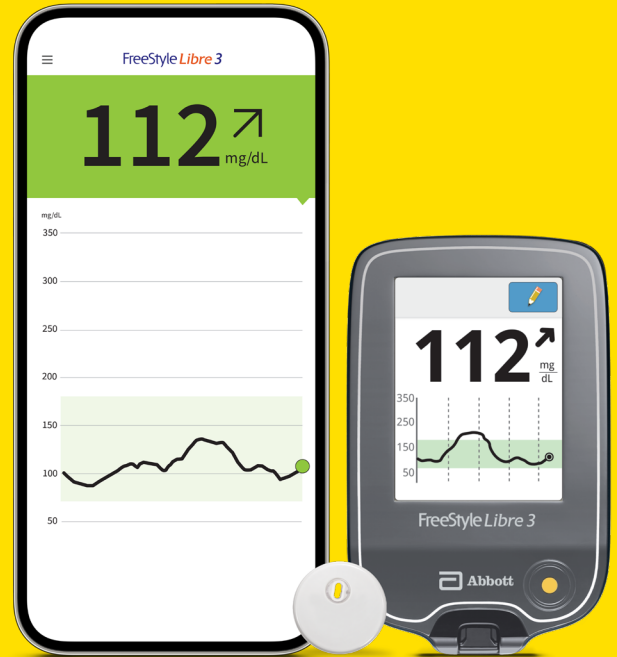




FREESTYLE LIBRE 3 SYSTEM

Formulary Kit



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July 2024

Dear Health Plan Administrator,

We are pleased to present Abbott's next-generation system, the FreeStyle Libre 3 system.

The FreeStyle Libre 3 system is a real-time continuous glucose monitoring (CGM) device with real-time alarms* indicated for use in people living with diabetes ages 4 and older.

The FreeStyle Libre 3 system evolves the portfolio with new features, such as:

- **Real-time** glucose readings **every minute** to your members' smartphones[†] or readers[‡]
- **The FreeStyle Libre 3 sensor: Unsurpassed 14-day** accuracy¹ with a 7.9% overall MARD¹ (Adults and Pediatrics)
- **The FreeStyle Libre 3 Plus sensor: Longest data storage**^{§2}, 15-day data storage makes data gaps a thing of the past
- **Easy to use**^{||3}, one-piece sensor application, requiring **no in-person training**⁴
- **The world's smallest, thinnest**[¶] and **most discreet**⁴ sensor

This FreeStyle Libre 3 system Formulary Kit contains the following:

- Product information
- Clinical guidelines
- Clinical highlights
- Digital health tools
- Pricing information
- Prescribing information
- Resources

Please reach out to your Abbott account manager for more information about the FreeStyle Libre 3 system.

Best regards,

Jody Boeddeker

General Manager, Market Access

The FreeStyle Libre 3 system is indicated for use in people with diabetes age 4 and older.

The FreeStyle Libre 3 Plus sensors are indicated for use in people with diabetes age 2 and older

* Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information. † The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. ‡ The FreeStyle Libre 3 app and the FreeStyle Libre 3 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see the Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations. § In comparison with Dexcom G7 and Medtronic Guardian Connect System User Guide. || Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 has the same features as FreeStyle Libre 14 day system with real-time glucose alarms. Therefore the study data is applicable to both products. ¶ Among patient-applied sensors.

References: **1.** FreeStyle Libre 3 User's Manual. **2.** Based on FreeStyle Libre 3 User's Manual, Dexcom G7 CGM User Guide and Medtronic Guardian Connect System User Guide. **3.** Haak, T. *Diabetes Ther* (2017): <https://doi.org/10.1007/s13300-016-0223-6> **4.** Data on file, Abbott Diabetes Care.

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System Components

The FreeStyle Libre 3 system helps to build a complete glycemic picture that enables patients, caregivers, and healthcare providers to make informed disease management and treatment decisions.

