Competitive Bidding:
Pressure Sore, Urological and Diabetes Equipment & Supplies

The Expanded Case for Medicare Investment in DME in 2022

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For the past decade, we have studied and reported on Medicare spending on durable medical equipment (DME)[1]. Our goal, starting in 2011, was to determine how successful the Centers for Medicare and Medicaid Services (CMS) was in providing Medicare beneficiaries with DME that they needed to avoid or minimize illness and injury. In particular, we wanted to understand the impact of the DMEPOS Competitive Bidding Program on Medicare beneficiaries and the suppliers of DME to beneficiaries, a program which effectively launched that same year.

Competitive bidding was mandated by Congress through the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The statute required that Medicare construct a competitive bidding process for selected Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) items. The intent was to save Medicare program money by reducing Medicare payments and decrease beneficiary out-of-pocket expenses for DME, all while ensuring continued beneficiary access to quality items and services. The reality was a series of price cuts imposed by CMS in an attempt to squeeze every dollar they could out of the system, often without due regard to the needs of their Medicare beneficiaries or the realities of the DME marketplace.

By the end of the decade, competitive bidding had effectively stalled out. The 2019 round was 'delayed'[2] as the program approached what may be its natural end – CMS was no longer able to effectively squeeze more cost out of the system. The 2021 round, characterized in the trade as a 'failed round'[3], was limited to only two product categories—off-the-shelf (OTS) back braces and OTS knee braces.

To understand the impact of competitive bidding in our previous studies, we focused on three large bundles of DME: mobility equipment (e.g., wheelchairs, walkers and power chairs) to avoid falls; oxygen therapy equipment to counter symptoms of COPD; and continuous positive airway pressure equipment to treat obstructive sleep apnea (OSA). In four studies conducted over the decade, we looked at Medicare spending to provide these categories of DME to Medicare beneficiaries in need and also at Medicare spending to treat fall injuries, COPD, OSA and related exacerbations.

Each time we analyzed the data, we saw that CMS was spending orders of magnitude more on treating these injuries and illnesses after the fact than it spent on proactively providing

preventative DME that could minimize or eliminate the massive treatment spending in the first place. We concluded that when DME is not provided, Medicare incurs substantially greater costs to treat the range of medical complications that result from not having the needed DME. Over the decade of competitive bidding, we found that the treatment costs continued to soar as CMS progressively forced DME prices down further in each new round of competitive bidding.[4]

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As CMS forced prices down and treatment costs continued to rise, the power of a dollar spent on preventative DME became ever more powerful. Yet despite this evidence, CMS continues to spend its budget dollars on treating the very illnesses and injuries that could be avoided if they would just invest in providing the right DME to beneficiaries before they need it.

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In this study, we have expanded the range of DME to include three additional categories of Medicare spending that are significant to Medicare beneficiaries: equipment and supplies to prevent pressure sores (also referred to as pressure ulcers, bedsores or pressure injuries); catheters and related urological supplies to resolve urine retention and incontinence; and diabetic test strips and meters to monitor blood glucose levels.

Pressure sores, urinary complications and diabetes negatively impact the health and wellbeing of millions of Medicare beneficiaries and their treatment costs Medicare billions each year:

- We estimate that over 1 million Medicare beneficiaries are annually diagnosed with a pressure sore and that half of those are hospitalized at some point.[5] Medicare spending on treating pressure sores for 2022 will be $11.6 Billion.[6] Beneficiaries will bear an additional $3.5 Billion in deductibles and copays.[7] On top of these numbers, acute care hospitals will incur between $2.5-$5.0 Billion in costs absorbed for hospital-acquired pressure injuries (HAPIs)[8], costs that were imposed on them starting in 2009 when CMS stopped reimbursing for HAPIs. CMS effectively blamed hospitals for pressure injuries that arose during a beneficiary's hospital stay and forced them to find ways to minimize or eliminate pressure sore formation.

