

December 30, 2020

**SUBMITTED ELECTRONICALLY**

Ms. Seema Verma, Administrator  
Centers for Medicare & Medicaid Services (CMS)  
Department of Health and Human Services  
Attention: CMS-1738-P  
P.O. Box 8013  
Baltimore, MD 21244-8010

**RE: CMS-1738-P – Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)**

Dear Administrator Verma:

Medtronic is the world's leading medical technology company, specializing in implantable and interventional therapies that alleviate pain, restore health, and extend life. We are committed to the continual research and development necessary to produce high-quality products and to support innovative therapies that improve patients' lives. We offer deep gratitude to CMS for the proposal to expand recognition of continuous glucose monitors (CGMs) in the proposed DMEPOS rule and we appreciate the opportunity to comment.

The COVID-19 crisis has put a strain on Medicare beneficiaries, providers, and policymakers alike. We greatly appreciate CMS' ongoing leadership during this crisis and support the steps taken to expand access to innovative technologies and therapies for Medicare beneficiaries. The DME proposed rule comes at a critical time, and our comments support building on CMS' momentum in previous regulations over the last several months to improve patient access to innovative, life-sustaining technologies, particularly for people with diabetes, during the public health emergency and beyond.

Expanding access to patients on certain types of CGMs, specifically those that CMS classifies as "adjunctive" and still require fingerstick testing, is essential. This type of CGM is particularly critical for Medicare beneficiaries when used in conjunction with automated insulin delivery systems, such as hybrid closed loop artificial pancreas device systems, which automatically adjust basal insulin delivery based on readings from the CGM sensor. We support CMS policies that expand patient access to important diabetes technologies and supplies, and this specific change is an important step forward that should be finalized and implemented as quickly as possible.

In this comment letter, we address the provisions of the proposed rule that classify all CGMs as DME under Medicare Part B and establish fee schedule amounts for these items and related supplies and accessories. Medtronic is providing comment on the codification of the HCPCS

process in a separate letter. Our comments in this letter are organized into the following sections:

- I. Classification of All Continuous Glucose Monitors as DME
- II. Applicable Coding for Adjunctive and Non-Adjunctive CGMs
- III. Coverage and DME MAC Implementation of the Proposed CGM Policies
- IV. Proposed DMEPOS Pricing for Adjunctive and Non-Adjunctive CGMs

To ensure a quick and smooth implementation of this rule, we provide supportive feedback along with identifying areas where further clarity is needed from CMS. We respectfully ask CMS to finalize these proposals expeditiously, with added clarity, to assure Medicare recognition of all CGMs and to fully achieve the improved access to care for Medicare beneficiaries who rely on hybrid-closed loop artificial pancreas device systems involving CGM to manage their diabetes.

### **I. Classification of All Continuous Glucose Monitors as DME**

We applaud CMS for providing Medicare beneficiaries with improved access to critical life-sustaining, continuous glucose monitoring technology. CMS is doing so by proposing to change the previous determination regarding whether adjunctive CGMs are primarily and customarily used to serve a medical purpose and thus meet that component of the definition of DME. As noted in the proposed rule, the Agency's previous determination has been rejected by several district courts (85 *Federal Register* 70401), causing confusion and inconsistency in patient access. We strongly support CMS' proposal to address this by classifying all CGMs as DME.

The classification of adjunctive CGMs under the DME benefit category is well justified. Adjunctive CGM technology is intended to help patients with insulin-dependent diabetes improve glycemic control. Clinical studies have demonstrated that the use of adjunctive CGMs either alone or in the context of sensor-augmented pumps can lead to improvement in HbA1c (a measure of glycemic control and an indication of the relative risk of developing diabetes-related complications), reduction in the percentage of time spent in hypoglycemia, reduction in the time spent in hyperglycemia, and significant reduction in glycemic variability.<sup>123</sup>

Beyond use in a standalone capacity, adjunctive CGM is a critical component in closed-loop artificial pancreas device systems, which combine insulin pump, CGM, and control algorithm software technology together to automate the delivery of basal insulin for people with insulin-dependent diabetes. Medtronic's MiniMed™ 670G Hybrid Closed Loop system is one such system, and it has been shown to improve HbA1c and time in range compared to sensor-

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<sup>1</sup> Bergenstal, R.M. et al., "Effectiveness of Sensor-Augmented Insulin-Pump Therapy in Type 1 Diabetes," July 22, 2010, *New England Journal of Medicine* 363(4):311-320.