The FreeStyle Libre 3 sensor is easy to apply¹, using a 1-piece applicator, and easy to use^{*2}, requiring no in-person training¹.



FreeStyle Libre 3 sensor

The FreeStyle Libre 3 sensor is the smallest CGM sensor on the market, designed to be discreet¹ and provide patients with greater flexibility. The sensor provides glucose readings that can be streamed directly to your members' smartphone[†] or reader[‡]. The sensor has 14-day wear and data storage, and simplified sensor application in the position of attachment. The sensor stores retrospective glucose data over the full 14-day wear period.

FreeStyle Libre 3 Plus sensor

The FreeStyle Libre 3 Plus sensor brings the latest innovative technology to the FreeStyle Libre 3 system, adding the following new features to the FreeStyle Libre 3 sensor:

- Extends the sensor wear up to 15 days³
- Allows for future integrated experiences with automated insulin delivery systems
- Expands the age indication to 2 years and older³

The FreeStyle Libre 3 Plus sensor is compatible with the current FreeStyle Libre 3 app[†] and FreeStyle Libre 3 reader[‡].



FreeStyle Libre 3 app[†]

The FreeStyle Libre 3 app is designed to be used by people living with diabetes. The app enables the user to carry out routine glucose monitoring using a compatible smartphone and the FreeStyle Libre 3 sensor. The FreeStyle Libre 3 app is designed to offer 3 optional alarms[§] (low glucose, high glucose, and signal loss) and 1 mandatory urgent low alarm (set at 55 mg/dL).



FreeStyle Libre 3 reader[‡]

The reader obtains glucose readings via streaming from the sensor and can issue glucose alarms[§]. It is handheld and lightweight, with a backlit color touchscreen. The reader can store approximately 90 days of glucose history and notes entered about activities, such as taking insulin, eating food, or exercising. This information can help patients understand how these activities affect their glucose. The reader also includes a built-in meter for blood glucose testing. To use the built-in meter, patients need the FreeStyle Precision Neo blood glucose test strips, control solution, a lancing device, and lancets. These items are not included in the reader kit and must be obtained separately from their FreeStyle Libre 3 system provider (pharmacy or mail-order supplier).

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FreeStyle Libre 3 system is indicated for use in people with diabetes age 4 and older.

FreeStyle Libre 3 Plus sensors are indicated for use in people with diabetes age 2 and older

* Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 has the same features as FreeStyle Libre 14 day system with real-time glucose alarms. Therefore the study data is applicable to both products. † The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. ‡ The FreeStyle Libre 3 app and the FreeStyle Libre 3 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see the Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations. § Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information.

References: 1. Data on file, Abbott Diabetes Care. 2. Haak, T. *Diabetes Ther* (2017): <https://doi.org/10.1007/s13300-016-0223-6> 3. FreeStyle Libre 3 User's Manual.

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Alarms*

The FreeStyle Libre 3 system provides real-time glucose alarms* with readings streaming every minute¹. The system is designed to offer 3 optional alarms (low glucose, high glucose, and signal loss) and 1 mandatory urgent low alarm (set at 55 mg/dL).



Optional, low glucose alarm:

Notifies when glucose is **BELOW** a set level (60 -100 mg/dL)



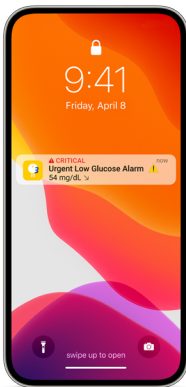
Optional, high glucose alarm:

Notifies when glucose is **ABOVE** a set level (120 - 400 mg/dL)



Optional, signal loss alarm:

Notifies when sensor is not communicating with smartphone[†] or reader[‡] and that low or high glucose alarms will not be received



The FreeStyle Libre 3 app[†] has a mandatory Urgent Low Glucose Alarm that lets users know when their glucose value is below 55 mg/dL.

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FreeStyle Libre 3 system is indicated for use in people with diabetes age 4 and older.

