

2022 CGM Review: FDA Approves Abbott's Freestyle Libre 3 System

In May of 2022, the FDA approved Abbott's newest continuous glucose monitoring system, the Freestyle Libre 3. Consisting of a disposable sensor worn for 14 days and a mobile app, the newest member of the Libre family removes the feature of a separate reader device and requires glucose data to be reported straight to a smartphone. Glucose monitoring is completed through the Freestyle Libre 3 app, currently available to IOS and Android products only, and the Libreview cloud-based website¹. The Libre 2 reader device remains available on the market for those who require a reader in the absence of a compatible smartphone. Abbott's goal is to make their CGMs accessible to all diabetics to allow for improved disease management.

The table below includes comparison between the three available Freestyle products – Libre 14-day, Libre 2, and Libre 3 - along with the Dexcom G6, and the Dexcom G7 continuous glucose monitoring system, currently pending FDA approval. Of note, this review includes the market-dominated CGM devices given current status of insurance coverage, affordability, access, and smartphone and pump compatibility; this does not include review of the Medtronic Guardian Connect (7-day wear) or Senseonics Eversense (90-day implant requiring provider insertion) systems.

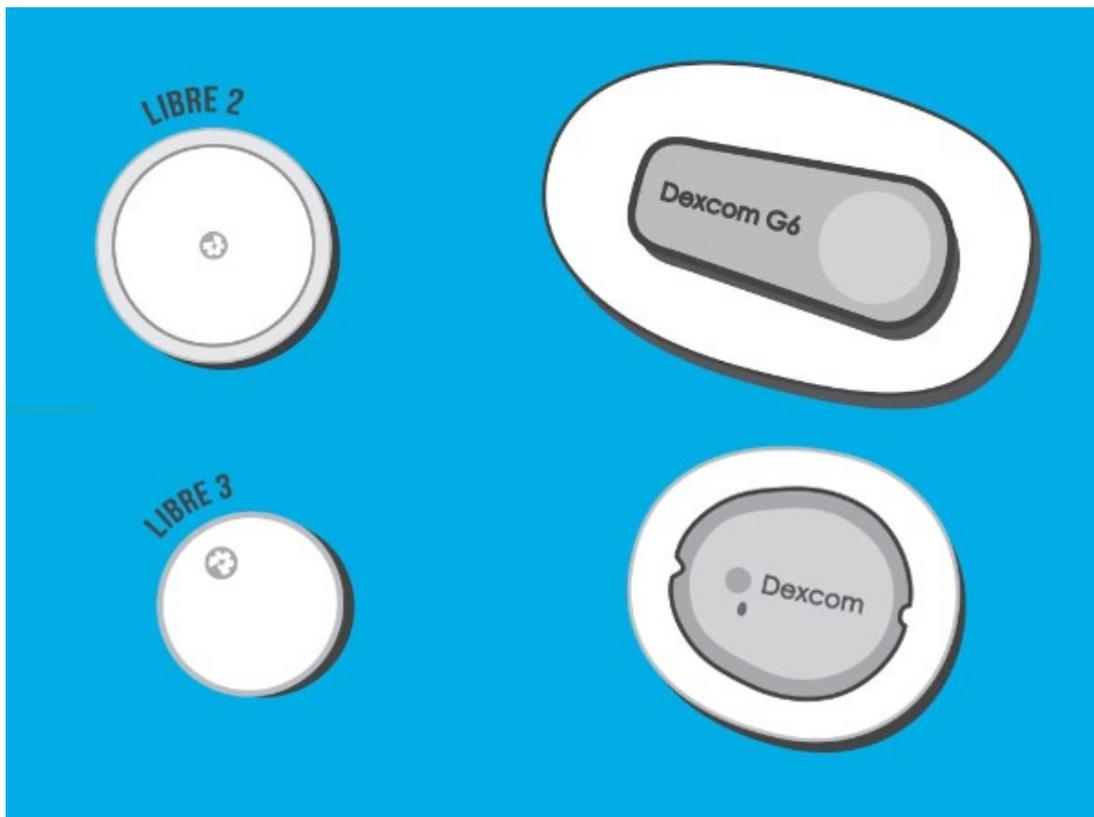


Figure 1: Image taken from [Typeonedabetic-life.com](https://www.typeonedabetic-life.com)