<sup>2</sup> Comparative Effectiveness Review No. 57. (Prepared by Johns Hopkins University Evidence-based Practice Center under Contract No. 290-2007-10061-I.) AHRQ Publication No. 12-EHC036-EF. Rockville, MD: Agency for Healthcare Research and Quality. July 2012

<sup>3</sup> Hermanides, J. et al., "Sensor-augmented pump therapy lowers HbA1c in suboptimally controlled Type 1 diabetes; a randomized controlled trial," *Diabetic Medicine* 28:1158-1167.

augmented pump (SAP) therapy in both adults and adolescents<sup>4</sup> and pediatrics<sup>5</sup> in both at-home and outpatient clinical trial settings.<sup>6</sup> Medtronic also recently launched the MiniMed™ 770G System, which builds on the success of 670G.

Despite these findings, and despite the fact that sensor readings taken every five minutes from the CGM included in Medtronic's 670G and 770G systems are used to adjust basal insulin delivery on a constant, ongoing basis, Medicare beneficiaries previously were unable to benefit from 670G and 770G because the CGM sensor included in the systems has adjunctive labeling from the FDA and thus was not recognized by Medicare as a covered DME benefit. The proposed rule classification of all CGMs as DME will remove this barrier and enable Medicare beneficiaries on 670G, 770G, and subsequent systems that use adjunctive CGM to benefit from important closed-loop therapies.

In proposing to classify all CGMs as DME, CMS proposes to establish the following three categories of CGM: (1) automatic non-adjunctive CGM; (2) automatic adjunctive CGM; and (3) manual non-adjunctive CGM. As long as a durable receiver component is present, each of these three types of CGM would meet the definition of DME and thus have an applicable Medicare benefit category for coverage. It is important to note that hybrid closed loop systems such as Medtronic's MiniMed 670G and 770G systems and all subsequent systems use the insulin pump itself to display sensor readings from the CGM, and thus the pump serves as the durable component of the CGM system in lieu of a separate dedicated receiver (which is unnecessary in this context). We ask that CMS specify this in the final rule to eliminate any confusion or doubt for providers and beneficiaries moving forward.

The clarity on CGM provided in the proposed rule is essential for ensuring that Medicare benefit and coverage policies do not prohibit access to critical technologies for the management of insulin-dependent diabetes. We strongly encourage CMS to finalize the classification of CGM in this rule and designate all CGMs as DME to provide coverage of such devices. Such a change would usher in much needed relief and clarity to beneficiaries who have been interested in accessing these innovative devices but have been prohibited previously due to the lack of Medicare benefit classification.

## **II. Applicable Coding for Adjunctive and Non-Adjunctive CGMs**

Coding provides the infrastructure through which coverage and payment occurs. Often coding is discussed and implemented through sub-regulatory guidance. However, in the interest of improving patient access to the innovative, life-sustaining technology of adjunctive CGMs, we urge CMS to swiftly address the coding component of this issue so the policies are not prevented from being promptly implemented on April 1, 2021.

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<sup>4</sup> Garg SK, Weinzimer SA, Tamborlane WV, et al. Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. *Diabetes Technol Ther*. 2017;19(3):155-163.

