10 years of increasing glucose management device use among Medicare FFS beneficiaries with Type 1 diabetes

A claims-based, longitudinal analysis of device utilization in the context of changes to access

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Glucose management devices have undergone rapid technological advancement since their initial approval and had meaningful changes in coverage over the past decade. These coverage changes align with increases in utilization among Medicare beneficiaries with Type 1 diabetes, highlighting the impact of treatment coverage to patient access.

Type 1 diabetes mellitus (T1D) affects 1.7 million adults age 20 years or older in the United States (U.S.), accounting for 5.7% of all U.S. adults with diagnosed diabetes[1]; T1D is increasingly prevalent among older adults. As devices have evolved and improved over the past few decades, many leading professional organizations now recommend people with T1D use continuous glucose monitors (CGMs) and insulin pumps to help manage their insulin administration and blood glucose levels. In response to changing diabetes prevalence rates and improved device technologies, the Centers for Medicare and Medicaid Services (CMS) has updated their coverage policies for devices over the past decade.

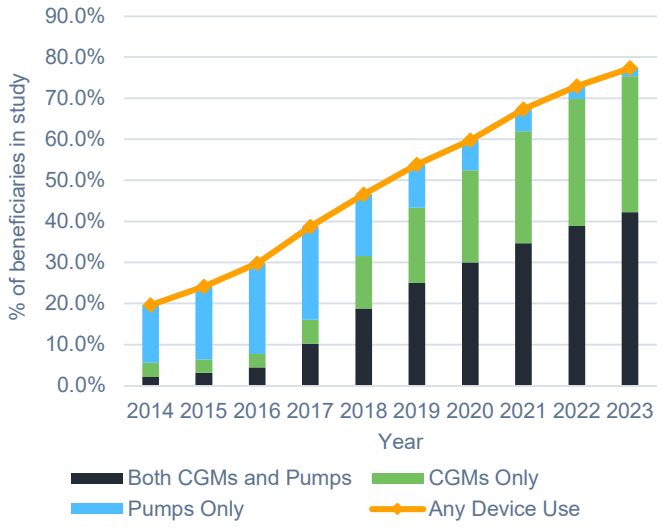
While insulin pumps have been covered by Medicare since the early 2000s,[2] CGMs were not covered by Medicare until 2017.[3] Initial coverage of CGMs was based on clinical symptoms and was limited to people who used insulin, had frequent hypoglycemia, or required frequent glucose monitoring. In 2023, CMS updated rules for CGM coverage to include people with T1D or Type 2 diabetes (T2D), people with sufficient training to use a CGM, people with a history of problematic hypoglycemia, and/or people who are insulin-treated, regardless of diabetes type.[4]

Medicare FFS beneficiaries with T1D have increasingly used devices over the past decade, driven primarily by uptake of CGMs

We assessed national and regional patterns in CGM and insulin pump use among Medicare fee-for-service (FFS) beneficiaries with T1D from 2014 to 2023 and estimated rates of consistent usage among device users to investigate the effects of these coverage changes over time. Claims-based T1D prevalence ranged from 0.41% in 2014 to 0.47% in 2023. T1D prevalence was slightly higher in the Midwest (0.53% in 2023) and lower in the South and West (0.45% and 0.43% in 2023, respectively).

We found that the share of beneficiaries with T1D with any device usage increased each year, from 19.7% in 2014 to 77.4% in 2023 (Figure 1). In particular, rates of CGM use increased significantly starting in 2017, with more beneficiaries either adopting CGMs alongside insulin pumps or using CGMs on their own. The timing of this increase coincides directly with Medicare's initial coverage of CGMs in 2017.

FIGURE 1: PROPORTION OF BENEFICIARIES IN STUDY WITH T1D AND ANY DEVICE USE, 2014–2023



Rates of any device usage by beneficiaries in the study population were consistent between regions in the U.S. over the analysis period. Relative to national patterns of device usage, beneficiaries in the West and Midwest regions had similar levels of usage for CGMs and insulin pumps alone or in combination, the Northeast had a greater share of beneficiaries using CGMs only, and the South had a greater share of beneficiaries using both CGMs and pumps over the entire period. These findings suggest that not only did Medicare's coverage of CGMs contribute to national growth in device utilization rates, but it may have also had particular influence on increasing device use in regions of the country where insulin pump use is less common.