FreeStyle Libre 3 Plus sensors are indicated for use in people with diabetes age 2 and older.

* Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information. † The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. ‡ The FreeStyle Libre 3 app and the FreeStyle Libre 3 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see the Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations.

Reference: 1. FreeStyle Libre 3 User's Manual.

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Overall Accuracy to YSI

FreeStyle Libre 3 sensor¹

Patient population	Number of subjects	Total number of paired CGM-Reference	Percent within 20/20% Reference	MARD (%)
Overall	95	6836	93.2	7.9
≥ 18 years	56	4768	94.7	7.6
6-17 years	39	2068	89.7	8.7
4-5 years*	5	72	88.9	10.1

FreeStyle Libre 3 Plus sensor¹

Subject Group	Number of CGM Reference Pairs	Number of Subjects	Percent within ±20%/±20 mg/dL	Percent within ±20%/±20 mg/dL on Day 1	Percent within ±20%/±20 mg/dL in first 12 hours	MARD (%)
Adults	20497	149	93.7	82.9	79.2	8.2
Children (age 6-17)	7025	124	93.5	89.8	90.5	8.2
Children (age 2-5) [†]	135	10	86.7	78.9	88.9	9.7

* Using BGM reference. † No YSI measurements were obtained for children ages 2-5; results displayed are from CGM-SMBG matched paired measurements obtained during clinic visits from 10 of the 12 subjects. Two of the 12 subjects did not have CGM-SMBG matched paired measurements obtained from clinic visits.

Reference: 1. FreeStyle Libre 3 User's Manual.





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FreeStyle Libre 2 system^{1,2}

FreeStyle Libre 3 system³



Glucose data transfer to reader/smartphone	Real-time glucose readings and real-time alarms*	Real-time glucose readings and real-time alarms†
Glucose viewing	FreeStyle Libre 2: Scan (to app‡ or reader§) FreeStyle Libre 2 Plus sensor: Scan (to app or reader) or Stream (to AID device)	Stream (to app or reader#)
Sensor wear	FreeStyle Libre 2 sensor: 14-day FreeStyle Libre 2 Plus sensor: 15-day	FreeStyle Libre 3 sensor: 14-day FreeStyle Libre 3 Plus sensor: 15-day
Indication	The FreeStyle Libre systems are indicated for all people with diabetes, including those with type 1 diabetes, type 2 diabetes, or gestational diabetes.	
Configuration	Sensor with app‡ or reader§ 	Sensor with app or reader# 
Applicator	2-piece	1-piece
Age	FreeStyle Libre 2 sensor: 4 and older FreeStyle Libre 2 Plus sensor: 2 and older	FreeStyle Libre 3 sensor: 4 and older FreeStyle Libre 3 Plus sensor: 2 and older
Sensor size	1.18" x 0.2" 	0.83" x 0.11" 

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FreeStyle Libre 3 system is indicated for use in people with diabetes age 4 and older.

FreeStyle Libre 2 Plus and FreeStyle Libre 3 Plus sensors are indicated for use in people with diabetes age 2 and older.

* Notifications will only be received when alarms are turned on and the sensor is within 20 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 2 User's Manual for more information. † Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information. ‡ The FreeStyle Libre 2 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. Use of the FreeStyle Libre 2 app requires registration with LibreView. § The FreeStyle Libre 2 app and the FreeStyle Libre 2 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations. || The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. # The FreeStyle Libre 3 app and the FreeStyle Libre 3 reader have similar but not identical features. Fingersticks are required for treatment decisions when you see the Check Blood Glucose symbol and when your glucose alarms and readings from the system do not match symptoms or expectations.

References: 1. FreeStyle Libre 2 User's Manual. 2. FreeStyle Libre 2 Plus User's Manual. 3. FreeStyle Libre 3 User's Manual.