<sup>5</sup> Forlenza GP, Pinhas-Hamiel O, Liljenquist DR, et al. Safety Evaluation of the MiniMed 670G System in Children 7-13 Years of Age with Type 1 Diabetes. *Diabetes Technol Ther*. 2019;21(1):11-19.

<sup>6</sup> Tauschmann M, Thabit H, Bally L, et al. Closed-loop insulin delivery in suboptimally controlled type 1 diabetes: a multicentre, 12-week randomised trial. *Lancet*. 2018;392(10155):1321-1329.

The essential coding issue is the applicable HCPCS codes for the three types of CGMs: automatic non-adjunctive (therapeutic), automatic adjunctive, and manual non-adjunctive. For non-adjunctive (therapeutic) CGMs, new codes K0554 for the receiver/monitor and K0553 for the associated supplies (sensor, transmitter) were rolled out over the course of six months to implement the previous CMS ruling (CMS-1682-R) in January 2017. However, currently there appear to be no unique HCPCS codes defined or otherwise appropriate for automatic adjunctive CGMs and manual non-adjunctive CGMs. Differentiating between the three types of CGMs is necessary for key administrative purposes, including device class, pricing, and payment.

Given the administrative need to differentiate between the categories, we request that CMS clarify the HCPCS codes which apply to all three types of CGMs and their corresponding supplies as of April 1, 2021. We appreciate that evaluating, developing and implementing codes can be time-consuming. Still, on a practical basis, coding issues such as these can keep claims tied up in the adjudication process for months, if not longer. Time is of the essence to achieve the rule's purpose of improving patient access to these life-sustaining technologies.

It is not clear if codes K0554 and K0553 will continue to apply to non-adjunctive CGMs, or how manual non-adjunctive CGMs will be distinctly identified. It is also not clear if existing codes will continue to apply to automatic adjunctive CGMs. We suggest that there are several coding options available in the short-term and for the longer-term. CMS may find that appropriate existing codes are in fact available. If not, existing CGM and supply codes A9278, A9276, and A9277 can be made to serve in the short-term by applying specific modifiers to identify automatic adjunctive CGMs, or DME miscellaneous code E1399 can be used for this purpose until specific new HCPCS codes can be created for the longer-term.

In the interest of clarity and timely implementation, we ask that CMS publish its coding guidance, including temporary allowances as needed, either in the final rule itself or in sub-regulatory coding guidance provided concurrently with the publication of the final rule. As CMS has full oversight of HCPCS codes, we believe CMS will be able to ensure the necessary infrastructure is in place to appropriately populate and adjudicate a claim for all covered CGMs.

### **III. Coverage and DME MAC Implementation of the Proposed CGM Policies**

In addition to these coding considerations, in order to ensure that patients can easily access all CGM technologies once the finalized policies take effect, we seek to anticipate all the various elements and actions that must be put in place or carried out to implement coverage and access for all CGMs on a timely basis, consistent with the April 1, 2021 effective date stated in the proposed rule.

Following the January 2017 ruling, for example, a change request was issued to identify the codes that would be adopted to fulfill the administrative requirements for implementation. The DME MACs made necessary changes to the Glucose Monitors LCDs and claims processing systems to effectively roll out the policies and process therapeutic CGM claims. A coding verification process was established by the Pricing, Data Analysis and Coding contractor (PDAC) to identify products eligible for coding and coverage.

As the DME rule is finalized, we ask CMS not only to streamline the regulatory and sub-regulatory guidance for implementation, but also to work with the DME MACs to keep them as prepared as possible to expeditiously implement the changes that fall within their jurisdictions, thereby ensuring that patients can access these necessary and innovative life-sustaining technologies as early as possible, consistent with the April 1, 2021 effective date noted in the proposed rule. The DME MACs would need to receive updates on forthcoming changes to policies so they can begin their transparent process to address the fact that the current Glucose Monitors LCDs need to have certain elements updated and integrated into them in order to accomplish the aims set forth in the CMS proposals.