- Voiding or urinating is a fairly complex neurologically controlled process. Any factors that interfere with the neurologic control of the voiding process can result in urinary retention or urinary incontinence. Significantly more prevalent in men than women, urinary retention problems also dramatically increase with age. Urinary retention is the inability to void voluntarily despite a full, distended bladder. Retention can be ether acute or chronic. Acute urinary retention commonly presents in the emergency department, most often in older men with benign prostatic hypertrophy (BPH), commonly known as an enlarged prostate. Chronic urinary retention develops gradually and can worsen over

time. People with chronic urinary retention can urinate, but they just can't empty their bladders completely. In either case, the first line of treatment for urinary retention is catheterization. To date, research has shed light on the causes, diagnoses and procedures for treatment of urinary retention but no studies with any currency have looked at the cost to treat urinary retention or the impact on Medicare spending.

Urinary incontinence is the partial or complete loss of urine control. Urinary incontinence is significantly more prevalent in men than in women. Urinary incontinence has a particularly significant impact on long-term care facilities and is one of the main reasons for the admission of elderly people in institutionalized care. Treatments include behavioral therapy, surgery, medication and the use of absorbent products. The bulk of absorbent products for adult incontinence account for between $3-4 Billion annually in the U.S. and are sold directly to consumers through traditional retail channels with no prescription required. Medicare and private insurers do not consider these products to be reimbursable DME.

- Some 37 million U.S. adults (11.3% of the total U.S. population) have been diagnosed with diabetes.[9] Another 8.5 million (2.6%) have diabetes but remain undiagnosed.[10] Two and one-half times those percentages of Medicare beneficiaries suffer with diabetes.[11] In 2022, the U.S. healthcare system will spend approximately $250 Billion treating diabetes.[12] Medicare will bear the brunt of that spending, approximately $153.6 Billion.[13] Beneficiaries will spend an additional $45.9 Billion.[14] On average, people with diagnosed diabetes have medical expenditures approximately 2.3 times higher than what expenditures would be in the absence of diabetes.[15]

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In our 2021 study, we acknowledged that investing in DME alone was not sufficient to achieve the full potential of savings in Medicare spending. We recommended that CMS concurrently invest in screening, identification and education programs to help providers find beneficiaries in need before the massive treatment costs started to accrue. While we were not certain exactly how much it might cost CMS to develop an effective set of tools and promotional materials for such programs, we recommended that a good starting point would be to spend an amount that equaled what it was currently spending on providing the needed DME.[16] The same approach will apply to the new categories we are including in this study.

Pressure Sores and Pressure Relief Supplies and Equipment

Medicare beneficiaries require care for a wide range of chronic wounds. Every year nearly 15% receive treatment for arterial ulcers; chronic ulcers; diabetic foot ulcers; diabetic infections; bedsores; skin disorders and infections; surgical wounds and infections; traumatic wounds; and venous ulcers and infections.[17] While there is some overlap that is difficult to define, we estimate that Medicare spends about 1/3 of its total wound care payments on pressure sores.[18]

Pressure sores, also known as pressure ulcers or bedsores and broadly as pressure injuries, are caused by continuous pressure and friction on bony prominences, areas where bones are close to the skin. The pressure results in reduced blood flow to the area. Since most people rest on their backsides in either the lying or sitting position when they are ill or injured and their mobility is limited, pressure sores typically form in areas that protrude from the patient's back side, including the back of the head, the shoulder blades, elbows, hips, the tailbone and the heels of the feet. When pressure on the skin is continuous for any significant period of time, tissue begins to necrose, ultimately breaking the skin surface, becoming infected and painful and eventually life-threatening.

Pressure sores are present over the entire range of treatment settings: hospital inpatient; skilled nursing facilities; home health; hospital outpatient; and hospice. In all these settings, pressure sores are avoidable. The simple solution to avoid formation and exacerbation of pressure sores is to relieve pressure. This can be achieved by regimented turning and moving programs and the use of a range of wound care DME designed to reduce pressure, protect vulnerable or wounded areas of the skin or assist in regularly moving the patient. Wound care DME includes a broad range of wound dressings; support surfaces including pressure-reducing and low-air loss mattresses, beds, overlays and pads; negative pressure wound therapy technology; wound suction technology; and air fluidized beds.