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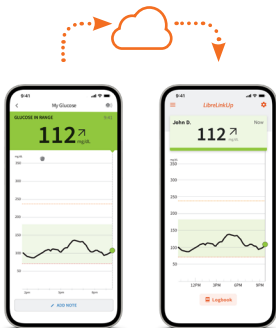


FreeStyle Libre 3 app* — *for the patient*

The FreeStyle Libre 3 app provides real-time glucose readings streamed every minute directly to your member's smartphone* so they can act faster and make timely diabetes treatment decisions.

With helpful reports, easy-to-read charts, and the ability to privately share user's glucose readings with up to 20 individuals from their care team, the FreeStyle Libre 3 app* helps users manage their diabetes daily.

The FreeStyle Libre 3 app is not compatible with the FreeStyle Libre 2 system.



LibreLinkUp app† — *for the caregivers*

The LibreLinkUp app is designed to be used by family, friends, and other caregivers of patients using the FreeStyle Libre 3 app. The LibreLinkUp app allows users to follow up to 20 different connections. LibreLinkUp users receive real-time glucose information (including a 12-hour graph) and can customize their own glucose alarms‡§.



LibreView desktop application|| — *for the healthcare professional and the patient*

LibreView is a secure#, cloud-based data management system. It is HIPAA compliant and allows data to be accessed at any time. Streamed glucose data is compiled into easy-to-read**1 reports, glucose patterns, and trends. LibreView is intended for use by both patients and healthcare professionals to assist people living with diabetes.

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Medicare and other payor criteria may apply.

* The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. † The LibreLinkUp app is only compatible with certain mobile devices and operating systems. Please check <http://www.librelinkup.com> for more information about device compatibility before using the app. Use of the LibreLinkUp app requires registration with LibreView. LibreLinkUp is not intended to be used for dosing decisions. The user should follow instructions on the continuous glucose monitoring system. LibreLinkUp is not intended to replace self-monitoring practices as advised by a physician. ‡ The user's device must have internet connectivity for glucose data to automatically upload to LibreView and to transfer to connected LibreLinkUp app users. § Notifications will only be received when alarms are turned on and the sensor is within 33 feet unobstructed of the reading device. You must enable the appropriate settings on your smartphone to receive alarms and alerts, see the FreeStyle Libre 3 User's Manual for more information. || The LibreView data management software is intended for use by both patients and healthcare professionals to assist people with diabetes and their healthcare professionals in the review, analysis and evaluation of historical glucose meter data to support effective diabetes management. The LibreView software is not intended to provide treatment decisions or to be used as a substitute for professional healthcare advice. # LibreView is ISO27001/27018/27701 certified and HITRUST CSF Certified. ** Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 system 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.

Reference: 1. Unger, J. *Postgrad Med* (2020): <https://doi.org/10.1080/00325481.2020.1744393>

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Clinical Guidelines for the Use of CGM: Highlights

Respected clinical organizations, including the ADA and AACE, have published guidelines for the use of continuous glucose monitoring (CGM) in the management of diabetes^{1,2}.

American Diabetes Association (ADA) American Diabetes Association.

2024 ADA Standards of Care Recommendations on CGM Use¹:

The ADA published diabetes treatment guidelines as part of the 2024 Standards of Care in Diabetes, making the following clinical and access recommendations for CGM:

- For all insulin-using patients as well as individuals at high risk for hypoglycemia
- To assess glycemic status by either A1c and/or appropriate CGM metrics at least 2 times a year
- For guiding medical nutrition therapy, physical activity, preventing hypoglycemia, and adjusting medications
- CGM users should have uninterrupted access through third-party payers

American Association of Clinical Endocrinology (AACE) AACE.

