermittent urinary catheters. We requested that suppliers provide and document the acquisition cost for each of the catheters in these claims. We compared the suppliers' acquisition costs to Medicare payment amounts in three ways: in total, across the three categories, and with regard to three specific features. Additionally, we interviewed the Centers for Medicare & Medicaid Services (CMS) to better understand the methods available to reduce payment rates while maintaining beneficiaries' access to the catheters that best serve their medical needs.

Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year

Key Takeaway

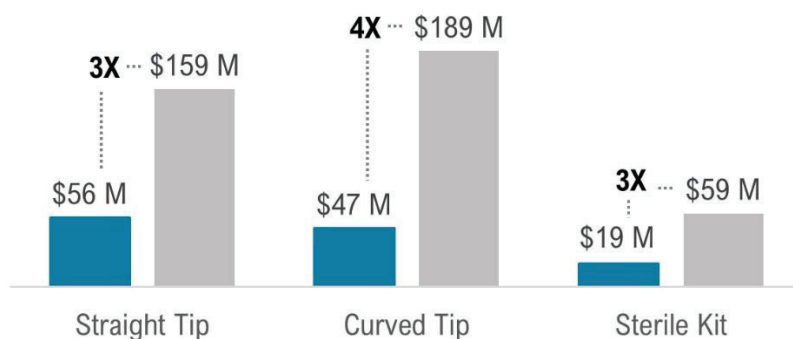
Medicare and its beneficiaries paid suppliers \$407 million for intermittent urinary catheters in fiscal year 2020, more than three times the suppliers' estimated acquisition costs of \$121 million. CMS should take steps to lower Medicare's payment rates for these catheters while continuing to ensure beneficiaries' access to the catheters that best serve their medical needs.

What OIG Found

From our analysis of data submitted by suppliers, we estimated that Medicare payments were 3.4 times suppliers' acquisition costs for intermittent urinary catheters in FY 2020. In total, Medicare allowed \$407 million in payments for these items, while suppliers paid approximately \$121 million to acquire them (see exhibit below). Medicare payments exceeded suppliers' acquisition costs by \$286 million. Each of the three billing categories of intermittent urinary catheters (straight tip, curved tip, and sterile kit) showed large differences between Medicare payments and acquisition costs, which indicates a potential for substantial savings both to Medicare and beneficiaries, who share responsibility for paying the Medicare-allowed amount.

Exhibit. Medicare payments greatly exceeded acquisition costs.

Total Medicare payment amounts (\$407 million) were more than three times the suppliers' acquisition costs (\$121 million).



Source: OIG estimates using documentation from suppliers for sampled claims, n = 574.

Note: Medicare payments (i.e., the allowed amounts) include the beneficiary responsibility. Because of rounding, the subtotals for acquisition costs do not sum to total acquisition costs.

We found potential savings across all categories of catheters. We also found potential savings when catheters had one or more of three specific features (hydrophilic coating, grip, or sleeve)—in these cases, there were smaller but still meaningful differences between Medicare payment rates and supplier acquisition costs, reinforcing the potential for savings.

We recognize that suppliers face other costs beyond the cost of acquiring catheters and need an opportunity to maintain a profit. However, the magnitude of the differences between Medicare reimbursements and suppliers' acquisition costs indicates that Medicare and its beneficiaries can achieve substantial savings while allowing for other costs. To provide an example of the potential for savings, we performed an illustrative analysis of suppliers' other costs. In this analysis, we used data in a report from the home health care industry (not specific to catheters), which estimated that for every dollar spent on acquisition costs, suppliers spent an additional 72 cents in other costs. We applied this same proportion of other costs to our data on acquisition costs in order to obtain an example of suppliers' total costs. This illustrative analysis yields a total cost of \$209 million, which would allow \$198 million in potential Medicare savings and supplier profits. We believe that this analysis likely underestimates potential savings by overstating suppliers' other costs.

What OIG Recommends and How the Agency Responded

We recommend that CMS lower Medicare's payment rates for intermittent urinary catheters. As it does so, CMS should continue to take steps to ensure beneficiaries' access to the catheters that best serve their medical needs. When CMS has previously sought to obtain savings for other items, it has used competitive bidding or its "inherent reasonableness" process. Each of these mechanisms has its own methods for ensuring beneficiary access. CMS did not explicitly indicate whether it concurred with the recommendation; instead, CMS stated that it will take our recommendation under consideration as it determines appropriate next steps.

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BACKGROUND

OBJECTIVE

To compare Medicare payments to supplier acquisition costs for intermittent urinary catheters provided in fiscal year (FY) 2020 and assess whether these differences demonstrate opportunities for cost savings to Medicare and beneficiaries.

Rationale

We conducted this study to assess whether CMS has an opportunity to obtain substantial cost savings for the Medicare program and its beneficiaries, after considering suppliers' acquisition costs and other costs. In FY 2020, Medicare Part B and its beneficiaries paid \$407 million for all intermittent urinary catheters.

CMS has not implemented the recommendation from a 2018 Medicare Payment Advisory Commission (MedPAC) report for it to incorporate certain items, including intermittent urinary catheters, into its competitive bidding program, thereby reducing the rates that Medicare pays. The MedPAC report found that in 2015 Medicare paid more than commercial payers for intermittent urinary catheters, specifically 45 percent more than commercial payers for straight tip catheters and 57 percent more for curved tip catheters.^{1, 2}

Intermittent Urinary Catheterization for Urinary Retention

Intermittent catheterization is a technique used to manage urinary retention, the inability to empty the bladder voluntarily. Users insert a special tube (a catheter) to drain the bladder, usually every four to six hours. The tube is removed after the bladder has been emptied.

Chronic urinary retention can be caused by a variety of medical problems that either block or narrow the urethra or interfere with the nerves and muscles that contract the bladder to empty it. Examples of problems that can cause urinary retention are

¹ MedPAC, *Report to the Congress*, ch. 6, "Issues in Medicare's medical device payment policies." June 2018. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun18_ch6_medpacreport_sec.pdf on March 10, 2022.

² If we apply these percentages to FY 2020, Medicare payment amounts may have exceeded what commercial payers paid by \$118 million (considering that the Medicare program and beneficiaries paid \$348 million for these two categories of catheters).

enlarged prostate, urethral scarring, spinal cord injury, multiple sclerosis, or bladder muscles that have been weakened or damaged by age or pregnancy and childbirth.³

If not addressed, urinary retention can lead to further medical complications. Urinary retention can lead to urinary tract infections (UTIs), which can damage the bladder or kidneys. Additionally, the Centers for Disease Control and Prevention (CDC) has strongly recommended that if intermittent catheterization is used, it should be performed at regular intervals to avoid overdistension (i.e., overstretching) of the bladder.⁴ Without catheterization, urinary retention can block the flow of urine from the kidneys and lead to swelling and kidney damage.⁵ Kidney damage, resulting from UTIs or bladder overdistension, can progress to chronic kidney disease and kidney failure.⁶

Although intermittent catheterization is used to treat urinary retention, catheter use carries some risk. Catheters can move bacteria into and up the urinary tract, causing UTIs. Additionally, insertion of the catheter may cause damage to the urinary tract.

Medicare Coverage and Billing Categories

When medically necessary and prescribed to replace the emptying function of the bladder, urinary catheters are covered under Medicare Part B's benefit for prosthetic devices. Intermittent urinary catheters are covered by Medicare when basic coverage criteria are met and the beneficiary or a caregiver can perform the catheterization.⁷ An appropriate health care professional must both prescribe catheter use and document medical necessity. The maximum number of catheters covered per month is 200, unless the prescriber documents medical necessity for a greater quantity.⁸

Suppliers bill Medicare for intermittent urinary catheters using one of three Level II Healthcare Common Procedure Coding System (HCPCS) codes established by CMS.

³ National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), *Symptoms & Causes of Urinary Retention*. Accessed at <https://www.niddk.nih.gov/health-information/urologic-diseases/urinary-retention/symptoms-causes> on April 15, 2022.