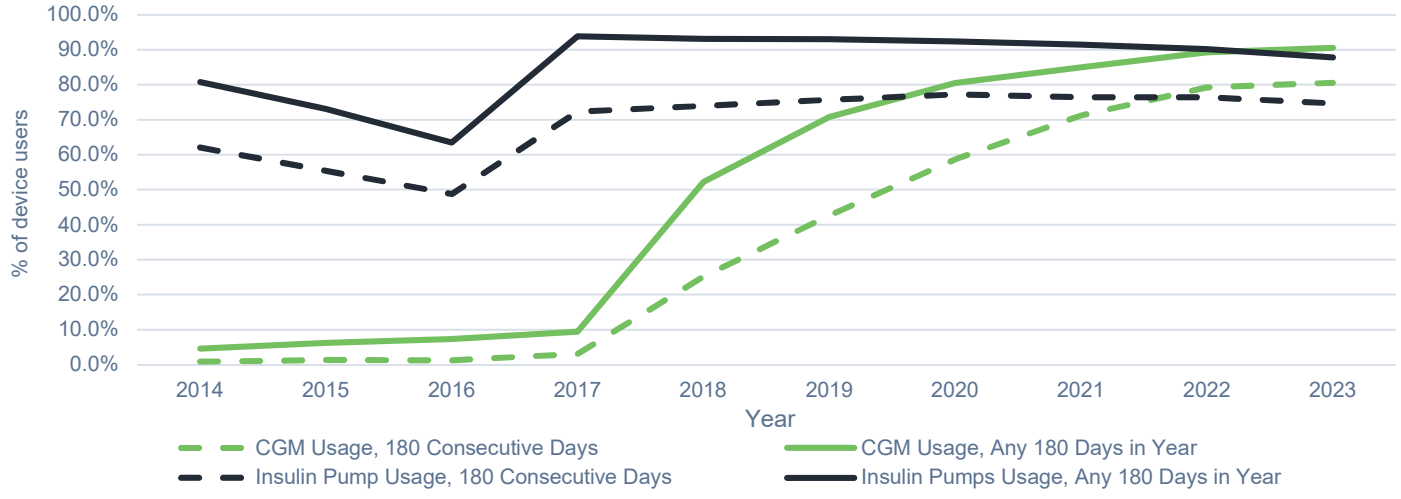
As of 2023, rates of device use among Medicare beneficiaries with T1D were comparable to those of people with T1D in other insurance markets. 83.0% of commercially insured members with T1D in our study had evidence of any device use in 2023, only marginally higher than overall device use rates in Medicare. Nearly all device users in our commercial population had evidence of CGM use, either alone or with insulin pumps. Only 0.5% of commercial members with T1D were solely using insulin pumps, compared to 2.0% of Medicare beneficiaries with T1D. These comparisons between Medicare and commercial insurance markets suggest that there may be further opportunities to help Medicare beneficiaries adopt CGMs through policy changes or other interventions. Additionally, some of the differences in CGM use between markets could be due to variations in age or personal preferences.

Expanded coverage of devices aligns with improved rates of consistent use

We identified beneficiaries with continuous device usage using two definitions: a) evidence of device usage for 180 consecutive days in a given year and b) evidence of device usage for at least 180 days in total in a given year. Under both definitions, we observed increases in rates of consistent utilization over the 10-year analysis period. The most substantial growth in consistent use of CGMs followed the 2017 adoption of CGM coverage by CMS. The proportion of insulin pump users who were consistently using insulin pumps increased greatly from 2016 to 2017. The increases coincided with advances in insulin pump technologies, including the technology allowing the CGM data to be used to adjust pump settings and the Food and Drug Administration's approval of Medtronic's MiniMed 670G hybrid closed loop system,[5] which may have put more clinician focus on insulin pump users and resulted in more consistent device usage.