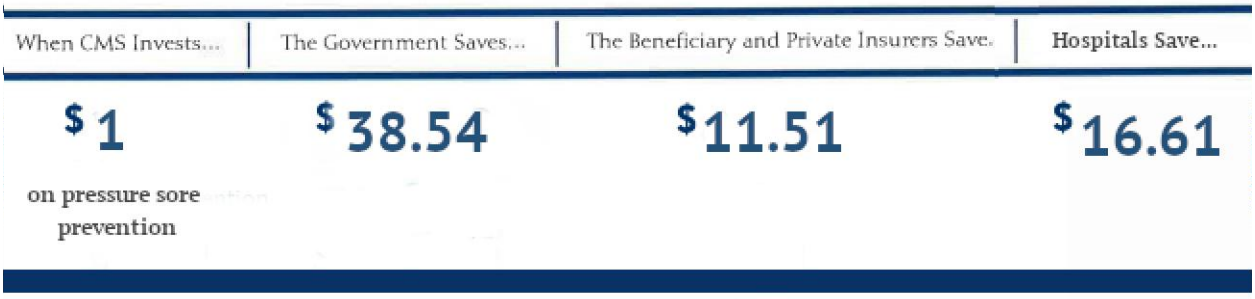
In 2022, Medicare will spend at least $11.6 Billion treating pressure sores for over one million Medicare beneficiaries.[19] Those beneficiaries will bear an additional 23% (in deductibles and

copays), equal to at least $3.5 Billion.[20] Approximately 25% of that spending will be for hospital inpatient treatment. The remaining 75% will be spread across all outpatient settings.[21]

Medicare and beneficiary spending would be significantly higher, but for a decision that shifted the cost burden of hospital-acquired pressure injuries (HAPIs) to the acute care hospitals. Reasoning that it should not have to pay for preventable pressure injuries not present upon admission to acute care settings, CMS in 2009 stopped reimbursing for HAPIs. CMS placed the burden on the hospitals to either bear the cost of those wounds or find ways to improve quality by minimizing or eliminating pressure sore formation. We estimate that the 2022 cost that acute care hospitals will absorb will be an additional $2.5-$5.0 Billion.[22]

In 2022, we project the CMS will spend $450 Million providing wound care DME for all types of chronic wounds. While CMS does not break out DME spending by type of chronic wound, we estimate that approximately 1/3 of that amount, $150 Million, will be specifically allocated for pressure sore-related DME.[23]

Again, recognizing that virtually all pressure sores are avoidable, it makes sense for CMS to increase its investment in DME and in prevention tools and programs. Using our recommendation that CMS spend at least as much on prevention tools and programs as it spends on providing DME (i.e., another $150 Million), the total annual spending would be $300 Million. In other words, for each additional $1 CMS invests in wound prevention DME and related tools and programs, it stands to return $38.54 in reduced or avoided treatment costs. Beneficiaries could receive an additional benefit of $11.51. Hospitals could reduce their burden by some $16.61. This brings the total potential return for the U.S. healthcare system to $66.65 for every $1 invested.



As we said earlier, investing in DME alone is not sufficient to achieve the full potential of savings in Medicare spending on pressure sore treatment. CMS needs to concurrently invest in screening, identification and education programs to help providers find beneficiaries in need before pressure sores become a problem. The literature reveals examples of programs designed to significantly reduce pressure sore formation and progression across the healthcare spectrum.[24] For HAPIs, examples of programs designed to reduce incidence include one developed by the Agency for Healthcare Research and Quality to reduce hospital-acquired pressure injuries by more than 60 percent. The program, the Hospital Pressure Ulcer Training Program, provided an AHRQ toolkit called Preventing Pressure Ulcers in Hospitals: A Toolkit for Improving Quality of

Care.[25] Another study shows reductions of 40% in value-based programs focused on reducing HAPIs.[26] Overall, CMS has a wide range of existing programs from around the world to choose from and the opportunity to develop even more effective tools with the goal of eliminating pressure sores.

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To date, we have been able to place a dollar value on the potential savings for Medicare investments in the DME categories we have studied. That was in large part due to our ability to establish a direct nexus between the DME being provided and the illnesses and injuries that resulted from not providing that DME in a timely manner and the availability of solid, recent data showing Medicare spending on DME and on treatment of the underlying illnesses and injuries. *But for* the DME, some very defined problems arose that required medical treatment and incurred a defined set of costs and Medicare payments.