⁴ CDC, *Guideline for Prevention of Catheter-Associated Urinary Tract Infections* (2009, updated 2019). <https://www.cdc.gov/infectioncontrol/pdf/guidelines/cauti-guidelines-H.pdf>. CDC has also stated that catheters with hydrophilic coatings might be preferable to other types for intermittent catheterizations. That recommendation is based on "very low-quality evidence." (See page 40 of CDC guidelines.)

⁵ National Kidney Foundation, *A to Z Health Guide: Hydronephrosis*. Accessed at <https://www.kidney.org/atoz/content/hydronephrosis> on March 1, 2022.

⁶ NIH, NIDDK, *Definition & Facts of Urinary Retention*. Accessed at <https://www.niddk.nih.gov/health-information/urologic-diseases/urinary-retention/definition-facts#complications> on March 1, 2022.

⁷ CMS, *Urological Supplies (L33803)*, available at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33803>.

⁸ The CMS standard maximum of 200 catheters per month allows for an average of 6 catheters per day in a 31-day month. (That is, 200 divided by 31 is approximately 6.5.)

CMS assigns catheters to one of the following three billing codes depending on the shape of its tip or if allows for sterile catheterization:

- **Straight tip catheters** are the most basic billing category (A4351) for intermittent catheters.
- **Curved tip catheters** are also called coudé tip catheters (A4352). CMS will cover these if medically necessary (e.g., the beneficiary is unable to catheterize with a straight tip catheter). Depending on physiology (e.g., having an enlarged prostate), a curved tip catheter may be easier or less painful to insert than a straight tip catheter. CMS advises that beneficiaries categorized as female rarely need curved tip catheters.
- **Sterile kit catheters** (A4353) can be either straight tip or curved tip catheters. This category includes catheters that come with a kit of supplies to facilitate sterile catheterization. This category also includes “no-touch” catheters that allow for sterile technique without the use of additional supplies. CMS covers a sterile kit catheter only in specific situations (i.e., if the beneficiary resides in a nursing facility; is immunosuppressed; is pregnant and has a spinal cord injury; or has a history of UTIs or backward flow of urine to the kidneys while using intermittent catheterization).

Other Intermittent Urinary Catheter Features

Catheters in each of the three billing categories can have one or more features. Different combinations of features give prescribers and beneficiaries options from which to choose. Catheter features are often promoted by manufacturers and suppliers as increasing comfort and ease of use. Manufacturer representatives told us that comfort and ease of use are important factors in patients’ compliance with their intermittent catheterization schedule.⁹

In our discussions with manufacturers, three features emerged as examples of features likely to be associated with higher acquisition costs:

- **Hydrophilic coating** – when exposed to water, a polymer on the catheter that forms a slippery coating intended to ease insertion
- **Grip** – an insertion aid that keeps the fingers from touching the catheter and potentially introducing bacteria
- **Sleeve** – a protective polymer wrapping over the entire catheter that keeps the fingers from touching the catheter and potentially introducing bacteria

⁹ We met with the American Association for HomeCare and some of its members, including representatives from Coloplast; Hollister; and Beckton, Dickinson, and Company.

Medicare Payment Rates and Beneficiary Utilization

Medicare payment rates vary among the three billing codes, as does beneficiary utilization. In this report, “Medicare payment rates” and “Medicare payment amounts” (i.e., allowed amounts) refer to the amounts paid by the Medicare program and beneficiaries or their supplemental insurance.

Payment Rates Under the DMEPOS Fee Schedule

Currently, the Medicare payment rate for intermittent urinary catheters is set through the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) fee schedule. The Medicare-allowed amount for catheters is the lesser of the amount charged by the supplier or the DMEPOS fee schedule amount.¹⁰

Intermittent urinary catheters are among the DMEPOS items with current payment rates based on historical charges adjusted for inflation over time. The current rates in the Medicare DMEPOS fee schedule are based on payments made in 1986 and 1987 under the prior “reasonable charges” payment methodology, adjusted for inflation annually for over 30 years since CMS implemented the fee schedule in 1989.^{11, 12}

Typically, the Medicare program pays 80 percent of the rate Medicare allows minus any annual deductible not yet paid by the beneficiary. The beneficiary is responsible for the remaining 20 percent, after paying the annual deductible.

As described in Exhibit 1 below, the FY 2020 Medicare payment rates per unit were \$1.98 for straight tip catheters, \$6.98 for curved tip catheters, and \$8.04 for sterile kit catheters. The presence of other features, such as a hydrophilic coating, grip, or sleeve, does not alter the Medicare payment rate for a catheter.

Beneficiary Utilization and Medicare’s Payments in FY 2020

Beneficiaries most frequently utilized straight tip catheters, but Medicare allowed higher total payments for curved tip catheters because of their higher per-unit payment rate (see Exhibit 1). Straight tip catheters accounted for 70 percent of the catheters utilized, while curved tip catheters account for 24 percent. However, curved

¹⁰ Social Security Act § 1834(h). The Medicare payment rate is set at the lesser of the fee schedule rate or the amount charged by the supplier for most items. Customized items and competitively bid items are subject to different payment rules.

¹¹ See 84 Fed. Reg. 60648, 60729-60730 (Nov. 8, 2019) for additional detail, including the exceptions to the 1986 and 1987 base period, such as surgical dressings, which have a base period of 1992.

¹² Generally, CMS bases reasonable charge determinations on customary and prevailing charges derived from historic charge data. Under the fee schedule, CMS adjusts payment rates annually by the percentage increase in the CPI-U (Consumer Price Index for All Urban Consumers), reduced by a productivity adjustment. See 84 Fed. Reg. at 60729-60730.

tip catheters accounted for 47 percent of spending (i.e., \$189 million out of \$407 million) as compared to 39 percent for straight tip catheters.

Exhibit 1. Beneficiary utilization and Medicare payments for intermittent urinary catheters in fiscal year 2020

Catheter Category	Medicare Payment Rate per Unit	Number of Units (Millions)	Percentage of Units	Payment Amounts (Millions)	Percentage of Total Payments
Straight Tip (A4351)	\$1.98	80.1	70%	\$158.7	39%
Curved Tip (A4352)	\$6.98	27.1	24%	\$189.1	47%
Sterile Kit (A4353)	\$8.04	7.3	6%	\$58.9	14%
Total	N/A	114.4	100%	\$406.7	100%

Source: OIG analysis of Medicare claims with a date of service from October 2019 through September 2020.

Note: Medicare payment amounts include beneficiary share.

Beneficiaries used different types of catheters, in part, according to their health condition or physiology (see Exhibit 2). Sterile catheter kits were mostly used by beneficiaries with a spinal cord injury or neurological condition (i.e., 61 percent of the 6,914 beneficiaries who used sterile kits).¹³ Curved tip catheters were used almost exclusively by beneficiaries categorized as male.¹⁴

Exhibit 2. Beneficiary characteristics by catheter type in fiscal year 2020

Catheter Category	Number of Beneficiaries Using	Beneficiaries with Spinal Cord Injury or Neurological Condition	Beneficiaries with Spinal Cord Injury or Neurological Condition	
			Male	Female
Straight Tip (A4351)	85,114	30%	61%	39%
Curved Tip (A4352)	34,031	19%	98%	2%
Sterile Kit (A4353)	6,914	61%	66%	34%
Total	122,704	28%	71%	29%

Source: OIG analysis of Medicare claims with a date of service from October 2019 through September 2020.

Note: The beneficiary subtotals do not sum to the total number of beneficiaries because one beneficiary may receive catheters in different billing categories.

CMS's Alternative Authorities To Adjust Payment Rates and Their Beneficiary Access Protections

Currently, CMS has the ability under Federal statute and regulations to adjust Medicare's payment rates for DMEPOS under two methodologies. The two methodologies are: (1) the **competitive bidding program** and (2) what is known as

¹³ For additional information about the medical conditions of beneficiaries who utilized intermittent urinary catheters, see Exhibit A-1 in Appendix A.

¹⁴ For this analysis, we used the sex categorization available from Medicare's National Claims History.

the **inherent reasonableness process**. Both methodologies have mechanisms to attempt to protect beneficiary access to medically necessary items.