Further, we seek clarity on whether any adjunctive CGMs need to be reviewed for correct coding by the PDAC to correctly appear on the product classification list(s) and to ensure that claims can be quickly and correctly processed upon implementation of a forthcoming final rule. Currently, therapeutic CGM systems that are billed using K0554 and that had not been reviewed and listed on the corresponding Product Classification List are denied as incorrect coding.

Again, we greatly appreciate the thoughtful proposals to expand benefit classification and coverage of all CGMs for Medicare beneficiaries. We welcome the opportunity to discuss the process for implementing the rule in greater detail with CMS in order to build on the momentum set with previous regulations that have increased access to innovative, life-sustaining technologies.

#### **IV. Proposed DMEPOS Pricing for Adjunctive and Non-Adjunctive CGMs**

In addition to classifying all CGMs as DME, the proposed rule addresses the payment for different types of CGMs and their corresponding supplies.

For CGM receivers/monitors, CMS proposes to continue using the fee schedule amounts established in the January 2017 ruling (CMS-1682-R), which are based on the updated 1986/87 average reasonable charges for blood glucose monitors. Different annual update factors for class III DME versus other DME items are applied so the fee schedule amounts for class III CGM receivers are slightly higher (from \$231.77 to \$272.63 in 2020) than the fee schedule amounts for class II CGM receivers (from \$208.76 to \$245.59 in 2020).

With regard to the fee schedule amounts for supplies and accessories for CGMs, CMS states that it does not believe these supplies and accessories are comparable to the supplies and accessories for blood glucose monitors, and there is a significant difference in the cost, lifetimes, and types of supplies and accessories used with the various types of CGMs. Further, the rule notes that the supplies used with the three types of CGMs currently on the market are very different (85 Federal Register 70402-70403). We agree with this assessment regarding the variability in supply and accessory costs of CGMs relative to blood glucose monitors, and among the different types of CGMs. However, as outlined below, we have concerns regarding the transparency by which CMS has calculated the payment levels for the various components and types of CGM, as well as their adequacy to be able to support patient access.

In the proposed rule, CMS proposes to pay for automatic non-adjunctive CGM supplies at the same level calculated previously for therapeutic CGM supplies (now identified by HCPCS K0553), but calculates new payments amounts for the automatic adjunctive CGM supplies and for manual non-adjunctive CGM supplies. As we review the payment amounts proposed in the rule, however, there appear to be marked variations with payment levels typically adopted in the commercial sector. This is the case not only for adjunctive CGM supplies, but also for both categories of non-adjunctive CGM supplies.

In the absence of a detailed discussion on how CMS arrived at its payment decisions for CGM accessories and supplies, Medtronic commissioned an analysis to estimate payments for these accessories and supplies with data obtained from publicly available sources (specifically, Internet retail prices). Using CMS' codified guidelines for determining payments amounts under the gap-filling approach, the analysis deflated the prices listed in supplier price lists to the fee schedule base period (1986 or 1987), and then applied the covered item update factors (as specified in statute) to establish the current fee schedule amounts. The results of the analysis are shown in the table below.

<b>CGM Type</b>	<b>CY 2020 Proposed Monthly Medicare Supply Amount</b>	<b>CY 2020 Calculated Monthly Medicare Amount Based on Publicly Available Pricing Information</b>	<b>Ratio of Calculated to Proposed Amount</b>
<b>Class II Devices</b>			
Automatic non-adjunctive	\$222.77	\$429	1.9
Automatic adjunctive	\$175.62	\$330	1.9
Manual non-adjunctive	\$46.86	\$97	2.1
<b>Class III Devices</b>			
Automatic non-adjunctive	\$259.20	\$472	1.8
Automatic adjunctive	\$198.77	\$366	1.8
Manual non-adjunctive	\$52.01	\$108	2.1

In summary, the analysis yielded Medicare payment level estimates for CGM supplies that are almost twice as high what CMS proposes for each of the CGM categories. The full details of this analysis are included as an appendix to our comments so that CMS can view the specific methodology used and information included in our assumptions. The significant difference in our calculations vs. CMS' proposed amounts raises questions for us about the Agency's proposed pricing, including the methodology CMS used for its analysis, the Agency's data sources, and the actual pricing data used to calculate payment levels for CGM accessories and supplies.