2023 AACE Clinical Practice Guidelines Recommendations on CGM Use²:

The AACE published recommendations in 2023 regarding the use of CGM systems in the management of people with diabetes. The following recommendations were highlighted with respect to continuous glucose monitoring:

- For all patients to reach glycemia goals safely
- For newly diagnosed T2DM patients and those at low risk for hypoglycemia
- For the use of CGM metrics, which can be used as a surrogate to HbA1c
- For the education of persons with T2DM (eg, effects on behaviors including diet and exercise)
- For alarms or alerts in persons with hypoglycemia who would benefit from these warnings
- For aiding clinicians in investigating avenues to improve glycemic control with medical therapies

Use of the FreeStyle Libre family of personal CGMs is associated with:

Reduced HbA1c across multiple groups of patients ^{*1-9}	Increased Time in Range (TIR) ^{*2,3,10,11}	Reduced number of hypoglycemic events ^{*11-13}	Reduced resource utilization ^{*5,9,14}
<p>↓ 0.42%-0.59% HbA1c reduction observed among patients with T1D/T2D in a meta-analysis^{*1}</p> <p>↓ 0.4-0.5% HbA1c reduction among children and teenagers (4-17 years) with T1D^{*2,3}</p> <p>↓ 0.4% HbA1c reduction among patients with T1D^{*4}</p> <p>↓ 0.9-1.6% reduction in HbA1c among people with T2D^{*5-8}</p> <p>↓ 2.4% reduction in HbA1c when used in combination with a GLP-1 RA among patients with T2D^{*9}</p>	<p>↑ 1-2.17 hrs/day increased TIR observed among patients with T1D^{*2,3,10}</p> <p>↑ 2.36 hrs/day increased TIR observed among patients with T2D^{*11}</p>	<p>↓ 26% reduction in number of hypoglycemic events among patients with T1D^{*11}</p> <p>↓ 28% reduction in number of hypoglycemic events among patients with T2D on intensive insulin regimens^{*12}</p> <p>↓ 44% fewer severe hypoglycemia admissions among patients with T2D^{*13}</p>	<p>↓ 83% reduction in number of diabetes-related hospital admissions among patients with T1D or T2D^{*14}</p> <p>↓ 37% reduction in acute diabetes event rates among patients with T2D on basal insulin^{*5}</p> <p>↓ 25% reduction in acute diabetes event rates among patients with T2D on non-insulin therapies^{*5}</p> <p>↓ 75% DKA-related hospital admissions among patients with T2D^{*9}</p>

* Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 3 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. † A meta-analysis of 75 real-world observational studies on the impact of flash continuous glucose monitoring on glycemic control as measured by HbA1c. ‡ Acute diabetes events include hospitalizations or outpatient emergency room visits associated with hyper- or hypoglycemic events.

References: **1.** Evans, M. *Diabetes Ther* (2022): <https://doi.org/10.1007/s13300-022-01253-9> **2.** Campbell, F. *Pediatr Diabetes* (2018): <https://doi.org/10.1111/pedi.12735> **3.** Leelarathna L, et al. *N Engl J Med* (2022): <https://doi.org/10.1056/nejmoa2205650> **4.** Tyndall, V. *Diabetologia*, no. 62 (2019): <https://doi.org/10.1007/s00125-019-4894-1> **5.** Miller M, et al. *Am J Manag Care*. (2021): <https://doi.org/10.37765/ajmc.2021.88780> **6.** Wright E, et al. *Diabetes Spectr* (2021): <https://doi.org/10.2337/ds20-0069> **7.** Miller R, et al. *Diabetes* (2020): <https://doi.org/10.2337/db20-84-LB> **8.** Aronson R, et al. *Diabetes Obes Metab*. (2022): <https://doi.org/10.1111/dom.14949> **9.** Wright E, et al. Initiating GLP-1 therapy in combination with FreeStyle Libre provides greater benefit compared to GLP-1 therapy alone. Abstract presented at: ATTD 2024, The International Conference on Advanced Technologies & Treatments for Diabetes, March 6-9, 2024; Florence, Italy, and online. **10.** Bolinder, J. *Lancet* (2016): [https://doi.org/10.1016/s0140-6736\(16\)31535-5](https://doi.org/10.1016/s0140-6736(16)31535-5) **11.** Wada E, et al. *BMJ Open Diabetes Res Care* (2020): <http://dx.doi.org/10.1136/bmjdr-2019-001115> **12.** Haak, T. *Diabetes Ther* (2017): <https://doi.org/10.1007/s13300-016-0223-6> **13.** Guerci B, et al. *Diabetes Technol Ther* (2022): <https://doi.org/10.1089/dia.2022.0271> **14.** Fokkert, M. *BMJ Open Diabetes Res Care* (2019): <https://doi.org/10.1136/bmjdr-2019-000809>