DMEPOS Competitive Bidding Program

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required CMS to create a competitive bidding program for DMEPOS items to obtain better payment rates for the Medicare program. CMS was allowed to conduct a phased implementation of items under competitive bidding and is allowed to exempt items from the program if the bidding process appears unlikely to result in significant savings.¹⁵

CMS has not included urological supplies, including intermittent urinary catheters, in previous phases of competitive bidding. In 2007, CMS interpreted the statute as giving CMS discretion to either include or exclude ostomy supplies (and by extension, urological supplies) in the competitive bidding program, but CMS did not take steps to include ostomy supplies at that time.¹⁶

In the competitive bidding program, CMS selects items for inclusion, defines competitive bidding areas (CBAs), and opens bidding to suppliers willing to provide the items in those CBAs. If the bids are expected to result in savings, CMS determines contract payment rates based on the bids. The suppliers that enter into contracts with CMS are obligated to provide the items at the contracted payment rates. Medicare Part B beneficiaries obtaining DMEPOS items in the CBAs must get those items from the contract suppliers if they want the Medicare program to cover the items.¹⁷

It remains unclear if and when CMS will begin subsequent rounds of the competitive bidding program. Before it introduces a new round, CMS takes several steps to set up the bidding process and obtain bids. For prior rounds, this process has taken about 1.5 years from the announcement of the bidding process to implementation of the contracts. The current round of the competitive bidding program ends in December 2023.¹⁸ For a subsequent round, CMS would need to announce details on

¹⁵ Statute also excludes certain DMEPOS items from the competitive bidding program (i.e., class III medical devices, certain types of wheelchairs, and certain drugs or biologicals). Social Security Act § 1847 (a)(2).

¹⁶ CMS characterized the statute as ambiguous. See 72 Fed. Reg. 17992, 18023 (April 10, 2007) for CMS's interpretation of the statute regarding ostomy supplies. We note that the statute addresses urological supplies and ostomy supplies together, so CMS's statements in the Federal Register about ostomy supplies would also be applicable to urological supplies.

¹⁷ In FY 2020, 56 percent of spending on intermittent urinary catheters was in former CBAs, and 44 percent was in non-CBAs, including 21 percent in rural areas.

¹⁸ CMS currently covers two product categories under Round 2021 of the competitive bidding program (i.e., off-the-shelf knee and back orthotics).

the bidding process; the methods to determine winning bids and payment rates; and which areas and product categories may be included.¹⁹

The competitive bidding program, whether local CBA-based or national mail order, includes an authorization process to safeguard the beneficiary's access to a specific brand name product when it is needed to avoid an adverse medical outcome. If the prescribing professional adequately documents the need for a particular product according to CMS requirements, a supplier must, as a term of its competitive bidding contract, ensure that the beneficiary receives the needed item. The competitively bid payment rate would apply to an item prescribed through this authorization process.²⁰

Inherent Reasonableness Process

CMS has "inherent reasonableness" authority to adjust the payment amounts for Medicare fee schedule items, or categories of items, if CMS determines that the standard rules for calculating payment amounts will result in grossly deficient or excessive payment amounts.²¹ For a payment amount to be considered grossly deficient or excessive, CMS must determine that an adjustment of 15 percent or more is necessary to produce a realistic and equitable payment amount.²² Furthermore, statute and regulations do not require CMS to implement the total necessary adjustment at one time; for example, if a reduction of 20 percent were required to produce a realistic and equitable payment amount, CMS could implement the reduction over 2 years. CMS has used inherent reasonableness to adjust fee schedule amounts once, in 1995, to lower Medicare's payment rates for standard home blood glucose monitors.²³

¹⁹ CMS decided not to issue contracts in Round 2021 for product categories that were previously competed because the payment amounts did not achieve expected savings. These products included commode chairs, continuous positive airway pressure devices, enteral nutrition, hospital beds, infusion pumps, nebulizers, negative-pressure wound therapy pumps, oxygen and oxygen equipment, patient and seat lifts, manual wheelchairs, power wheelchairs, support surfaces, transcutaneous electrical nerve stimulation devices, and walkers. Additionally, CMS has not rebid contracts for the diabetes testing supplies national mail-order program since 2016, and those contracts ended in 2018. For these product categories, fee schedule amounts in CBAs are based on the most recent competitive bidding program contract price as of December 31, 2018. Fee schedule amounts are increased for inflation once per year. Source: CMS, *Pub 100-04 Medicare Claims Processing*, Transmittal 10504: "CY 2021 Update for DMEPOS Fee Schedule." Accessed at <https://www.cms.gov/files/document/r10504cp.pdf> on March 15, 2021.

²⁰ 42 CFR § 414.420, Physician or treating practitioner authorization and consideration of clinical efficiency and value of items.

²¹ Social Security Act § 842(b).

²² 42 CFR §§ 405.502(g)(1)(ii), (g)(1)(iii), and (g)(1)(v).

²³ Subsequently, in 1999, CMS proposed to use the inherent reasonableness process for other durable medical equipment, but this process was halted by Congressional action. At the time, CMS proposed using a markup of 67 percent, which it considered to be the upper end of a range of acceptable markups. This markup would include both other costs and supplier profit and was based on data about medical equipment and devices submitted to CMS between 1989 and 1998. See 64 Fed. Reg. 44227, 44229 (Aug. 13, 1999).

CMS must take several steps to use the inherent reasonableness process. To identify grossly deficient or excessive payments and establish new limits that are realistic and equitable, CMS must use valid and reliable data that comply with guidelines in the regulations to the extent applicable.²⁴ Before adopting a new payment limit, CMS must publish proposed and final notices in the Federal Register.

CMS must take additional steps to propose adjustments of more than 15 percent in a single year.²⁵ Specifically, CMS must consult with supplier representatives and consider the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

The inherent reasonableness process includes some mechanisms to consider the protection of beneficiary access. When using the inherent reasonableness process, CMS must take public comment during rulemaking, which allows stakeholders to raise concerns about beneficiary access. CMS has stated that it will also monitor all complaints from beneficiaries, suppliers, providers, and others regarding beneficiary access to items with newly established payment limits.²⁶ If CMS were to adjust payment amounts by more than 15 percent in 1 year, regulations would require CMS to consider the potential impact on quality and beneficiary access. Additionally, when using its inherent reasonableness authority, CMS could adjust payments in ways that protect beneficiary access to specific items. For example, CMS may decide to create a new billing category and could potentially use a modifier to adjust payment amounts within a billing category.

Key Terms in This Report

Total costs – All the expenses paid by a supplier to provide the item to the beneficiary, including acquisition costs and other costs of the business.

Acquisition cost – The cost to the supplier of purchasing the item from the manufacturer or an intermediary, inclusive of any discount.

Other costs – All costs that are not acquisition costs. Examples: delivery fees, and overhead costs such as salaries for customer service personnel, rent, utilities, and capital expense.

Profit – What the supplier is paid minus the supplier's total costs.

²⁴ These criteria include, among other things, consistent data collection steps, ensuring that sampled prices represent the range of prices nationally, and considering geographic variations. 42 CFR § 405.502(g)(4).

²⁵ For example, if CMS determined that a 20-percent price reduction was necessary, CMS would have to take these additional steps if it implemented the 20-percent reduction in a single year. If CMS implemented a 10-percent reduction in 1 year, followed by a 10-percent reduction the next year, it would not have to take these additional steps.

²⁶ 70 Fed. Reg. 73623, 73628 (Dec. 13, 2005).

Methodology

To compare Medicare payments and supplier acquisition costs for intermittent urinary catheters, we analyzed Medicare claims and collected data from suppliers in our sample of claims for catheters provided in FY 2020. Among the population of 672,561 claims for catheters billed to Medicare in FY 2020, we selected a stratified random sample of 600 claims. Each stratum contained 200 claims from 1 of the 3 billing categories. For each sampled claim, we asked suppliers to report and document the acquisition cost for the catheters they provided. The responding suppliers provided documentation for claims, which resulted in a 97-percent overall weighted response rate. The data from the random sample includes catheters provided to beneficiaries who were representative of all beneficiaries who utilized intermittent urinary catheters (see Exhibit A-2 in Appendix A). We estimated the total supplier acquisition cost per unit for all claims. Additionally, we collected data on whether the catheters had specific features (i.e., hydrophilic coating, grip, and sleeve) and projected the acquisitions costs to the population of claims.

