

ABBOTT DIABETES CARE

CGM Access and Health Disparity Concerns for Medicare Beneficiaries

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Introductions and Agenda

Abbott Diabetes Care

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- **Jennifer Young**, Tarplin, Downs & Young LLC
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Agenda:

1. Abbott Diabetes Care, the FreeStyle Libre CGM Systems, and ADC's Commitment to Access for All
2. Health Equity Gaps in CGM Access and Adverse Patient Impacts from CMS' Non-Adjunctive CGM Proposal
3. Serious Concerns with CMS' Proposal for Non-Adjunctive CGM Devices

Abbott Diabetes Care (ADC)

Vision

A world where every person with diabetes is free to live life to the fullest

Mission

Making breakthrough technology approachable and accessible for all

Impact

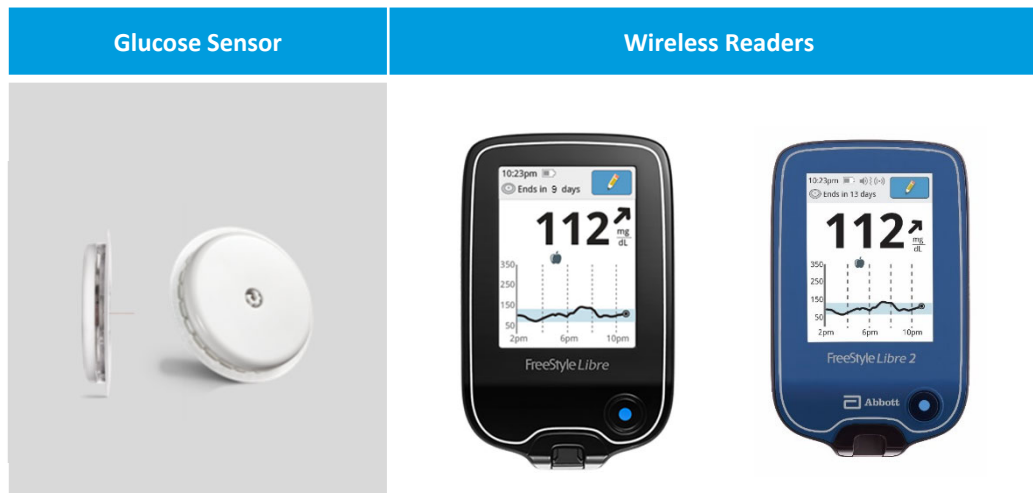
Approximately 200,000 Medicare patients rely on the FreeStyle Libre family of products for glucose monitoring and diabetes management

Leading partner in ADA's "Health Equity Now" Program, working to address health disparities for people with diabetes



Therapeutic CGM: Freestyle Libre Systems

- ADC manufactures the FreeStyle Libre 14-day System and FreeStyle Libre 2, both classified as therapeutic (non-adjunctive) CGM systems by Medicare.



FreeStyle Libre Products

- The FreeStyle Libre products reflect significant innovation:
 - Only therapeutic CGM system with a new glucose reading every minute;
 - Longest sensor life (14 days);
 - Uses an integrated transmitter; and
 - Has the smallest on-body sensor.
- The FSL 2 sensor housing includes a sensor and an integrated Bluetooth transmitter, sending **continuous glucose data** to the Reader and enabling **real-time, automatic alarms** for high and low glucose levels without any action by the patient.
- FreeStyle Libre 2 (FSL 2) was cleared by FDA in June 2020 within the “integrated CGM” (iCGM) category, and determined to be “substantially equivalent” to the Dexcom G6.

CLINICAL EVIDENCE

CGM Has Proven to Improve Diabetes Outcomes

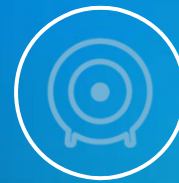
Results from clinical trials and real-world studies highlight the benefits of CGM across a variety of patients*¹⁻¹⁵



**Reduced
A1c**^{*1,2,3,4,5,6,7,8}



**Reduced
hospitalizations**^{*9,10}
Reduction in acute diabetes events



**Increased
Time in Range (TIR)**^{*7,8,11,12,13,14}
Deterring Microvascular/
Macrovascular complications¹⁸



**Reduce time
in hypoglycemia**^{*5,6,7,8,10,15,16}

*Data from these studies were collected with the outside US version of FreeStyle Libre 14 day system. FreeStyle Libre 2 has the same features as FreeStyle Libre 14 day system with optional, real-time glucose alarms. Therefore, the study data is applicable to both products.