As CMS finalizes the rule, we would respectfully ask that the Agency provide further information on the calculation of its pricing for all categories of CGM supplies. We believe CMS should adjust the proposed rates accordingly in the final rule based on a transparent presentation of the data and calculations used in its payment-setting methodology. This information, leading to accurate payment, is critical for ensuring that beneficiaries will have

access to technologies that have significantly improved patients' management of diabetes and their quality of life.

## **Conclusion**

The COVID-19 pandemic has tested the U.S. healthcare ecosystem, the Medicare program, and the nation. As we look to round the corner and return to our new normal, Medtronic stands at the ready to help patients access the right innovative, life-sustaining technologies for their CGM needs and sees the vast opportunity this rule provides in that regard.

We are delighted by CMS' intention to improve patient access to these critical life-sustaining technologies and we appreciate CMS' consideration of these comments that are provided to ensure a smooth implementation of the rule upon its finalization. If you have questions or need further information, please feel free to contact me at (202) 257-9324 or [jeff.a.farkas@medtronic.com](mailto:jeff.a.farkas@medtronic.com).

Sincerely,

A handwritten signature in black ink that reads "Jeff A. Farkas". The signature is written in a cursive, flowing style. The signature is placed on a white rectangular background that has a faint, light gray border.

Jeff Farkas  
Vice President  
Global Health Economics, Reimbursement, and Government Affairs  
Medtronic Diabetes

## APPENDIX



# **Simulation of Medicare Continuous Glucose Monitors (CGM) Fee Schedule Supply Amounts Based on Internet Retail Prices**

**December 21, 2020**

## **I. Summary of CMS Proposal**

On November 4, 2020, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule that addresses certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) policy issues and Healthcare Common Procedure Coding System (HCPCS) issues (85 *FR* 70358-70414). Among other proposals, CMS proposes to classify CGMs as DME under Medicare Part B and establish fee schedule amounts for these items and related supplies and accessories.

Specifically, CMS proposes to separate payment for CGM supplies and accessories into three separate categories to account for variation in the type of supplies needed for the three types of CGMs on the market.<sup>7</sup> In brief, the proposed rates are as follows:

- Non-adjunctive CGM system monthly supplies: \$222.77 (for class II) and \$259.20 (for class III); to be updated by 2021 update factor.
- Adjunctive CGM system monthly supplies: \$175.62 (for class II) and \$198.77 (for class III); to be updated by the 2021 update factor. Nets out blood glucose monitor and supplies.
- Manual non-adjunctive CGM system monthly supplies: \$46.86 (for class II) and \$52.01 (class III devices); to be updated by the 2021 update factor. Supplies pay for sensors and disposable batteries.

## **II. Analysis**

Using data available from public information (i.e., Internet retail prices), we replicated what CMS could pay for CGM supplies and accessories using its gap-filling approach based on these prices. CGM supplies and accessories from the following manufacturers were used to estimate payment rates for each group:

- Non-adjunctive CGM system – Dexcom G6® System (Class II)
- Adjunctive CGM system – Medtronic Guardian™ Connect System (Class III)
- Manual non-adjunctive CGM system—Abbott FreeStyle Libre 2 System (Class III)

The purpose of this analysis was to compare what CMS has proposed in its rule to amounts one could derive based on prices publicly available for these items. CMS' guidance states that it uses verifiable pricing information for input into its gap-filling methodology. The current program instructions specify that supplier price lists can be used—catalogs and other retail price lists (such as Internet retail prices)—as well as appropriate commercial pricing. Commercial pricing can include verifiable information from supplier invoices and non-Medicare payment data and payments made by Medicare Advantage plans. CMS does not use manufacturer suggested retail pricing (MSRP) as an input into its gap analysis.