To assess whether these differences demonstrate opportunities for Medicare and beneficiaries cost savings, we considered additional context. Specifically, we used a third-party report to perform an illustrative analysis of suppliers' total costs to supply catheters to beneficiaries and the potential for Medicare cost savings.²⁷ We also interviewed CMS officials for their perspectives on opportunities and challenges associated with obtaining cost savings for intermittent urinary catheters.

See the Detailed Methodology for more information.

Limitations

We did not independently verify the accuracy of supplier-reported information about the presence of specific catheter features. Further, we did not estimate an exact dollar amount for potential cost savings because we did not collect data on other costs from our sample. Rather, we used the results of the third-party report to perform an illustrative analysis of potential cost savings and profits.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

²⁷ Dobson DaVanzo & Associates, LLC, *Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding* (2016). Accessed at <https://www.aahomecare.org/> on April 15, 2022.

FINDING

Medicare payment amounts were 3.4 times suppliers' costs to acquire intermittent urinary catheters in FY 2020, and opportunities exist for savings

Overall, Medicare and beneficiary payments to suppliers were 3.4 times suppliers' acquisition costs for intermittent urinary catheters in FY 2020.²⁸ Acquisition costs increased according to specific features within a billing category; however, acquisition costs remained well below Medicare payment rates. Additionally, we conducted an illustrative analysis of suppliers' other costs beyond acquisition costs, which shows ample room for Medicare to reduce its payment rates while allowing suppliers an opportunity to maintain a profit.

Total Medicare payments exceeded suppliers' acquisition costs by \$286 million in FY 2020 across the three billing categories

Overall, Medicare allowed \$286 million more in payments for intermittent urinary catheters than the suppliers paid to acquire those catheters. Medicare allowed a total of \$407 million in payments for intermittent urinary catheters in FY 2020, while estimated acquisition costs were \$121 million.²⁹ Payments to suppliers were 3.4 times suppliers' acquisition costs (see Exhibit 3).

Exhibit 3. Medicare payment amounts exceeded suppliers' acquisition costs for intermittent urinary catheters.

Catheter Category	Medicare Payments (Millions)	Acquisition Cost (Millions)	Cost Difference (Millions)	Ratio of Medicare Payments to Acquisition Cost
Straight Tip (A4351)	\$158.7	\$55.5	\$103.2	2.9
Curved Tip (A4352)	\$189.1	\$46.9	\$142.3	4.0
Sterile Kit (A4353)	\$58.9	\$18.7	\$40.1	3.1
Total	\$406.7	\$121.2	\$285.6	3.4

Source: OIG analysis of Medicare claims and OIG estimates of acquisition costs using documentation from suppliers in our sample of claims, n = 574.

Note: Because of rounding, the numbers may not sum.

Medicare and beneficiary payments exceeded suppliers' acquisition costs in each of the three billing categories. Medicare's payment amounts exceeded suppliers' acquisition costs by \$103 million for straight tip catheters, \$142 million for curved tip

²⁸ The beneficiary responsibility includes payments made by the beneficiary or supplemental insurance.

²⁹ For detailed estimates of acquisition costs and confidence intervals, see Exhibit A-3 in Appendix A.

catheters, and \$40 million for sterile kit catheters. The ratio of the Medicare payments to the acquisition cost was 2.9, 4.0, and 3.1, respectively.

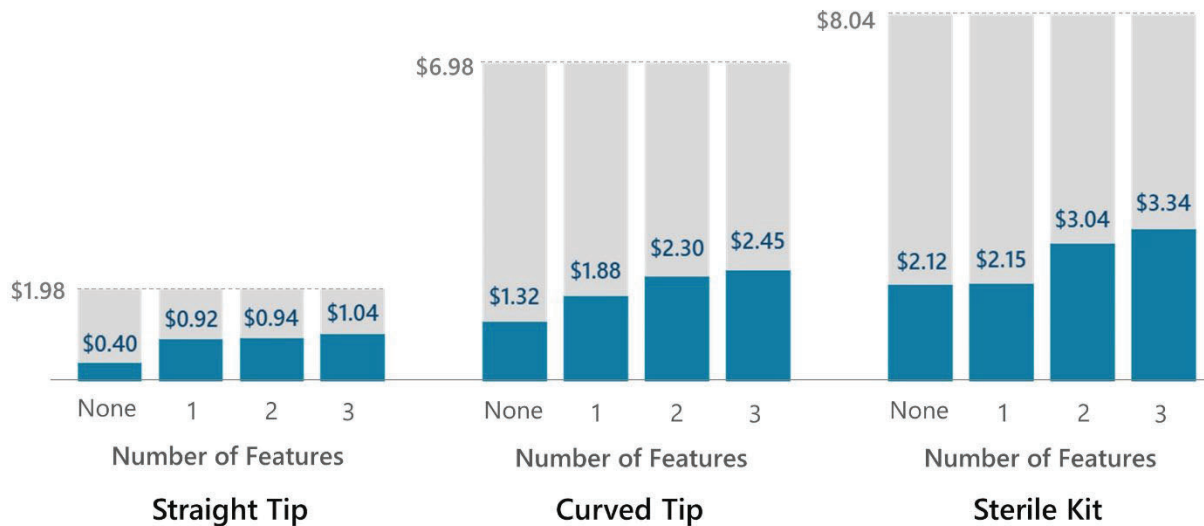
Beneficiaries were responsible for approximately 20 percent of the Medicare payments. Therefore, out of the \$286 million cost difference, the beneficiary portion was approximately \$57 million.

Suppliers' acquisition costs within each of the three categories increased somewhat by additional catheter features

Overall, acquisition costs increased for catheters with hydrophilic coating, grip, and sleeve, compared to catheters without these features.^{30, 31} However, the acquisition costs remained below Medicare's payment rates.

Exhibit 4. Average estimated acquisition cost per unit according to the number of features present (hydrophilic coating, grip, or sleeve)

The height of each column represents the Medicare payment rate per unit.



Source: OIG estimates of acquisition costs using documentation from suppliers in our sample of claims, n = 574.

Note: The differences in acquisition costs by number of features were not always statistically significant. For detailed estimates of acquisition costs including 95-percent confidence intervals, see Exhibit A-8 in Appendix A.

More than half of the catheters in each billing category had at least one of these features. Specifically, half of the catheters in the straight tip and curved tip billing categories had at least one of these features, and three out of every four catheters in the sterile kit billing category had at least one feature (see Exhibit A-5 in Appendix A).

³⁰ See Detailed Methodology for more information on how we selected these three features.

³¹ For details about the proportion of catheters with specific features, see Exhibit A-5 in Appendix A; for detailed estimates of acquisition costs and 95-percent confidence intervals, see Exhibit A-6 in Appendix A. Additionally, some catheters had multiple features (see Exhibit A-7 in Appendix A).

Potential savings exist after accounting for suppliers' other costs beyond acquisition costs

We recognize that suppliers have additional costs beyond acquiring catheters and need to make some profit to stay in business. However, the magnitude of the differences between Medicare payments and suppliers' acquisition costs indicate that Medicare and its beneficiaries could achieve substantial savings while accounting for these other factors. To perform an illustrative analysis of suppliers' other costs, we used data in a report from the home health care industry (not specific to catheters). Even after allowing for these estimates of other costs, there appears to be ample room to reduce Medicare payment rates and allow suppliers an opportunity to maintain a profit.

Illustrative analysis of other costs:

We used information from a third-party report to provide a conservative example of these other costs and the potential for Medicare cost savings.³² This report, commissioned by DMEPOS suppliers and issued in 2016, found that for every dollar spent on acquisition costs, suppliers spent 72 cents in other costs for providing certain DMEPOS items to beneficiaries. (These items did not include catheters.) To consider potential other costs, we applied the same ratio (\$1.00 in acquisition costs per \$0.72 in other costs) to our estimated acquisition costs from suppliers in our sample (i.e., \$121 million).