Feature	Freestyle Libre 3 ²	Freestyle Libre 2 ²	Freestyle Libre 14 day ²	Dexcom G7 ⁴	Dexcom G6 ³
Age	4+	4+	18+	2+	2+
CGM Type	Continuous	Flash	Flash	Continuous	Continuous
Sensor Memory	Every minute, offers real time readings and stores data within the smartphone app every 5 minutes for up to 14 days.	Measures glucose every minute, and stores readings every 15 minutes for up to 8 hours. Must be scanned at least once every 8 hours to save data.	Measures glucose every minute, and stores readings every 15 minutes for up to 8 hours. Must be scanned at least once every 8 hours to save data.	While the FDA has not approved the Dexcom G7, literature from other countries suggests sensor memory is similar to that of the Dexcom G6.	Measures glucose continuously, and provides updated readings every 5 minutes.
Scanning Frequency	No scanning required, glucose information updates automatically when paired with smartphone	Every 8 hours to save glucose data	Every 8 hours to save glucose data	No scanning required *More information will be available upon FDA approval of the Dexcom G7	Glucose information updates automatically every 5 minutes, no scanning required
Calibration by finger stick	None Needed	None needed	None Needed	Optional A sensor code may be used in place of calibration	Optional A sensor code may be used in place of calibration
Size	21 x 2.9 mm	35 x 5 mm	35 x 5 mm	24 x 27.3 x 4.6 mm	100 x 252 x 100 mm
Location	Use on the back of the upper arm, between the elbow and axilla region	Use on the back of the upper arm, between the elbow and axilla region	Use on the back of the upper arm, between the elbow and axilla region	Back of arm, abdomen, or upper buttocks in those ages 2-6 years old, avoid upper buttocks in those 6+	Use on the back of arm, abdomen or the upper buttocks for those aged 2-17 years old, avoid the upper buttocks in those 18+
MARD	7.9%	9.3%	9.4%	Arm: 8.2% ⁶ Abdomen: 9.1% ⁶	9%
Sensor Wear Time	14 Days	14 Days	14 Days	10 Days	10 Days
Alarm Features	Optional low and high glucose alarms, signal loss alarms, and a mandatory urgent low glucose alarm User must enable appropriate settings on their smartphone to receive alerts and alarms through the app	Optional high glucose, low glucose, signal loss alarms, mandatory urgent low glucose alarm set for 55mg/dL User must enable appropriate settings on their smartphone to receive alerts and alarms through the app	The system does not have alarms that will automatically notify users for severe low or high glucose events	Customizable alerts for high blood glucose, low blood glucose, rising fast and falling fast blood glucose Options for sound, vibrate and match phone settings	Customizable alerts for low, high, rise rate, and fall rate glucose events, along with a signal loss alert, mandatory urgent low glucose alarm set for 55mg/dL
Reader vs Smartphone App	Smartphone app only (Freestyle Libre 3), available for IOS and Android as of October 2022	Either smartphone app (Freestyle Libre 2) or Freestyle Libre 2 reader device	Either smartphone app (Freestyle Librelink) or Freestyle Libre reader device *The reader device can no longer be obtained for users new to the system	Compatibility for devices and products within the United States will be available upon FDA approval of the Dexcom G7	Either Dexcom G6 app or touchscreen reader device
Location	Use on the back of the upper arm, between the elbow and axilla region	Use on the back of the upper arm, between the elbow and axilla region	Use on the back of the upper arm, between the elbow and axilla region	Back of arm, abdomen, or upper buttocks in those ages 2-6 years old, avoid upper buttocks in those 6+	Use on the back of arm, abdomen or the upper buttocks for those aged 2-17 years old, avoid the upper buttocks in those 18+
Bluetooth Range	33 Feet	20 Feet	20 Feet	20 Feet	20 Feet
Water Resistance	Water resistant for up to 30 minutes in 3 feet of water	Water resistant for up to 30 minutes in 3 feet of water	Water resistant for up to 30 minutes in 3 feet of water	Water resistant in up to 8 feet of water for up to 24 hours	Water resistant in up to 8 feet of water for up to 24 hours
Use in gestational diabetes or dialysis patients	Neither	Neither	Neither	Safety information within the United States not currently available	Neither
Interfering Substances	>500mg of vitamin C per day	>500mg of vitamin C per day	vitamin C, aspirin *Doses not specified, level of inaccuracy depends on the amount active in the body	>1 g of acetaminophen every 6 hours, hydroxyurea (dose not specified)	>1 g of acetaminophen every 6 hours, hydroxyurea (dose not specified)

Billing for CGM Initiation and Interpretation

Coding for professional CGM interactions include CPT 95249 for procedural visits (device teaching and placement) as well as CPT 95251 for interpretation of data which can be billed once monthly. Each code requires the use of 72 hours of glucose data is available, and uploaded in the patients medical record

CGM Coverage and Pharmacy Access

Samples for the Freestyle Libre 3 are not currently available, and the product is not yet available for distribution to retail pharmacies, but can be provided through the following select DME providers listed below. Payer eligibility for Freestyle and Dexcom products are detailed, as well.