That nexus is not as direct for the next two categories we will consider. In the case of diabetes, the '*but for*' test doesn't really work. In the case of urinary retention and incontinence, the '*but for*' test doesn't always work and solid, recent treatment spending has not been reported. While we know that a case can be made for DME saving significantly more in treatment spending than it costs to provide, the nexus is simply not direct enough to allow us to draw quantitative conclusions on the power of DME investment.

So rather than try and develop an actual dollar value for the potential savings for Medicare investments in these categories, we will frame the problem and the opportunity and discuss the relationship between the DME and the illnesses and injuries that occur. We will share as much numerical information as we have been able to uncover and we will leave it to DME suppliers, beneficiaries and CMS to find the right balance between providing DME and spending on treatment. Suffice it to say that in both categories, there is a huge cost for treatment and the DME provide will return some level of savings to CMS and beneficiaries.

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Urinary Retention and Urological Supplies to Relieve Urinary Retention and Urinary Incontinence

Voiding or urinating is a fairly complex neurologically controlled process. Any factors that interfere with the neurologic control of the voiding process can result in voiding dysfunction, which typically manifests itself in urinary retention. Significantly more prevalent in men than women, urinary retention problems also dramatically increase with age.

Urinary retention is defined as the inability to void voluntarily despite a full, distended bladder. Retention can be ether acute or chronic. Acute urinary retention occurs when someone cannot urinate. This typically causes significant pain and discomfort and usually presents in the emergency department. Acute urinary retention most often presents in older men with benign prostatic hypertrophy (BPH), commonly known as an enlarged prostate. Approximately 10% of men in their 70's and 33% of men in their 80's present with at least one episode of acute urinary retention in emergency department settings. Patients presenting with acute urinary retention are often in severe pain and require urgent diagnosis and prompt treatment.[27]

Chronic urinary retention develops gradually and can worsen over time. People with chronic urinary retention can urinate, but they just can't empty their bladders completely[28]. Chronic urinary retention is almost always caused by another medical condition[29]. In men, it could be caused by prostate surgery for BPH and in women, complications from surgery for stress urinary incontinence and pelvic organ prolapse[30]. In both sexes, it can be caused by urethral strictures, pelvic masses, neurogenic damage (to nerves that innervate the bladder in conditions such as multiple sclerosis, spinal cord injury and spina bifida) or myogenic damage (to the smooth muscle of the bladder)[31]. In any case, the first line of treatment for urinary retention is to empty the bladder by catheterization. 41.3% of patients with neurogenic lower urinary tract dysfunction perform intermittent catheterization, making it the most common method of bladder drainage. 11% of patients with multiple sclerosis perform intermittent catheterization.[32]

Intermittent catheters are used to drain the bladder at certain intervals throughout the day; they do not remain inserted in the bladder. Intermittent catheterization involves the temporary insertion of a catheter via the urethra into the bladder to achieve bladder emptying or via a surgically created stoma and is the preferred method of bladder management among individuals

with urinary retention. Intermittent self-catheterization should be performed at regular intervals through the day, e.g., every 4-6 hours (4-6 times per day) to keep the amount of urine in the bladder less than 400-500mL.

There are two major types of intermittent catheters, uncoated and coated (with a slippery hydrophilic, silicone or Teflon surface coating) to make insertion and withdrawal touch-free, easier and more comfortable. Until the early 1980's, intermittent catheters were uncoated and a lubricating gel was applied before insertion. These catheters were reused after washing and were replaced after multiple uses. Today, sterile, single-use catheters are preferred. Prior to insertion, they can be immersed in a saline solution to facilitate safe and smooth insertion. Hydrophilic coated catheters have been shown to reduce catheter-related urinary tract infections by up to over 60%[33]. Medicare pays for up to 200 single-use catheters per month.[34] In 2020, Medicare payments covered 115 million single-use catheters at a cost of $317 Million.[35] Medicare beneficiaries and insurers spent another $94 Million.[36]