This example is conservative and likely underestimates potential savings. We believe this example likely underestimates the potential for savings by overstating suppliers' other costs because some items in the commissioned report, including oxygen and wheelchairs, generally require more services than do urinary catheters.³³ Further, we found that an estimated 96 percent of catheters were delivered by mail.³⁴ Supplier operating costs of mail order businesses are generally less than those for "brick and mortar" stores.³⁵

³² Dobson DaVanzo & Associates, LLC, *Analysis of the Cost of Providing Durable Medical Equipment to the Medicare Population: Measuring the Impact of Competitive Bidding* (2016). Accessed at <https://www.aahomecare.org/> on April 15, 2022. This report specifically looked at costs for different types of equipment including beds, oxygen items, sleep items, walkers, and certain types of wheelchairs.

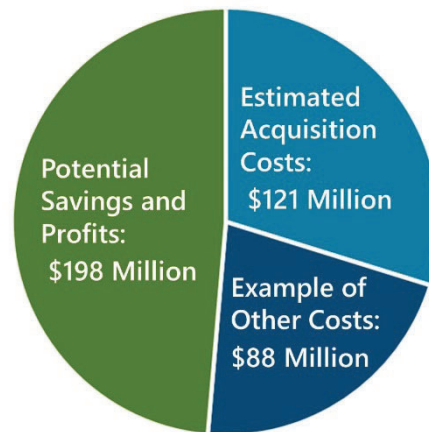
³³ CMS's DMEPOS Quality Standards include product-specific service requirements for several DMEPOS items, including oxygen and wheelchairs. CMS requires fewer services for intermittent urinary catheters.

³⁴ The 95-percent confidence interval ranged from 94.7 to 98.3 percent.

³⁵ US Chamber of Commerce, *The Pros and Cons of Brick-and-Mortar Locations* (April 22, 2019). Accessed at <https://www.uschamber.com/co/start/startup/opening-brick-and-mortar-location-for-your-business> on April 18, 2022.

Overall, Medicare and beneficiaries have a substantial potential for savings, even when factoring in other costs. In this conservative example illustrated by Exhibit 5, total costs (i.e., acquisition costs plus other costs) would have been 51 percent of the Medicare-allowed amount, leaving a 49-percent margin of payments over total costs (\$198 million). Some of this amount is necessary for suppliers to have profits to sustain their businesses, and some could be potential savings from reductions in Medicare’s payment rates. Of the \$198 million in potential savings and profits, the beneficiaries’ portion would have been approximately \$40 million (20%).³⁶

Exhibit 5. Our illustrative analysis shows \$198 million available for savings and profits.



Source: OIG analysis using acquisition costs estimated from suppliers in our sample (n = 574) and an example of other costs.

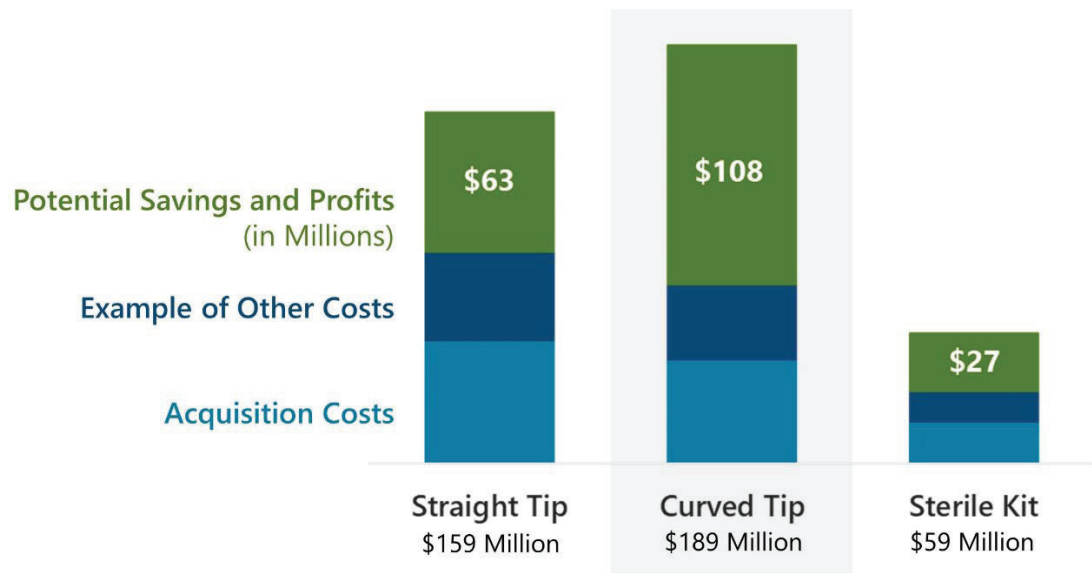
Note: There is potentially \$198 million available for savings and profits, assuming that for every dollar spent in acquisition cost, suppliers spent an additional 72 cents in other costs.

This example demonstrates that Medicare and beneficiaries have the opportunity for substantial savings, although we did not determine an exact target for cost savings. Overall, the potential savings were larger than the minimum 15 percent savings needed for Medicare to use its inherent reasonableness authority, which equated to \$61 million for FY 2020.

³⁶ When beneficiaries have supplemental insurance coverage, they may not pay the full cost-sharing amount. However, nearly one in five beneficiaries did not have supplemental coverage in 2018. See Kaiser Family Foundation, *A Snapshot of Sources of Coverage Among Medicare Beneficiaries in 2018*. Accessed at <https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries-in-2018/> on February 10, 2022.

Each of the three categories of catheters showed potential for significant savings, and the potential savings was greatest for the curved tip catheters (see Exhibit 6). The \$108 million in potential savings and profits for curved tip catheters represents about 57 percent of the total payments that Medicare allowed for curved tip catheters (\$189 million).

Exhibit 6. Curved tip catheters accounted for most of the total \$198 million in potential savings and profits in our illustrative analysis of acquisition costs plus an example of suppliers’ other costs.



Source: OIG analysis using acquisition costs from suppliers in our sample (n = 574) and an example of other costs.

Note: Total payments for intermittent urinary catheters were \$407 million. This includes straight tip catheters (HCPCS A4351), curved tip catheters (A4352), and sterile kit catheters (A4353). For additional details regarding cost estimates, see Exhibit A-9 in Appendix A.

Finally, the above analysis likely underestimates the potential for savings. We do not endorse the example of 72 cents in other costs per dollar of acquisition costs as appropriate for CMS to use to determine payment rates. We used this example solely to provide a conservative example of potential savings and profits based on an industry-commissioned report. In 1999, CMS considered 67 percent to be the upper end of a range of acceptable markups for durable medical equipment and devices. Markups include both other costs *and* profits. As we previously noted, the cost of furnishing intermittent urinary catheters is likely lower than that of furnishing many other DMEPOS items because intermittent urinary catheters are generally provided by mail order and may require fewer accompanying services. Therefore, our illustrative analysis likely underestimates the potential for savings.

CONCLUSION AND RECOMMENDATION

Medicare and beneficiaries paid suppliers \$407 million for intermittent urinary catheters in FY 2020, more than three times suppliers' estimated acquisition costs of \$121 million. Given the magnitude of this difference, Medicare has the opportunity to reduce its payment rates for intermittent urinary catheters while allowing suppliers adequate payments for the items and services they provide. Reducing Medicare's payment rates can save Medicare and beneficiaries millions of dollars annually.

The differences between Medicare payment amounts and supplier acquisition costs varied across the three categories of catheters (straight tip, curved tip, and sterile kit), but all showed substantial potential for savings to Medicare and beneficiaries. Catheters with features showed smaller but still meaningful differences between Medicare's payment rates and supplier acquisition costs, reinforcing the potential opportunities for savings.