There appears to have been a lag between any utilization of CGMs among Medicare beneficiaries and consistent use of CGMs over a consecutive 180-day period each year. The share of CGM users with at least 180 days of CGM use during the year first exceeded 50% in 2018, but the proportion of CGM users with 180 consecutive days of usage did not exceed 50% until 2020. Notably, there is still a difference in the proportion of beneficiaries who qualify as consistent device users under both definitions of consistent device usage, indicating that some beneficiaries may be receiving device supplies from non-Medicare sources or may be inconsistently filling their device supplies.

FIGURE 2: RATES OF CONTINUOUS DEVICE USAGE AMONG DEVICE USERS, 2014–2023



Device use is clinically recommended for older adults with T1D

Current clinical standards of care indicate that CGMs and insulin pumps are recommended and clinically appropriate for people with T1D. These recommendations are based on evidence demonstrating that adults with T1D who use devices experience meaningful improvements in glycemic control, reductions in hypoglycemia, and enhanced quality of life.[6-8] The American Diabetes Association (ADA) recommends that CGMs be offered to people with T1D early, even immediately following diagnosis, based on strong evidence from multiple high-quality studies.[9] The Endocrine Society also recommends the use of CGMs by people with T1D who are willing and able to use the devices on a near-daily basis.[10] Regarding insulin pumps, the Endocrine Society recommends subcutaneous insulin infusion over analog injections of insulin in people with T1D who have not achieved their A1C goal or who have achieved their A1C goal but continue to experience symptoms like high glucose variability and severe hypoglycemia; it also suggests that people with T1D who prefer to use subcutaneous insulin infusion should be able to do so based on the quality of data available.[10] The Endocrine Society's recommendation on subcutaneous insulin infusion does not include any laboratory testing requirements to demonstrate insulinopenia (low levels of insulin production). By adopting coverage of CGMs for Medicare beneficiaries, CMS has not only improved beneficiaries' ability to follow current clinical standards of care, but it has also increased the likelihood of beneficiaries having positive health outcomes in managing their diabetes.

We note that the ADA indicates automated insulin delivery systems (AIDs), which are devices that include features of both CGMs and pumps, "should be the preferred insulin delivery method to improve glycemic outcomes and reduce hypoglycemia and disparities in youth and adults with type 1 diabetes," also based on strong evidence.[9] While AIDs are important technical innovations that present many positives for people with T1D, we did not specifically analyze these devices in our current work as it is difficult to definitively determine beneficiaries are using an AID based on claims data. Follow-up studies can focus specifically on trends of utilization of AIDs for people with T1D.

Conclusions

Device use among FFS beneficiaries with T1D increased substantially between 2014 and 2023, with the most substantial growth seen in CGM adoption after 2017. Medicare's initial coverage of CGMs in 2017 and advances in insulin pump technologies in 2016 greatly contributed to increasing usage of devices among older adults during this period as these changes improved access to devices for Medicare beneficiaries. The widespread increases in device utilization following policy changes underscore the potential for beneficiaries with T1D to rapidly adopt new technologies when access barriers are reduced. Many medical organizations indicate that CGM and insulin pump usage are clinically appropriate standards of care for people with T1D, and expanded use of devices could improve both short- and long-term health outcomes. Future research should study the real-world impact that more recent policy changes have had on device utilization and healthcare outcomes for beneficiaries with T1D, especially considering Medicare's further expansion of CGM coverage eligibility in March 2023.

While this study found increases in the number of beneficiaries with T1D with any device usage, the observed lag between initial utilization of CGMs and consistent use of devices suggests that other barriers may have limited beneficiaries from consistently using devices during the study period. These barriers may persist to this day. Additional research is necessary to determine what may be driving inconsistent device utilization for beneficiaries with T1D, as well as whether rates of inconsistent use differ based on other demographic factors, such as race/ethnicity, income, urban/rural residence, or educational attainment. Ongoing monitoring of Medicare beneficiaries' device utilization is also warranted to track the effects of policymakers' decisions on Medicare coverage of durable medical equipment and supplies, especially in relation to changes in device access and patient care.