Catheters that are left in the bladder are known as indwelling urinary catheters and some individuals use this method of bladder emptying throughout their lifetime. Most often, indwelling catheters are used in acute care hospital settings where patients have a need for bladder emptying assist for some extended period of time while recovering from illness, injury or surgery. When recovery progresses, patients can either regain normal bladder emptying or switch over to intermittent catherization when needed. In 2020, Medicare payments covered just over 235,000 indwelling catheters at a cost of $4.3 Million.[37] Medicare beneficiaries and insurers spent another $1.5 Million.[38]

A much less frequently used category of catheters are external urinary catheters. They are urine collection devices with tubing that use either gravity or suction to drain urine away from the urethral opening. External catheters are not inserted into the body and are contraindicated for those with urinary retention. They are mostly prescribed for urinary incontinence. In 2020, Medicare payments covered 3.2 million external catheters at a cost of $5.6 Million.[39] Medicare beneficiaries and insurers spent another $2 Million.[40]

Category	2020 Units Covered	Medicare Payments	Beneficiary/Insurer Payments
Intermittent	115,000,000	$317 Million	$94 Million
Indwelling	235,000	$4.3 Million	$1.5 Million
External	3,200,000	$5.6 Million	$2.0 Million

Summary: 2020 Medicare Catheter Usage and Cost

The way CMS handles two issues of critical importance to Medicare beneficiaries (caps on the number of intermittent catheters for which CMS will reimburse and its failure to distinguish between pricing for uncoated and coated intermittent catheters) is particularly troubling.

We know Medicare limits reimbursement to 200 intermittent catheters per month. This cap is an impediment to beneficiary planning; beneficiaries are forced to develop contingency plans to address possible delayed shipments, lost or damaged products, accelerated catheter "burn" rates and normal fluctuations in lifestyle that may require higher usage rates. Stockpiling by reducing the number of catheters used is not uncommon. CMS needs to provide effective mechanisms to accommodate these fluctuations.

Controversially, Medicare codes the higher-priced coated catheters the same as uncoated catheters and reimburses the same amount as the less expensive uncoated catheters. This results in an impediment to access for Medicare beneficiaries. CMS pays one price for any product within the specified code regardless of quality. Accordingly, Medicare beneficiaries are constrained to pick a catheter at or under the CMS price point. CMS focuses on providing the minimally appropriate system that safely supports the strictly physiological function of urination. This makes it extremely difficult for beneficiaries to take charge of their bladder health and navigate their way to a catheterization solution that optimizes their personal needs.

Manufacturers have petitioned CMS on multiple occasions to expand coding to create differential coding for sterile, single-use coated catheter, citing the numerous studies that show significant reductions in urinary tract infections and the lower cost of treating those infections by using coated intermittent catheters.[41] An increasing number of studies report a lower incidence of urinary tract infections using hydrophilic versus uncoated catheters. Despite the significant opportunity for cost savings that promoting the use of single-use coated catheters would provide, CMS has denied these petitions, stating that the current codes were adequate. The codes remain unchanged.

Contrary to the impression created by the reimbursement codes, the technology behind intermittent catheters is under constant evolution, incorporating features to reduce the risk of infection and to enhance user comfort and convenience. The current US health care system, through its reimbursement policies, endorsing the minimally appropriate system that safely supports the strictly physiological function of urination. This makes it extremely difficult for people to take charge of their bladder health and navigate their way to a catheterization solution that is optimizes their personal needs.

Urinary incontinence is the loss of urine control. Symptoms can vary from slight leakage of urine, to not having any control, or feeling strong urges to urinate. Urinary incontinence is significantly more prevalent in men than in women. Urinary incontinence has a particularly significant impact on long-term care facilities and is one of the main reasons for the admission of elderly people in institutionalized care.

Treatments for urinary incontinence include behavioral therapy, surgery, medication and the use of absorbent products. The market for absorbent products for adult incontinence is between $3-4 Billion annually in the U.S. They are sold directly to consumers through traditional retail channels with no prescription required. Absorbent products are the primary product for managing urinary incontinence that might be considered to be DME but Medicare and private

insurers do not consider these products to be reimbursable. Incontinent adults who qualify for Medicaid, however, may be eligible to have a small percentage of the cost for at-home disposable hygiene supplies covered through that program.