We recommend that CMS:

Lower Medicare's payment rates for intermittent urinary catheters

CMS should employ a mechanism to lower Medicare's payment rates for intermittent urinary catheters. In the past, CMS has sought to use two mechanisms to lower payment rates for DMEPOS items. These include introducing items into the competitive bidding program and use of the inherent reasonableness process. The competitive bidding program could attain substantial savings for intermittent urinary catheters, depending on the bids that suppliers submit to Medicare. The inherent reasonableness process would allow CMS to directly modify Medicare's payment rates for these items.

As it lowers Medicare's payment rates, CMS should also take steps to ensure continued access for beneficiaries to the catheters that best serve their medical needs. As we noted in our findings, an estimated 96 percent of catheters were delivered by mail, so CMS can factor this into its considerations about how to maintain sufficient access throughout the country.

AGENCY COMMENTS AND OIG RESPONSE

CMS did not explicitly agree or disagree with our recommendation to lower Medicare’s payment rates for intermittent urinary catheters. Instead, CMS stated that it will determine appropriate next steps while considering our recommendation. CMS noted that it would need to engage in a public notice and comment period to use either of its mechanisms to reduce Medicare payment rates. We ask CMS to specify—in its Final Management Decision—its plans to lower payment rates for intermittent urinary catheters. OIG will monitor CMS’s progress in implementing this recommendation.

For the full text of CMS’s comments, see the Agency Comments appendix at the end of the report.

DETAILED METHODOLOGY

We based this evaluation primarily on analysis of Medicare claims data and data from suppliers included in our sample of claims for intermittent urinary catheters. We reviewed claims information, including data about our sample with an FY 2020 date of service (October 1, 2019, through September 30, 2020).

Comparison of Medicare Payments to Supplier Acquisition Costs

To compare Medicare payments and supplier acquisition costs for intermittent urinary catheters, we analyzed Medicare claims and collected data from suppliers of catheters that were provided to beneficiaries in FY 2020. We took a random sample of 600 claims for intermittent urinary catheters. We asked suppliers to report the acquisition cost for the catheters they provided for that claim, the features of the catheters, and whether the catheters were delivered by mail order. We used documentation from suppliers to verify their responses about acquisition costs and the mode of delivery. We determined supplier acquisition costs on a per-unit basis and projected these costs to the population of claims.

Population of Medicare Part B DMEPOS Claims

Using CMS's National Claims History file, we identified the population of Medicare Part B claims for straight tip intermittent catheters (A4351), curved tip intermittent catheters (A4352), and intermittent catheters with a kit of sterile insertion supplies (A4353). We used claims data for services provided in FY 2020 (i.e., October 1, 2019, through September 30, 2020). There were 672,561 claim lines for which the Medicare-allowed amount was greater than \$0. We used the Medicare-allowed amounts in this study, which slightly overestimates the amount of money received by suppliers since budgetary sequestration resulted in decreases to the Medicare responsibility amount of 2 percent during 7 of the 12 months in FY 2020.³⁷

Data Collection from Suppliers in the Sample

From the population of claims, we selected a stratified random sample of 600 claims, with 200 claims randomly selected from each of the three HCPCS codes. We sent documentation requests to the 157 suppliers associated with our sampled claims. For each claim, we asked the supplier to (1) indicate the type (model and manufacturer) of catheter(s) that it provided to the Medicare beneficiary we identified; (2) indicate the per-unit acquisition cost for that catheter, inclusive of any discounts received from manufacturers or intermediaries; (3) indicate if the catheter had a hydrophilic coating,

³⁷ The 2-percent adjustment was temporarily suspended for all Medicare fee-for-service claims with dates of service starting from May 1, 2020, meaning sequestration impacted 7 months (i.e., October 2019 through April 2020) of the time period.

grip, or sleeve; (4) indicate if the item was delivered by mail order; and (5) submit documentation about the acquisition cost and mode of delivery for the catheters provided for the specific claim. We did not independently verify the accuracy of the information that suppliers reported about whether the catheter had specific features.

We consulted with suppliers and manufacturers before selecting the specific features to focus on when collecting data from the suppliers in our sample. We spoke with stakeholders including suppliers, their trade association, manufacturers, and beneficiary organizations about potential access concerns. We asked which features of intermittent urinary catheters may increase acquisition costs for suppliers and may be more desirable for beneficiaries. Due to sample size limitations and to reduce the burden upon suppliers in our sample, we decided to focus data collection on three features of catheters that emerged as potentially associated with higher acquisition costs (i.e., hydrophilic coating, gripping aids, and protective sleeves).

We obtained a 97-percent weighted response rate. Of the 157 suppliers associated with our sampled claims, 155 responded. These 155 responding suppliers provided documentation for 574 of the 600 sampled claims. The stratum-specific response rates were 98 percent for straight tip catheters, 99 percent for curved tip catheters, and 91 percent for sterile kit catheters. Together, after weighting by the relative number of claims in the population, these responses were representative of 97 percent of the population. We made at least three attempts to obtain acquisition cost information from the suppliers associated with the claims in our sample (e.g., emails, phone calls, and traditional mailings).

Illustrative Analysis of Other Costs

To better understand Medicare's potential for savings, we considered other costs in addition to acquisition cost. We used a third-party report to calculate an example of these other costs and the potential for Medicare cost savings. To perform our illustrative analysis of other costs, we used the values from the report and multiplied our estimate of acquisition costs by approximately 0.724 (i.e., we multiplied by $42/58$, because the report estimated other costs as 42 percent of costs and acquisition costs as 58 percent of costs).

In our report, we described the ratio as \$1.00 in acquisition costs and \$0.72 in other costs, which approximates the percentage values from the third-party report. We used the monetary example because it may be easier for readers to understand, and we note that 0.72 is nearly the same value as 42 percent divided by 58 percent, or approximately 0.724.

We opted to use this ratio to provide a conservative example of the potential for savings and profits, although other ratios may be more appropriate to use. For example, in 1999, CMS attempted to use a markup of 67 percent, which it described as the upper end of a range of acceptable markups. Such markups would account for both other costs and profits. The ratio we use is marginally higher than this markup, but it does not include profits, making it more conservative. As we noted in our

report, the \$0.72 estimate came from an industry-commissioned report and likely overstates suppliers' other costs for intermittent urinary catheters; with this being the case, our illustrative analysis likely underestimates the opportunity for savings.

Additional Sources of Information

Interview of CMS

We conducted interviews with CMS to better understand CMS's opportunities and challenges associated with obtaining cost savings for intermittent urinary catheters. For example, during our interview with CMS, we asked whether and how it might take steps to address potential concerns about beneficiary access to intermittent urinary catheters if payment rates were reduced.

Additional Data Obtained from Medicare Claims

Utilization in Former Competitive Bidding Areas

We classified each claim for intermittent urinary catheters in FY 2020 according to its geographic area. We used CMS's DMEPOS Fee Schedule file available on CMS's website, which includes two zip code files.³⁸ This file allowed us to classify each claim as occurring in a former competitive bidding area (CBA) and non-competitive bidding area (non-CBA). We used the former CBA zip code file to identify claims from CBAs, and we classified claims from all other zip codes as occurring in non-CBAs. Additionally, we used the rural zip code file to identify which claims in non-CBAs came from a rural area.

Identification of Beneficiary Health Conditions

We identified if a beneficiary had a spinal cord injury or a neurological condition using information from CMS's integrated data repository. Specifically, we used the hierarchical condition categories (HCC) that CMS assigns to each Medicare beneficiary for risk adjustment scoring.³⁹ CMS assigns each beneficiary to applicable HCC groups on the basis of the diagnosis codes included in Medicare claims for that beneficiary. After obtaining the HCC data for each beneficiary in the population, we used CMS's

³⁸ CMS, *DMEPOS Fee Schedule*. Accessed at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSFeeSch/DMEPOS-Fee-Schedule> on January 23, 2022.

³⁹ CMS, *Medicare Advantage Rates & Statistics: Risk Adjustment*. Accessed at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors> on February 18, 2022.

categorization of HCC groupings to determine if the beneficiary had a spinal injury or neurological condition.⁴⁰

Analyzing the Data

We determined supplier acquisition costs on a per-unit basis and projected this to the population of claims.