Using CMS' gap-filling approach we deflated the prices listed in supplier price lists to the fee schedule base period (1986 or 1987), and then applied the covered item update factors (as

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<sup>7</sup> As proposed by CMS in its November 4, 2020 proposed rule (85 *FR* 70358-70414).

specified in statute) to establish the current fee schedule amounts.<sup>8</sup> This analysis was repeated for each of the three separate categories of supplies and accessories CMS proposed and then converted these amounts into monthly amounts. These CGM supply amounts were calculated for class II and class III devices and its related supplies (as CMS did), recognizing that there may not be products on the market that fall into those categories.

### III. Estimates of CGM Monthly Supply Amounts Based on Internet Retail Prices

Based on a search of retail prices from the Internet, we derived average prices for CGM supplies needed within the three categories of CGM supplies. For each of the supply items listed, we calculated an average Internet retail price based on the data collected—3 prices were obtained for almost all the items (prices and sources are detailed in Appendix A). Table 1 shows the average Internet retail price, the estimated price based on our simulation of the gap-fill analysis, and how often the sensors and transmitters need to be replaced. For example, we calculated for Dexcom G6 Sensors (3-Pack) an estimated price of \$304 based on CMS’ gap-fill approach for Class III devices; this is about 72 percent of its average Internet retail price of \$420. Sensors and transmitters vary by manufacturer in how often the user needs to replace them. Sensors examined, for example, vary in replacement from once every 7, 10, or 14 days. This information is needed to calculate the average monthly Medicare supply allowance for each of the three categories of CGM supplies.

**Table 1: Estimated Price of CGM Supplies Based on CMS’ Gap-Fill Approach Using Average Internet Retail Price**

Type of CGM	Average Internet Retail Price Based on Publicly Available Information	Estimated Price Based on Gap-fill Analysis (Class II)	Estimated Price Based on Gap-fill Analysis (Class III)	Replacement Assumption Used in Calculating Monthly Medicare Amount
<b>Non-adjunctive CGM</b>				
Dexcom G6 Sensors (3-Pack)	\$420	\$274	\$304	Once every 10 days (36 per year)
Dexcom G6 Transmitter	\$554	\$361	\$401	Once every 3 months (4 per year)
<b>Adjunctive CGM</b>				
Medtronic MiniMed Guardian 3 Sensor (5 pack)	\$493	\$321	\$357	Replace every 7 days (52 per year)
Medtronic MiniMed Guardian Link 3 Transmitter Kit	\$937	\$612	\$679	Once a year
<b>Manual non-adjunctive CGM</b>				
Abbott Freestyle Libre	\$74	\$49	\$54	Replace every 14 days (24 per year or 2 per month)*

Source: Simulation of CMS’ gap-filling approach based on publicly available supply prices.

\*Based on manufacturer’s description of quantity per month at <https://www.freestylelibre.us/support/buying-guide.html>

<sup>8</sup> The covered item updates for DMEPOS are specified in Section 1834(a)(14) of the Social Security Act. The update varies by year; for example, in some years (1993-1997, 2003), it was the percentage increase in the consumer price index for all urban consumers (CPI-U); in 2002, 2004-2008 it was 0 percentage points; and in more recent years (2011 and after), the annual update is the CPI-U reduced by a productivity adjustment. The update factor applied each year also depends in certain years on whether the device is classified as Class III device or other item.