Attempts to place a dollar value on the savings that CMS and beneficiaries could realize from investing in urinary retention and incontinence-related DME have not been fruitful. The nexus, embodied in the '*but for*' test (*but for* the DME, some very defined problems will arise that require medical treatment and incur a defined set of costs and Medicare payments) doesn't work for urinary incontinence since there are no meaningful DME products for which CMS reimburses. For urinary retention, solid, recent treatment spending is not readily available. As a result, it isn't possible for us to draw meaningful, quantitative conclusions on the power of DME investment in this category.

Diabetes and Diabetic Test Strips

Diabetes mellitus (diabetes) is one of the most common lifelong chronic diseases in the world. Some 34.2 million Americans, 10.5% of the U.S. population, have diabetes.[42] It is estimated that another 7.4 million Americans have diabetes but have not yet been diagnosed.[43] In the Medicare population, 27.5% of beneficiaries (17.2 million) are diabetic.[44] Among this population, approximately 1.9 million have Type 1 diabetes and 15.3 million have Type 2.[45]

There are two main types of diabetes – Type 1 and Type 2. Type 1 or insulin-dependent diabetes is the most severe form of the disease. Type 1 diabetes is also known as juvenile diabetes because it usually develops in children and teenagers, but people of all ages can develop Type 1 diabetes. Type 2 diabetes is also called adult-onset diabetes, since it typically develops after age 35.

In Type 1 diabetes, the body's immune system attacks the insulin-producing islet cells in the pancreas. The islet cells sense glucose in the blood and produce the right amount of insulin to normalize blood sugars. This attack on the body's own cells is an autoimmune disease. Once the insulin-producing cells are destroyed, a person can no longer produce their own insulin. Without insulin, the sugar stays in the blood and builds up. As a result, the body's cells starve. And, if left untreated, high blood sugar levels can damage eyes, kidneys, nerves and the heart and can also lead to coma and death. Because of these risks, Type 1 diabetes must be treated through a daily regimen of insulin therapy.

Type 2 diabetes or non-insulin dependent diabetes is the most common form of diabetes. About 90% of people with diabetes have Type 2. People with Type 2 diabetes can produce some of their own insulin but often the amount produced is not enough. And sometimes, the insulin will try to serve as the "key" to open the body's cells, to allow the glucose to enter. But the key won't work. The cells won't open. This is called insulin resistance. Treatment for type 2 diabetes focuses on improving ways to better use the insulin the body already produces to normalize blood sugar levels. Treatment programs for type 2 diabetes focus on diet, exercise and weight loss. If blood sugar levels are still high, medications are prescribed to help the body use its own insulin more efficiently. In some cases, insulin injections are necessary.[46]

On average, people with diagnosed diabetes have medical expenditures approximately 2.3 times higher than what their expenditures would be in the absence of diabetes.[47] In the U.S., we estimate that $200 Billion is spent annually to treat diabetes in the Medicare population. Of that, Medicare will spend $154 Billion and beneficiaries and insurers will spend another $46 Billion.[48] Spending includes inpatient and outpatient expenses and a range of medications, insulin and diabetic supplies.

Self-testing blood glucose levels can be an important tool in managing diabetes and preventing complications. Most Medicare beneficiaries test blood glucose levels using a blood sugar meter and a diabetic test strip. A finger prick produces a small drop of blood that is applied to the tip of the test strip. The meter measures the user's blood glucose level.

Blood sugar testing provides useful information for diabetes management, including the ability to:

- monitor the effect of diabetes medications on blood glucose levels
- identify blood glucose levels that are too high or low
- track progress in reaching overall treatment goals
- see how diet and exercise affect blood glucose levels; and
- understand how factors such as illness or stress affect blood glucose levels

Medicare beneficiaries with Type 1 diabetes will typically test 4 to 10 times a day. Those with Type 2 diabetes will test several times a day, depending on the type and amount of insulin used. Beneficiaries who manage Type 2 diabetes with noninsulin medications or with diet and exercise alone will likely test several times weekly.[49]

Competitive bidding had a substantial impact on Medicare spending for diabetic test strips. From 2010 to 2017, spending dropped by 88%, from $1.6 Billion to $200 Million.[50] The most recent data shows that in 2020, Medicare spending on diabetes test strips, meters and related supplies has continued to drop to $108.8 Million.[51]

On July 1, 2013, CMS began its national mail-order competitive bid program. This meant that beneficiaries could no longer have the option of delivery from a local vendor even if the local business delivered other items to them. They could either receive test strips by mail order or go to local vendors and pick up their strips.