We determined the dollar differences between Medicare-allowed amounts and supplier acquisition costs in the population using our sample of claims. To estimate the beneficiary responsibility, we attributed 20 percent of the allowed amount to beneficiaries. Medicare Part B covers the cost of DMEPOS items, and after beneficiaries pay their annual deductible, Medicare pays for 80 percent of the allowed amount and beneficiaries pay the remaining 20 percent.

Overall and for each HCPCS code, we estimated the acquisition costs including 95-percent confidence intervals. We used the estimates of average acquisition costs to determine the cost differences that Medicare and beneficiaries paid compared to supplier acquisition costs. We also used these estimates of average acquisition costs for each billing code when performing the illustrative analysis. Additionally, we estimated acquisition costs and 95-percent confidence intervals for intermittent urinary catheters according to the presence of specific features.

⁴⁰ CMS's HCC categorization defined the "spinal" grouping (which we referred to as spinal cord injury) to include HCCs 70, 71, and 72, which captured the following conditions: quadriplegia and other extensive paralysis; paraplegia; and spinal cord disorders/injuries, including spina bifida. CMS's HCC categorization defined the "neurological" grouping (which we referred to as neurological conditions) to include HCCs 73 through 80, which captured the following conditions: amyotrophic lateral sclerosis and other motor neuron disease; cerebral palsy; myasthenia gravis/myoneural disorders and Guillain-Barré syndrome/inflammatory and toxic neuropathy; muscular dystrophy; multiple sclerosis; Parkinson's and Huntington's diseases; seizure disorders and convulsions; and coma, brain compression/anoxic damage.

APPENDICES

Appendix A: Data Summaries, Cost Estimates, and 95-Percent Confidence Intervals

Exhibit A-1. Prevalence of certain medical conditions among beneficiaries who utilized intermittent urinary catheters, from October 2019 through September 2020

	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353	Total
Have Either Condition (Count)	29.6% (25,187)	18.5% (6,311)	60.5% (4,185)	28.0% (34,383)
Neurological Condition (Count)	15.3% (13,025)	11.0% (3,734)	19.7% (1,362)	14.3% (17,588)
Spinal Cord Injury (Count)	17.9% (15,215)	9.6% (3,262)	50.0% (3,459)	17.1% (20,999)
Do Not Have a Neurological Condition or Spinal Cord Injury (Count)	70.4% (59,927)	81.5% (27,720)	39.5% (2,729)	72.0% (88,321)
Count of Total Beneficiaries*	85,114	34,031	6,914	122,704

Source: OIG analysis of Medicare claims.

*Note: Information on medical conditions was not available for 30 out of 122,734 beneficiaries. Subtotals may not sum to totals due to overlap among subgroups. For example, one beneficiary may receive intermittent urinary catheters in different billing categories. Additionally, 4,204 beneficiaries had both a spinal cord injury and a neurological condition.

Exhibit A-2. Beneficiary characteristics in the sample were similar to those in the population.

Characteristics	Percentage of Beneficiaries with the Characteristic		
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353
Beneficiaries with Spinal Cord Injury or Neurological Condition			
Sample	33%	18%	67%
Population	30%	19%	61%
Male			
Sample	60%	97%	64%
Population	61%	98%	66%
Female			
Sample	40%	3%	36%
Population	39%	2%	34%

Source: OIG analysis of Medicare claims with a date of service from October 2019 through September 2020, and OIG analysis of beneficiaries included in our sample of claims, n = 574.

Note: There were 570 unique beneficiaries included in the 574 claims for which we received a response.

Exhibit A-3. Estimated acquisition costs for Medicare Part B, October 2019 through September 2020

	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353	Total
Estimated Cost	\$55,533,973	\$46,886,664	\$18,735,692	\$121,156,329
95-Percent Confidence Interval	(\$51,259,285, 59,268,548)	(\$43,280,464, 50,313,539)	(\$17,536,337, 19,947,583)	

Source: OIG estimated the total acquisition costs by multiplying the total number of units for each category by the estimated acquisition cost per unit. OIG determined the total number of units using Medicare claims data and estimated the acquisition cost per unit using documentation from suppliers in our sample of claims, n = 574.

Exhibit A-4. The differences between Medicare payment rates and supplier acquisition costs were more substantial for curved tip catheters and sterile kits compared to straight tip catheters.

	Billing Codes for Intermittent Urinary Catheters		
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353
Medicare Payment Rate per Unit	\$1.98	\$6.98	\$8.04
Estimated Acquisition Cost per Unit	\$0.69	\$1.73	\$2.56
Difference per Unit	\$1.29	\$5.25	\$5.48

Source: OIG analysis using Medicare claims and information from suppliers in our sample of claims, n = 574.

Note: The 95-percent confidence intervals for the estimated acquisition cost were \$0.64 to \$0.74 for straight tip catheters, \$1.60 to \$1.86 for curved tip catheters, and \$2.40 to \$2.73 for sterile kit catheters.

Exhibit A-5. Estimated proportion of intermittent urinary catheters with specific features, by billing code

Features of Sampled Catheters	Billing Codes for Intermittent Urinary Catheters		
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353
Have Any of These Features (95-Percent Confidence Interval)	54.3% (47.2, 61.2%)	55.6% (48.6, 62.4%)	73.2% (66.2, 79.1%)
Hydrophilic Coating (95-Percent Confidence Interval)	46.3% (39.4, 53.3%)	51.0% (44.1, 57.9%)	58.7% (51.4, 65.6%)
Grip (95-Percent Confidence Interval)	15.5% (11.0, 21.3%)	20.6% (15.5, 26.8%)	27.4% (21.4, 34.4%)
Sleeve (95-Percent Confidence Interval)	20.9% (15.8, 27.2%)	14.2% (10.0, 19.8%)	43.0% (36.0, 50.4%)
Do Not Have These Features (95-Percent Confidence Interval)	45.7% (38.8, 52.8%)	44.4% (37.6, 51.4%)	26.8% (20.9, 33.8%)

Source: OIG estimates used Medicare claims data and data from suppliers in our sample of claims, n = 574.

Exhibit A-6. Estimated acquisition costs per unit were higher for catheters that had specific features compared to those that did not have any of these features.

Features of Sampled Catheters	Billing Codes for Intermittent Urinary Catheters		
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353
Have Any of These Features (95-Percent Confidence Interval)	\$0.94 (\$0.88, 0.99)	\$2.07 (\$1.92, 2.22)	\$2.71 (\$2.51, 2.91)
Hydrophilic Coating (95-Percent Confidence Interval)	\$1.01 (\$0.97, 1.06)	\$2.09 (\$1.94, 2.25)	\$2.88 (\$2.65, 3.11)
Grip (95-Percent Confidence Interval)	\$0.93 (\$0.82, 1.03)	\$2.32 (\$2.04, 2.59)	\$3.06 (\$2.69, 3.43)
Sleeve (95-Percent Confidence Interval)	\$0.85 (\$0.75, 0.96)	\$2.29 (\$1.97, 2.61)	\$2.91 (\$2.66, 3.17)
Do Not Have These Features (95-Percent Confidence Interval)	\$0.40 (\$0.37, 0.44)	\$1.32 (\$1.13, 1.51)	\$2.12 (\$1.88, 2.37)

Source: OIG estimates used Medicare claims data and data from suppliers in our sample of claims, n = 574.

Note: For each of the three categories of catheters, acquisition costs were significantly lower for items without features when compared to items with any feature (p<0.0001, p<0.0001, and p=0.0003 respectively).

Exhibit A-7. Estimated proportion of intermittent urinary catheters with multiple features, by billing code

Number of Features	Billing Codes for Intermittent Urinary Catheters		
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353
Three Features (95-Percent Confidence Interval)	7.8% (4.7, 12.5%)	8.9% (5.7, 13.8%)	14.4% (10.0, 20.4%)
Two Features (95-Percent Confidence Interval)	12.7% (8.7, 18.1%)	12.5% (8.6, 17.9%)	26.0% (20.1, 32.9%)
One Feature (95-Percent Confidence Interval)	33.9% (27.5, 40.8%)	34.2% (27.9, 41.0%)	32.8% (26.3, 39.9%)
None (95-Percent Confidence Interval)	45.7% (38.8, 52.8%)	44.4% (37.6, 51.4%)	26.8% (20.9, 33.8%)

Source: OIG estimates used Medicare claims data and data from suppliers in our sample of claims, n = 574.

