FreeStyle Libre

FREESTYLE LIBRE 2 SYSTEM

Formulary Kit

See Important Safety Information on page 13.

September, 2025

Dear Health Plan Administrator,

The FreeStyle Libre 2 system provides patients with real-time glucose readings every minute with a simple scan[1]. The FreeStyle Libre 2 system is part of the FreeStyle Libre portfolio, and provides accurate, up-to-the minute sensor readings[2], and features:

- FreeStyle Libre 2 Plus sensor: The ease*[3] of the FreeStyle Libre 2 system, now with 15-day sensor wear
- An iCGM sensor easy to apply*[3,4] with no in-person patient training required[5]

This FreeStyle Libre 2 system Formulary Kit contains the following:

- Product information
- Product comparison
- 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 2 system.

Best regards,
Jody Boeddeker
General Manager, Market Access

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* Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms.

References: 1. Alva, S. ADCES. Accessed December 17, 2024. https://www.adces.org/docs/default-source/dana-files/adc-23842v3-revised-august-3-2020cd070ee4-83cd-472c-a990-892684a26df3.pdf?sfvrsn=26ee6959_5. **2.** FreeStyle Libre 2 User's Manual. **3.** Haak T, et al. *Diabetes Ther* (2017): https://doi.org/10.1007/s13300-016-0223-6. **4.** Campbell, F. *Pediatr Diabetes* (2018): https://doi.org/10.1111/pedi.12735. **5.** Data on file. Abbott Diabetes Care.

The FreeStyle Libre 2 system has two main parts: a compatible smartphone* or handheld reader†, and a disposable sensor that patients wear on their bodies. They use their compatible smartphone or reader to wirelessly scan the sensor and display their glucose readings. The reader only works with FreeStyle Libre 2 sensors and cannot be used with other sensors.

The FreeStyle Libre 2 Plus sensor is easy to apply and comfortable to wear‡1.

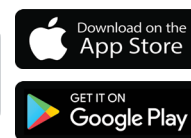## FreeStyle Libre 2 Plus sensor

The FreeStyle Libre 2 Plus sensor brings the latest innovative technology to the FreeStyle Libre 2 system, adding the following features:

- Extends the sensor wear up to 15 days[2]
- Accurate, minute-to-minute glucose data can be combined with compatible automated insulin delivery systems
- Expands the age indication to 2 years and older[2]
- Is compatible with the current Libre app* and FreeStyle Libre 2 reader†

The Libre app*

The Libre app performs some similar functions as the FreeStyle Libre 2 reader. Patients can use it to start a sensor, receive glucose alarms§, get glucose readings from a scan of the FreeStyle Libre 2 Plus sensor, and store glucose history and entered notes. The Libre iOS app is available for download from the App Store. The Libre Android app is available for download from the Google Play Store.

FreeStyle Libre 2 reader

The reader gets glucose readings from a scan of 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 2 system provider (pharmacy∥ or mail-order supplier).

* The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. ✚ The FreeStyle Libre systems apps and the FreeStyle Libre systems readers 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. ‡ Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms. § Alarm notifications will only be received when alarms settings are enabled and turned on and sensor is within 20 feet unobstructed of the reading device. ∥ Participating pharmacies are subject to change without notice. Product availability may vary by retailer or DME.

References: 1. Haak, T. *Diabetes Ther* (2017): https://doi.org/10.1007/s13300-016-0223-6 **2.** FreeStyle Libre 2 User's Manual.

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Alarms

The FreeStyle Libre 2 system provides optional real-time glucose alarms* with readings every minute[1]. When in range, the sensor automatically communicates to give real-time high and low glucose alarms. These alarms are on by default.

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

Overall Accuracy to YSI

FreeStyle Libre 2 Plus sensor[1]

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

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Product images are for illustrative purpose only.

* Alarm notifications will only be received when alarms settings are enabled and turned on and sensor is within 20 feet unobstructed of the reading device.
† The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. ‡ The FreeStyle Libre systems apps and the FreeStyle Libre systems readers 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. § 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; 2 of the 12 subjects did not have CGM-SMBG matched paired measurements obtained from clinic visits.
Reference: 1. FreeStyle Libre 2 User's Manual.
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FreeStyle Libre