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FreeStyle Libre 3 system



	FreeStyle Libre 3 Sensor Kit	FreeStyle Libre 3 Plus Sensor Kit	FreeStyle Libre 3 Reader Kit
SKU #	72081-01	78768-01	72079-01
Package Size	1 sensor	1 sensor	1 reader
Unit Price	\$68.07	\$72.93	\$70.00
NRC	57599-0818-00	57599-0844-00	57599-0820-00
UPC	357599818005	357599844004	357599820008
Unit Pkg. Weight	0.13 lb	0.13 lb	0.865 lb
Storage Temperature	36°F to 82°F (3°C to 28°C)	36°F to 82°F (3°C to 28°C)	-4°F to 140°F (-20°C to 60°C)
Storage Humidity	10% to 90%	10% to 90%	10% to 90%
Contains Battery	Yes	Yes	Yes

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Pharmacy

Commercially insured / cash-pay patients

FreeStyle Libre 3 system Rx includes:

- FreeStyle Libre 3 app*
- FreeStyle Libre 3 sensor
 - Quantity: 2 sensors/month NRC # 57599-0818-00
 - Sensor refills: PRN or 12 refills annually

Durable Medical Equipment (DME)

Medicare-eligible patients

1. **Determine if patient's coverage is Medicare Fee-for-Service or Medicare Advantage**
 - Medicare Fee-for-Service: Refer to CMS Continuous Glucose Monitors coverage criteria and documentation requirements to confirm coverage^{†‡}
 - Medicare Advantage: Contact the patient's insurance for eligibility criteria
2. FreeStyle Libre DME Supplier Grid provides options to select a DME[§]: <https://www.freestyleprovider.abbott/us-en/dme.html>
3. Medicare Detailed Written Order form to be completed with the patient's information^{†||}
 - Medicare Detailed Written Order form can be found at: <http://www.freestylefoundations.abbott>
4. Patient to receive a call from the DME

How to get the FreeStyle Libre 3 app*

Once your member receives their prescription for the FreeStyle Libre 3 system, they can download the app to their compatible smartphone at no cost.



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* The FreeStyle Libre 3 app is only compatible with certain mobile devices and operating systems. Please check our website for more information about device compatibility before using the app. † See Local Coverage Determination: Glucose Monitors (L33822), July 2021. <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822>. ‡ Patients must meet Medicare eligibility coverage criteria. § DMEs are subject to change without notice.

|| See Local Coverage Article: Glucose Monitors (A52564). <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464>

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- How to Prescribe
- Practice Resources

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- Support for Members
- Patient Stories
- Getting Started and MyFreeStyle Program

CPT Billing and Coding Reference Guide PDF: FreeStyleProvider.Abbott

- CGM Billing Reference
-



FREESTYLE LIBRE 3 SYSTEM
Important Safety
Information

FreeStyle Libre 2 and FreeStyle Libre 3 systems: Failure to use FreeStyle Libre 2 or FreeStyle Libre 3 systems as instructed in labeling may result in missing a severe low or high glucose event and/or making a treatment decision, resulting in injury. If glucose alarms and readings do not match symptoms or expectations, use a fingerstick value from a blood glucose meter for treatment decisions. Seek medical attention when appropriate or contact Abbott at 855-632-8658 or <https://www.FreeStyle.abbott/us-en/safety-information.html> for safety info.

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FreeStyle
Libre 3



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