1. Yaron et al. *Diabetes Care* (2019): 10.2337/dc18-0166. 2. Pratley et al. *JAMA* (2020): 10.1001/jama.2020.692. 3. Lind et al. *JAMA* (2017): 10.1001/jama.2016.19976. 4. Beck et al. *JAMA* (2017); 0.1001/jama.2016.19975. 5. Beck et al. *Annals of Int Med* (2017): 10.7326/M16-2855. 6. Ruedy et al. *JDS* (2017): 10.1177/1932296817704445. 7. Wada et al. *BMJ Open Diabetes Res & Care* (2020): 10.1136/bmjdr-2019-001115. 8. Martens et al. *JAMA* (2021): 10.1001/jama.2021.7444. 9. Fokkert, Marion et al. *BMJ Open Diab Res Care* (2019): doi:10.1136/bmjdr-2019-000809. 10. Charleer et al. *Diabetes Care* 43, no. 2 (2020): DOI: <https://doi.org/10.2337/dc20-1531>. 11. Bolinder et al. *Lancet* (2016): 10.1016/S0140-6736(16)31535-5. 12. Charleer et al. *Diabetes Care* 43, no. 12 (2020): DOI: <https://doi.org/10.2337/dc20-1531>. 13. El Malahi, Anass, et al. "Chronic Complications Versus Glycaemic Variability, Time in Range and HbA1c in People with Type 1 Diabetes: Sub Study of the RESCUE-trial." European Association for the Study of Diabetes 56th Congress, Vienna, Austria, September 22, 2020. DOI: <https://doi.org/10.1530/endoabs.71.012>. 14. Berganstal et al. *Diabetes* 69 (suppl 1) (2020). DOI: <https://doi.org/10.2337/db20-21-LB>. 15. Haak et al. *Diabetes Ther* (2017): 10.1007/s13300-016-0223-6. 8. van Beers et al. *Lancet Endocrinol* (2016): 10.1016/S2213-8587(16)30193-0. 16. Heinemann et al. *Lancet* (2018): 10.1016/S0140-6736(18)30297-6. 17. Dunn, T. *Diabetes Research and Clinical Practice* (2020): <https://doi.org/10.1016/j.diabres.2017.12.015>. 18. Danne et al. *Diabetes Care* (2017) DOI: 10.2337/dc17-1600.

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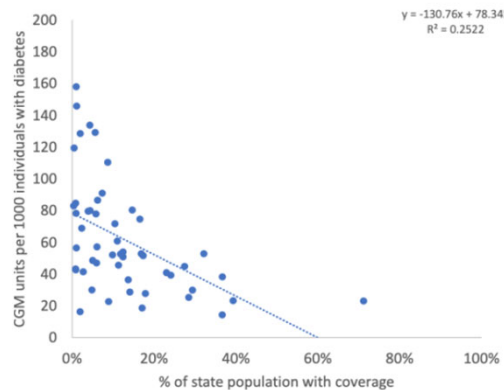
PATIENT ACCESS TO CGM

Current Health Equity Gaps to CGM Access

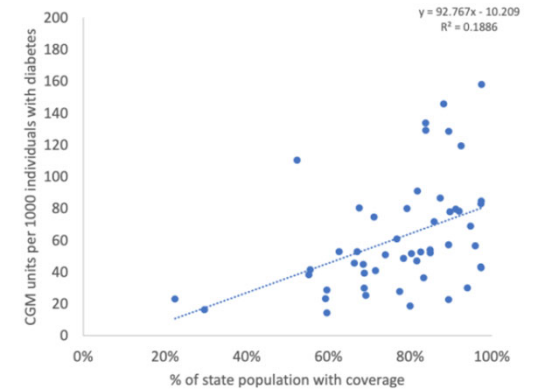
Patients with diabetes deserve equal access to the health benefits of CGM, but racial- ethnic disparities in CGM access persist.

- Analysis from the American Diabetes Association (ADA) shows that states with higher rates of Black Medicare beneficiaries with diabetes have lower CGM utilization rates than states with higher percentages of White beneficiaries.¹

Black Medicare FFS Population with Diabetes



White Medicare FFS Population with Diabetes



- Published analysis shows racial-ethnic disparities in CGM use begins within the first year of a Type 1 diabetes diagnosis.²

Racial / Ethnic Group	% Starting CGM within 1 year	% Continuing CGM at 1 year
Non-Hispanic White	54%	86%
Non-Hispanic Black	31%	61%

1. ADA. Health Equity and Diabetes Technology: A Study of Access to Continuous Glucose Monitors by Payer and Race Executive Summary. <https://www.diabetes.org/sites/default/files/2021-10/ADA%20CGM%20Utilization%20White%20Paper.pdf>.

2. Lai CW, Lipman TH, Willi SM, Hawkes CP. Racial and Ethnic Disparities in Rates of Continuous Glucose Monitor Initiation and Continued Use in Children With Type 1 Diabetes. Diabetes Care. 2021 Jan;44(1):255-257. doi: 10.2337/dc20-1663.

Summary

- Abbott Diabetes Care is dedicated to ensuring access to CGMs for all patients with diabetes who are clinically qualified for CGM, regardless of race, ethnicity, or socioeconomic status.
- Our commitment to the Medicare program and its beneficiaries is proven through the 200,000 Medicare patients who use the FreeStyle Libre family of products.
- ADC looks forward to further discussion on ensuring fair and equitable access to CGMs for all patients who benefit from this life-changing technology.