In an attempt to ensure that beneficiaries are afforded the widest range of choice in test strips, CMS is prohibited from awarding a contract to a supplier of diabetes test strips if the supplier's bid does not cover at least 50 percent, by volume, of all types of diabetes test strips on the market. (This is known as the "MIPPA 50-percent rule."). While the rule is well intended, evidence published in 2018 from investigations by the American Association of Diabetes Educators showed that most mail-order suppliers were not in compliance with the MIPPA 50-percent rule because they did not carry 50% of the blood glucose models offered to Medicare beneficiaries, potentially resulting in a failure to receive trusted supplies and/or training to use diabetic test strips.[52]

The mail order and non-mail order channels are dominated by a small number of players. Two brands account for over 50% of strips provided by mail order to beneficiaries and three brands account for the majority of strips provided by local suppliers. A total of ten manufacturers account for well over 90% of all mail order test strips. Similarly, ten manufacturers account for well over 90% of all non-mail order test strips.[53] Interestingly, only two manufacturers appear on both lists.[54] While the advent of the mail order competitive bidding program was expected to make dramatic inroads to the non-mail order supply by forcing prices down, it appears that by 2019, mail order sales to Medicare beneficiaries only accounted for 15% of the total supply and non-mail order sales maintained an 85% share.[55]

The advent of the national mail-order competitive bid program led to controversy over whether the massive price drops in test strips led to a decline in quality and service that resulted in poorer outcomes for Medicare beneficiaries. Industry and government studies yielded different conclusions – industry studies showed that competitive bidding led to reduced access to DME[56], a "race to the bottom" in both price and accuracy, as low-quality test strips flooded the market, resulting in poor health consequences for seniors. Data showed a 35% overall decline in test strip suppliers from 2013 to 2017.[57] A 2016 report by the American Diabetes Association showed that hospital admissions and mortality rates for those in the DMEPOS test markets were significantly higher (nearly double) than those beneficiaries that did not reside in the competitive bidding test regions.[58]

To the contrary, government studies showed no negative impacts.[59] While the differences in the reports were not resolved, the test strip mail order program continued.

From a technology standpoint, it is worth noting that a new technology has surfaced in recent years that shows significant promise for the future and cracks open a potential doorway for traditional DME suppliers to expand their presence in diabetes testing and recoup some of the revenue lost due to competitive bidding. Continuous glucose monitoring (CGM) came on the Medicare reimbursement scene in 2017. Combined Medicare and beneficiary spending on CGM has risen dramatically from zero in 2016 to $9 Million in 2017, when CMS first began to reimburse for CGM; to $108 Million in 2018; $216 Million in 2019; and $354 Million in 2020.[60] First approved by the FDA in 1991 for home use, the technology offers an alternative to taking blood from the fingertips.

Instead of requiring users to prick their fingertips as many as 7-10 times per day, CGMs utilize a tiny sensor wire that the user inserts below the surface of the skin and secures with an adhesive patch. The sensor usually is worn on the abdomen or the back of the arm, and it monitors a person's glucose levels throughout the day and night. The readings taken by the sensor are transmitted to a handheld electronic receiver/reader or to a smart device, where real-time data is provided to users about their glucose levels. Current models can be worn for 7-14 days or longer.[61]

Since CGMs continually collect blood sugar data, they can help identify issues and patterns that traditional finger-prick technology cannot. For example, CGMs can record low blood sugar levels while a person is sleeping, track spikes between meals and in the early morning, evaluate diet changes, and provide insight about how medications and exercise regimens are impacting the body. The devices also make it easier for a patient's health care provider to adjust treatment plans. CGMs can provide daily, continuous guidance on how to adjust therapy to keep blood glucose levels more consistently within the target range and avoid prolonged, severe highs and lows.[62]

CGM has proven to be effective for people with Type 1 diabetes who use an insulin pump to manage blood sugar levels. Recent research suggests that CGMs may also be helpful for people with Type 2 diabetes, which would dramatically expand the population of Medicare beneficiaries that could be candidates for CGM.[63] Non-invasive, Bluetooth-enabled CGM systems are now reaching the market[64] and Medicare beneficiaries can begin to envision a future where blood glucose levels wil be monitored in real time without finger pricks or any invasions of the skin.