Note: We asked suppliers if the catheters provided on the claim had certain features, specifically a hydrophilic coating, a grip, or a sleeve.

Exhibit A-8. Estimated acquisition costs per unit were higher for catheters with multiple features compared to those that did not have features.

Number of Features	Billing Codes for Intermittent Urinary Catheters		
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353
Three Features (95-Percent Confidence Interval)	\$1.04 (\$0.91, 1.18)	\$2.45 (\$2.05, 2.86)	\$3.34 (\$2.82, 3.86)
Two Features (95-Percent Confidence Interval)	\$0.94 (\$0.84, 1.03)	\$2.30 (\$1.97, 2.63)	\$3.04 (\$2.74, 3.34)
One Feature (95-Percent Confidence Interval)	\$0.92 (\$0.84, 0.99)	\$1.88 (\$1.71, 2.05)	\$2.15 (\$1.92, 2.39)
None (95-Percent Confidence Interval)	\$0.40 (\$0.37, 0.44)	\$1.32 (\$1.13, 1.51)	\$2.12 (\$1.88, 2.37)

Source: OIG estimates used Medicare claims data and data from suppliers in our sample of claims, n = 574.

Note: We asked suppliers if the catheters provided on the claim had certain features, specifically a hydrophilic coating, a grip, or a sleeve. Only some types of catheters had statistically significant differences in acquisition costs. For both straight tip and curved tip catheters, those items with one or more feature were significantly more expensive than items with none of these features; $p < 0.0001$ and $p < 0.0001$, respectively. For sterile kit catheters, those items with two or more features were significantly more expensive than items with one or none of these features ($p < 0.0001$).

Exhibit A-9. The illustrative analysis of other supplier costs plus acquisition costs found approximately \$198 million in potential savings and profits.

Type of Expense (in Millions)	Billing Codes for Intermittent Urinary Catheters			Total
	Straight Tip A4351	Curved Tip A4352	Sterile Kit A4353	
Medicare Payments	\$158.7	\$189.1	\$58.9	\$406.7
Example of Total Costs	\$95.7	\$80.8	\$32.3	\$208.9
Estimated Acquisition Costs	\$55.5	\$46.9	\$18.7	\$121.2
Example of Other Costs	\$40.2	\$34.0	\$13.6	\$87.7
Potential Savings and Profits (Medicare Payments – Example of Total Costs)	\$63.0	\$108.3	\$26.6	\$197.8

Source: OIG analysis using acquisition costs from suppliers in our sample of claims (n = 574) and an example of other costs.

Note: Because of rounding, the numbers may not sum. The illustrative analysis uses an example of other costs that we obtained from a third-party report and assumes that for every dollar spent in acquisition cost, suppliers spent an additional 72 cents in other costs.

Appendix B: Agency Comments

Following this page are the official comments from CMS.

*Administrator*

Washington, DC 20201

DATE: August 11, 2022

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure *Chiq B LaS*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Reducing Medicare's Payment Rates for Intermittent Urinary Catheters Can Save the Program and Beneficiaries Millions of Dollars Each Year (OEI-04-20-00620)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. One of the ways in which we do this is by protecting our programs' sustainability for future generations by serving as a responsible steward of public funds.

The DMEPOS Competitive Bidding Program has been an essential tool to help Medicare set market-based payment rates for DMEPOS items, save money for beneficiaries and taxpayers, and limit fraud and abuse in the Medicare Program. The program has saved billions of dollars since implementation while safeguarding access to quality items and services. Under the DMEPOS Competitive Bidding Program, DMEPOS suppliers compete to become Medicare contract suppliers by submitting bids to furnish certain items in competitive bidding areas. The statute requires that single payment amounts replace the current Medicare DMEPOS fee schedule payment amounts for competitively bid DMEPOS items and services furnished in competitive bidding areas of the country. The single payment amounts are determined by using bids submitted by DMEPOS suppliers.

At this time, intermittent urinary catheters have not been included in the DMEPOS Competitive Bidding Program. CMS stated in the 2007 Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies and Other Issues final rule that we believe we have discretion to interpret section 1847(a)(2)(A) of the Social Security Act (the Act) to include or exclude ostomy products and supplies in the competitive bidding programs.¹ In the 2007 final rule, we stated that while we were not exercising our authority to include ostomy items in the DMEPOS Competitive Bidding Program at that time, we would continue to review this issue. Therefore, at a minimum, CMS would need to address section 1847(a)(2)(A) of the Act and

¹Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues; Final Rule (72 FR 17991) (04/10/2007). Accessed at: <https://www.govinfo.gov/content/pkg/FR-2007-04-10/pdf/07-1701.pdf#page=94>

ostomy products and supplies through further notice and comment rulemaking before including intermittent urinary catheters in the DMEPOS Competitive Bidding Program.

As OIG notes, another mechanism that CMS may utilize to reduce Medicare payment for intermittent urinary catheters is the inherent reasonableness process, which is a process for establishing a realistic and equitable payment amount for Medicare Part B services (other than physicians' services) when the existing payment amounts are inherently unreasonable because they are either grossly excessive or grossly deficient. Sections 1842(b)(8) and (9) of the Act and our regulations at 42 CFR 405.502(g) and (h) set forth the steps that the Secretary must follow in determining whether a payment amount is grossly excessive and in setting a special payment limit. This process also includes a public notice and comment period regarding the proposed payment amount or method proposed to be established.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS lower Medicare's payment rates for intermittent urinary catheters.

CMS Response

CMS thanks OIG for the work done on this issue. We will consider the OIG's recommendation when determining appropriate next steps. As stated above, one of the mechanisms available to lower Medicare's payment rates for intermittent urinary catheters, inclusion in the DMEPOS Competitive Bidding Program, would, at a minimum, require notice and comment rulemaking. The inherent reasonableness process, the other mechanism for lowering Medicare payment rates, requires the use of valid and reliable data. CMS would need to consider what steps may be necessary to obtain data necessary to determine whether the Medicare fee schedule amounts are grossly excessive and to determine what realistic and equitable payments would be for these items. CMS notes that any policies established as a result of rulemaking or the inherent reasonableness process would ultimately determine any potential savings for the Medicare program and beneficiaries.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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This report was prepared under the direction of Dwayne Grant, Regional Inspector General for Evaluation and Inspections in the Atlanta regional office; Evan Godfrey, Deputy Regional Inspector General; and Jaime Stewart, Assistant Regional Inspector General.

Contact

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ABOUT THE OFFICE OF INSPECTOR GENERAL

The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These audits help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

The Office of Evaluation and Inspections (OEI) conducts national evaluations to provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. These evaluations focus on preventing fraud, waste, or abuse and promoting economy, efficiency, and effectiveness of departmental programs. To promote impact, OEI reports also present practical recommendations for improving program operations.

The Office of Investigations (OI) conducts criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs, operations, and beneficiaries. With investigators working in all 50 States and the District of Columbia, OI utilizes its resources by actively coordinating with the Department of Justice and other Federal, State, and local law enforcement authorities. The investigative efforts of OI often lead to criminal convictions, administrative sanctions, and/or civil monetary penalties.

The Office of Counsel to the Inspector General (OCIG) provides general legal services to OIG, rendering advice and opinions on HHS programs and operations and providing all legal support for OIG's internal operations. OCIG represents OIG in all civil and administrative fraud and abuse cases involving HHS programs, including False Claims Act, program exclusion, and civil monetary penalty cases. In connection with these cases, OCIG also negotiates and monitors corporate integrity agreements. OCIG renders advisory opinions, issues compliance program guidance, publishes fraud alerts, and provides other guidance to the health care industry concerning the anti-kickback statute and other OIG enforcement authorities.