Methodology

We used enrollment and medical and pharmacy claims data for Medicare FFS beneficiaries from the CMS 100% Research Identifiable Files (RIF) from 2012–2023 for this analysis. Eligible Medicare FFS beneficiaries were required to have continuous enrollment in Medicare FFS Parts A, B, and D for the entire 12 months of the analysis year or until death, whichever came first. Beneficiaries were not required to meet enrollment criteria for all 10 analysis years to be included in the study; they were only included in the study population for analysis years where they met enrollment criteria.

After identifying eligible beneficiaries, we identified the total diabetes population in Medicare FFS for each analysis year. In order to be identified as having diabetes, beneficiaries needed to have either at least two outpatient, urgent care, observation, emergency department (ED), non-acute inpatient, or acute inpatient claims incurred at least 30 days apart with a diabetes diagnosis code in any position or at least one prescription fill for a hypoglycemic, antihyperglycemic, insulin, or insulin device and at least one qualified outpatient, urgent care, observation, ED, non-acute inpatient, or acute inpatient claim with a diabetes diagnosis code in any position. Claims in the analysis year and the

preceding two-year lookback period were considered when identifying beneficiaries with diabetes.

Beneficiaries identified with diabetes were classified as having either T1D or T2D in each analysis year based on the count of claims with either ICD-9 or ICD-10 diagnosis codes for each type of diabetes. Beneficiaries with T2D were excluded from further steps in this analysis. If beneficiaries had both T1D and T2D diagnosis codes, T1D designation was determined using a plurality of diagnosis codes present during the analysis year. We also looked at dispensed drugs or drug combinations to confirm assignment to either T1D or T2D. Because claim volume can vary for beneficiaries from year to year, which influences the likelihood of T1D assignment, some beneficiaries were identified with T1D in some analysis years but not others. For beneficiaries with inconsistent diabetes type assignments across multiple years, we reassigned their diabetes type to T1D for all years if the beneficiary was assigned as T1D for at least two analysis years in the 10-year period.

Once we identified beneficiaries with T1D, we looked for evidence of CGM and/or insulin pump usage in each analysis year. Beneficiaries were classified as having "any device utilization" if they had evidence of at least one medical or pharmacy claim for a CGM or insulin pump or related supplies at any point in a given analysis year. Evidence of consistent usage was assessed for a given device type for each beneficiary (e.g., claims for CGMs were used to identify consistent utilization for CGMs only; these claims would not count as evidence of consistent utilization for insulin pumps).

Finally, we identified a national comparison population of commercially insured members with T1D in 2023 using 2021–2023 data from Milliman's Consolidated Health Cost Guidelines™ (HCG) Sources Database (CHSD). These members in our comparison population were required to have continuous enrollment for the entire analysis year. We used the same approaches for identifying people with T1D and identifying evidence of any device utilization in both the commercial and Medicare populations.

Caveats and limitations

This study had several limitations. The study was based on FFS Medicare beneficiaries. While we followed beneficiaries longitudinally over the entire 10-year study period, if a beneficiary left Medicare FFS and enrolled in Medicare Advantage (MA), we no longer observed them or their device utilization in our study results. Rates of device usage may differ for people who move between Medicare FFS and MA compared to those who remain enrolled in FFS.

Administrative claims data do not capture when devices and/or supplies are procured through means other than submission of a claim, such as when devices are given to beneficiaries for free as part of a clinical trial or beneficiaries purchase supplies out of pocket. This could lead to understated rates of device usage for some populations. Additionally, we use claims as proxies for device usage in this analysis. Claims do not perfectly represent device adherence as a patient may regularly fill a script for a device or related supplies but not use them. Our results may overstate the number of people using devices or using devices continuously.

Milliman has developed certain models to estimate the values included in this analysis. The intent of the models was to estimate the size of the population of people with T1D in Medicare FFS and summarize device usage information for those beneficiaries over time. We have reviewed the historical claims-based algorithms, including their assumptions and outputs for consistency, reasonableness, and appropriateness to the intended purpose and in alignment with generally accepted clinical expectations.

ENDNOTES

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