Having said all this, attempts to place a dollar value on the savings that CMS and beneficiaries could realize from investing in diabetic test strips and CGM have not been fruitful. The nexus, embodied in the '*but for*' test (*but for* the DME, some very defined problems will arise that require medical treatment and incur a defined set of costs and Medicare payments) doesn't work for these DME products. Diabetic testing is an excellent screening tool and can identify medical problems and thereby avoid some spending on treatment, but forging consistent, direct links between test readings and avoidance of treatment spending is tenuous at best. Once diagnosed, diabetes is usually treated by prescription medications or insulin. For the most part, it is these medicines that pass the '*but* for' test, controlling diabetes and minimizing the need for the numerous inpatient and outpatient services that run up Medicare spending. As a result, while it

is certainly clear that diabetes testing is a gateway to treatment spending management, it isn't possible for us to draw meaningful, quantitative conclusions on the power of DME investment in this category.

The Bottom Line

In this study, we analyzed Medicare spending in three additional categories that are important to Medicare beneficiaries: equipment and supplies to prevent pressure sores; catheters and related urological supplies to resolve urine retention and incontinence; and diabetic test strips and meters to monitor blood glucose levels. Our earlier studies concluded that it made sense for CMS to increase its investment in DME and in prevention tools and programs in the three categories that we have followed over the last decade (mobility equipment to avoid falls; oxygen therapy equipment to counter symptoms of COPD; and CPAP equipment to treat sleep apnea) In this study, we reach the same conclusion for these additional three categories.

Medicare treatment spending in these three additional categories is massive and current Medicare investments in related DME pales in comparison. With these levels of spending on treatment, it is evident that increased CMS DME investments will generate savings and improve beneficiaries' quality of life and medical outcomes.

Projected 2022 Medicare Spending

To Treat:	Pressure Sores	Urological Complications	Diabetes
Medicare cost:	$11.6 Billion	$25.0 Billion	$153.6 Billion
Beneficiary cost:	$3.5 Billion	$7.5 Billion	$45.9 Billion

Since virtually all pressure sores are avoidable, it makes sense for CMS to increase its investment in DME and in tools and programs to prevent pressure sores. For each incremental $1 CMS invests, we project that it stands to return $38.54 in reduced or avoided treatment costs. Beneficiaries could receive an additional benefit of $11.51. Hospitals could reduce their burden by some $16.61, bringing the total potential return for the U.S. healthcare system to $66.65 for every $1 invested.

For catheters, there are two scenarios where the connection is close to direct - acute and chronic urinary retention. When retention is chronic, the beneficiary must be catheterized or they cannot

continue to survive. Typically brought on by some chronic illness, the beneficiary can not urinate and the urine builds up in the bladder. It quickly becomes very painful and life-threatening so one either uses intermittent catheters or has an indwelling catheter. Whenever possible, intermittent catheterization provides a better quality of life and better outcomes (less UTIs). When retention is acute, the but for connection is basically the same as with chronic but the catheterization can be stopped when the acute problem is resolved. While we can't put a specific number on the savings, it is crystal clear that the DME saves ER visits; acute care stays; physician and urgent care visits; and reduces mortality.

For diabetic test strips (or the growing continuous glucose monitoring segment), the case is just not as direct. The true value of this DME product category is that it gives more flexibility to beneficiaries in maintaining healthier lifestyles through data. The periodic knowledge of one's blood glucose level allows beneficiaries to adjust their dietary intake, physical activity and medication protocols and reduce their need for medical treatment and the cost of that treatment. Again, we can't put a specific number on the savings but we know that CMS investments will generate savings and improve beneficiaries' quality of life and medical outcomes.

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