Using the gap-fill information estimated above, we calculated the estimated 2020 Medicare fee schedule amounts based on using average Internet retail prices, application of its gap-fill approach, and manufacturers' instructions on how often its sensors and transmitters need to be replaced (See Table 2). For example, for the adjunctive CGM supply calculation (Class III), we calculated the combined monthly cost of the sensors and transmitter as follows:

Step 1: Calculation of monthly sensors:  $((\$357 \text{ gap-fill price}/5 \text{ sensors in pack}) * 52 \text{ sensors in year})/12 \text{ months} = \$309.40 \text{ per month}$

Step 2: Calculation of transmitter:  $\$679 \text{ gap-fill price}/12 \text{ months} = \$56.58$

Step 3: Total estimated monthly adjunctive CGM supply amount=  $\$365.98$   
 $(\$309.40 + \$56.58)$

This amount is about 1.8 times the amount that CMS proposes for this category of supplies in its proposed rule. Among all the categories, estimates of CGM supplies from this analysis are almost twice what CMS proposes for each of these categories. For the non-adjunctive CGM category \$34.35 was added to the estimated total to account for blood glucose supplies used for calibration that CMS includes for this category. Totals do not include the cost of batteries needed for the CGM monitor/receiver for adjunctive and manual non-adjunctive CGMs, though these costs are minimal.

**Table 2: Estimated 2020 Medicare Fee Schedule Amounts for CGM Supplies Using Average Internet Retail Prices Compared to Proposed Amounts**

Type of CGM	2020 Proposed Monthly Medicare Supply Amount	2020 Estimated Monthly Medicare Amount Based on Internet Prices	Ratio of Estimated to Proposed Amount
<b>Class II Devices</b>			
Non-adjunctive CGM	\$222.77	\$429	1.9
Adjunctive CGM	\$175.62	\$330	1.9
Manual non-adjunctive CGM	\$46.86	\$97	2.1
<b>Class III Devices</b>			
Non-adjunctive CGM	\$259.20	\$472	1.8
Adjunctive CGM	\$198.77	\$366	1.8
Manual non-adjunctive CGM	\$52.01	\$108	2.1

Note: Non-adjunctive CGM totals includes the cost of sensors, transmitters, and blood glucose supplies used for calibration. Adjunctive CGM totals include the cost of sensors and transmitters. Manual non-adjunctive CGM totals include the cost of sensors. Assumptions for replacement of sensors and transmitters varies based on manufacturer. Source: Simulation of CMS' gap-filling approach based on publicly available supply prices.

Payment estimates are sensitive to the starting price used in calculations; to the extent that the price of the device provided to other payers is significantly lower than the prices used in these estimates, this will affect the estimated payment level that CMS could pay under its DMEPOS fee schedule. These Internet retail prices may not be representative of prices typically paid for these items and estimates are also sensitive to how frequently the sensors and transmitters need to be replaced.