Of note, this is not a comprehensive list and is current as of October 2022. Plans may require prior authorization or step therapy prior to coverage of a continuous glucose monitor. While not ubiquitous across all payers, most plans require clinical documentation supporting use with a CMN, requiring chart notes that speak to current blood glucose monitoring frequency (usually requires documentation of at least 4 times per day testing), and insulin injection frequency and dose (usually requires use of both bolus and basal insulin, or insulin pump; most plans require at least 2 injections of bolus insulin per day and/or documented "frequent self-adjustments of insulin", eg. use of a sliding scale). Specific questions related to each product and payer can be directed to the GLIN Pharmacy Team for review.

DME Supplier/Email	Phone/FAX	Freestyle Libre Payer Eligibility	Dexcom Payer Eligibility
<p>Advanced Diabetes Supply LibreIntakes@northcoastmed.com</p>	<p>P: 866-976-9110 F: 760-496-0234</p>	<p>United Healthcare – Medicaid/Medicare</p>	<p>Highmark</p>
<p>Better Living Now</p>	<p>P: 877-262-2179 F: 800-654-7515</p>	<p>Fidelis Care – Medicaid Univera Healthcare – Medicaid Highmark – Medicaid/Medicare United Healthcare – Medicaid/Medicare</p>	<p>Fidelis (type 1 diabetes only)</p>
<p>Bridgewater Health Supplies</p>	<p>P: 800-974-2055 F: 877-297-5127</p>	<p>Empire BCBS – Medicaid Highmark – Medicaid Fidelis Care – Medicaid Molina Healthcare – Medicaid Wellcare – Medicaid/Medicare Independent Health Association - Medicare</p>	
<p>Byram Healthcare AbbottReferrals@byramhealthcare.com</p>	<p>P: 800-775-4372 F: 866-387-1127</p>	<p>Molina Healthcare – Medicaid Univera Healthcare – Medicaid Highmark – Medicaid/Medicare United Healthcare – Medicaid/Medicare Wellcare - Medicare</p>	
<p>CCS Medical Libre@ccsmed.com</p>	<p>P: 800-599-7521 F: 800-557-8256</p>	<p>Univera Healthcare – Medicaid Independent Health Association – Medicare Wellcare - Medicare</p>	<p>IHA Self-Funded Plans Univera Highmark</p>
<p>Edgepark Medical Supplies diabetesreferrals@cardinalhealth.com</p>	<p>P: 844-619-4650 F: 866-510-6583</p>	<p>Empire BCBS – Medicaid Highmark – Medicaid/Medicare Fidelis Care – Medicaid Molina Healthcare – Medicaid Wellcare – Medicaid Independent Health Association – Medicare United Healthcare – Medicaid/Medicare</p>	
<p>US Med abbott@usmed.com</p>	<p>P: 877-270-6508 F: 866-347-8544</p>	<p>Empire BCBS – Medicaid Wellcare - Medicaid</p>	<p>Blue Cross Blue Shield of WNY Empire BCBS</p>
<p>Pharmacy Coverage</p>		<p>Empire BCBS – Medicaid Highmark – Medicaid Molina Healthcare – Medicaid IHA – Commercial IHA – Medicaid</p> <p>*Of note, the Freestyle Libre 3 is only available through DME suppliers, regardless of payer</p>	<p>IHA *Walgreens Community Pharmacy Molina Health United Healthcare Wellcare</p>

References:

1. Abbott's Freestyle Libre® 3 Receives U.S FDA Clearance- Features world's smallest, thinnest, and most accurate 14-Day glucose sensor. Retrieved July 13, 2022, from: <https://abbott.mediaroom.com/2022-05-31-Abbotts-FreeStyle-Libre-R-3-Receives-U-S-FDA-Clearance-Features-Worlds-Smallest,-Thinnest-and-Most-Accurate-14-Day-Glucose-Sensor>
 2. FreeStyle Libre Systems (CGM) | Healthcare Providers. Retrieved October 17, 2022 from www.freestyleprovider.abbott. <https://www.freestyleprovider.abbott/us-en/home.html>
 3. What is the Dexcom G6 Continuous Glucose Monitoring System. Retrieved July 14th, 2022 from <https://www.dexcom.com/faqs/what-is-dexcom-g6-cgm-system>
 4. Ilbyttebier. Dexcom G7 Glucose Monitor Device for Type 1 and Type 2 Diabetes | Dexcom UK. Dexcom. Published April 8, 2022. Accessed October 17, 2022. <https://www.dexcom.com/en-GB/dexcom-g7-cgm-system>
 5. Dexcom Announces Global Rollout of G7. diaTribe. Published October 4, 2022. Accessed October 17, 2022. <https://diatribe.org/dexcom-g7-global-release>
 6. Garg SK, Kipnes M, Castorino K, et al. Accuracy and Safety of Dexcom G7 Continuous Glucose Monitoring in Adults with Diabetes. *Diabetes Technology & Therapeutics*. 2022;24(6):373-380. doi:10.1089/dia.2022.0011
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