## Appendix A: Summary of Internet Retail Prices of CGM Supplies

CGM Supply Category	Internet Retail Price	Source (Prices as of 11-12-2020)
<b>Non-adjunctive CGM</b>		
Dexcom G6 Sensors (3-Pack)	\$319.99	Total Diabetes Supply.Com <a href="https://www.totaldiabetessupply.com/products/dexcom-g6-sensors-3-pack">https://www.totaldiabetessupply.com/products/dexcom-g6-sensors-3-pack</a>
Dexcom G6 Sensors (3-Pack)	\$490	ADW Diabetes <a href="https://www.adwdiabetes.com/product/20804/dexcom-g6-sensors">https://www.adwdiabetes.com/product/20804/dexcom-g6-sensors</a>
Dexcom G6 Sensors (3-Pack)	\$449.99	DiabeticWarehouse <a href="https://www.diabeticwarehouse.org/products/dexcom-g6-sensors">https://www.diabeticwarehouse.org/products/dexcom-g6-sensors</a>
<b>Average price of Dexcom G6 Sensors (3-Pack)</b>	<b>\$419.99</b>	
Dexcom G6 Transmitter	\$600.99	Total Diabetes Supply.Com <a href="https://www.totaldiabetessupply.com/products/dexcom-g6-transmitter">https://www.totaldiabetessupply.com/products/dexcom-g6-transmitter</a>
Dexcom G6 Transmitter	\$560.90	ADW Diabetes <a href="https://www.adwdiabetes.com/product/20802/dexcom-g6-transmitter">https://www.adwdiabetes.com/product/20802/dexcom-g6-transmitter</a>
Dexcom G6 Transmitter	\$499.99	DiabeticWarehouse <a href="https://www.diabeticwarehouse.org/products/dexcom-g6-transmitter">https://www.diabeticwarehouse.org/products/dexcom-g6-transmitter</a>
<b>Average price of Dexcom G6 Transmitter</b>	<b>\$553.96</b>	
<b>Adjunctive CGM</b>		
Medtronic MiniMed Guardian 3 Sensor (5 pack)	\$588.00	Total Diabetes Supply.Com <a href="https://www.totaldiabetessupply.com/products/guardian-3-sensor-for-670-g-box-of-5-sensors-each-with-7-day-wear-time">https://www.totaldiabetessupply.com/products/guardian-3-sensor-for-670-g-box-of-5-sensors-each-with-7-day-wear-time</a>
Medtronic MiniMed Guardian 3 Sensor (5 pack)	\$609.90	ADW Diabetes <a href="https://www.adwdiabetes.com/product/20723/minimed-guardian-3-sensor-5ct">https://www.adwdiabetes.com/product/20723/minimed-guardian-3-sensor-5ct</a>
Medtronic MiniMed Guardian 3 Sensor (5 pack)	\$279.99	DiabeticWarehouse <a href="https://www.diabeticwarehouse.org/products/minimed-guardian-sensor-3-cgm-5-pack">https://www.diabeticwarehouse.org/products/minimed-guardian-sensor-3-cgm-5-pack</a>

CGM Supply Category	Internet Retail Price	Source (Prices as of 11-12-2020)
<b>Average price of MiniMed Guardian 3 Sensor</b>	<b>\$492.63</b>	
Medtronic MiniMed Guardian Link 3 Transmitter Kit	\$884.79	Total Diabetes Supply.Com <a href="https://www.totaldiabetessupply.com/products/guardian-link-3-transmitter-kit-for-670g-box-includes-transmitter-one-press-insertion-device-watertight-tester-charger-1">https://www.totaldiabetessupply.com/products/guardian-link-3-transmitter-kit-for-670g-box-includes-transmitter-one-press-insertion-device-watertight-tester-charger-1</a>
Medtronic MiniMed Guardian Link 3 Transmitter Kit	\$990	ADW Diabetes <a href="https://www.adwdiabetes.com/product/20722/minimed-guardian-link-3-transmitter-kit">https://www.adwdiabetes.com/product/20722/minimed-guardian-link-3-transmitter-kit</a>
<b>Average price of Medtronic MiniMed Guardian Link 3 Transmitter Kit</b>	<b>\$937.40</b>	
<b>Manual non-adjunctive CGM</b>		
Abbott Freestyle Libre (1 per box)	\$92.99	Total Diabetes Supply.Com <a href="https://www.totaldiabetessupply.com/products/freestyle-libre-14-day-sensor">https://www.totaldiabetessupply.com/products/freestyle-libre-14-day-sensor</a>
Abbott Freestyle Libre (1 per box)	\$94.99	ADW Diabetes <a href="https://www.adwdiabetes.com/product/20830/freestyle-libre-sensor-kit">https://www.adwdiabetes.com/product/20830/freestyle-libre-sensor-kit</a>
Abbott Freestyle Libre	Most privately insured patients pay between \$10 and \$75 per month (assumes 2 sensors) * assume \$35 per sensor for calculations	Abbott website. <a href="https://www.freestylelibre.us/support/buying-guide.html">https://www.freestylelibre.us/support/buying-guide.html</a>
<b>Average price of Abbott Freestyle Libre</b>	<b>\$74.33</b>	