	FreeStyle Libre 2 system with FreeStyle Libre 2 Plus sensor[1]	FreeStyle Libre 3 system with FreeStyle Libre 3 Plus sensor[2]
Glucose data transfer to reader/smartphone	Real-time glucose readings and real-time alarms*	
Glucose viewing	**Scan or stream** [to app†, reader‡, automated insulin delivery device (AID)]	**Stream** [to app, reader, or AID]
Sensor wear	15-day	
Indication	The FreeStyle Libre systems are indicated for all people with diabetes, including those with type 1 diabetes and type 2 diabetes.	
Configuration	Sensor with app or reader	
Applicator	2-piece	1-piece
Age	2 and older	
Sensor size	1.18 x 0.2 in	0.83 x 0.11 in
AID compatibility	Yes	

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

* Alarm notifications will only be received when alarms settings are enabled and turned on and sensor is within 20 feet (FreeStyle Libre 2) or 33 feet (FreeStyle Libre 3) unobstructed of the reading device. † The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. ‡ The FreeStyle Libre systems apps and the FreeStyle Libre systems readers 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 3 User's Manual.

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The Libre app* — *for the patient*

The Libre app is designed to be used by people living with diabetes. The app enables the user to carry out routine glucose monitoring using a smartphone* and FreeStyle Libre 2 Plus sensor. The Libre app is only compatible with certain mobile devices and operating systems. The user can access glucose data and receive optional, real-time high and low glucose alarms[†] on the Libre app.

The Libre app is not compatible with FreeStyle Libre 14 day sensors.

LibreLinkUp app[‡] — *for the caregivers*

LibreLinkUp is designed to be used by family, friends, and other caregivers of patients using the Libre app. This app allows users to follow up to 20 different connections. LibreLinkUp users receive glucose information (including a 12-hour graph) and 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 are compiled into easy-to-interpret[1] reports, glucose patterns, and trends. LibreView is intended for use by both patients and healthcare professionals to assist people with diabetes.

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* The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. **✝** Alarm notifications will only be received when alarms settings are enabled and turned on and sensor is within 20 feet unobstructed of the reading device **‡** Check https://www.librelinkup.com for information about mobile device and operating system compatibility. LibreLinkUp is not intended to be used for dosing decisions or to replace self-monitoring practices as advised by a physician, and requires registration with LibreView. **§** The user's device must have internet connectivity for glucose data to automatically upload to LibreView and to transfer to connected LibreLinkUp app users. **∥** Glucose alarms will transfer to the LibreLinkUp app users when users are connected and alarms are enabled on the Libre app. **¶** 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. **#** The user's device must have internet connectivity for glucose data to automatically upload to LibreView.

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)

2025 ADA Standards of Care Recommendations on CGM Use[1]:

The ADA published diabetes treatment guidelines as part of the 2025 Standards of Care in Diabetes, making the following clinical and access recommendations for CGM:

- Recommend CGM for all individuals with diabetes on any type of insulin therapy and CGM should be used as close to daily as possible for maximal benefit
- Consider using CGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic goals
- The choice of device should be made based on the individual's circumstances, preferences, and needs
- People with diabetes should have uninterrupted access to their supplies to minimize gaps in CGM
- CGM can help achieve glycemic goals and A1c goal in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy

American Association of Clinical Endocrinology (AACE)

2023 AACE Clinical Practice Guidelines Recommendations on CGM Use[2]:

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

References: 1. American Diabetes Association Professional Practice Committee. "Erratum. 7. Diabetes Technology: Standards of Care in Diabetes-2025. *Diabetes Care* 2025;48(Suppl. 1):S146-S166." *Diabetes Care*, April 1, 2025. https://pmc.ncbi.nlm.nih.gov/articles/PMC11932807/. Accessed July 9, 2025. **2.** Samson SL, et al. *Endocr Pract* (2023). https://doi.org/10.1016/j.eprac.2023.02.001

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Use of FreeStyle Libre 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]
↓0.42%-0.59% HbA1c reduction observed among patients with T1D/T2D in a meta-analysis[*†1]	**↑1-2.17 hrs/day** increased TIR observed among patients with T1D[*2,3,10]	**↓26%** reduction in number of hypoglycemic events among patients with T1D[*11]	**↓83%** reduction in number of diabetes-related hospital admissions among patients with T1D or T2D[*14]
↓0.4-0.5% HbA1c reduction among children and teenagers (4-17 years) with T1D[*2,3]	**↑2.36 hrs/day** increased TIR observed among patients with T2D[*11]	**↓28%** reduction in number of hypoglycemic events among patients with T2D on intensive insulin regimens[*12]	**↓37%** reduction in acute diabetes event rates among patients with T2D on basal insulin[*‡5]
↓0.4% HbA1c reduction among patients with T1D[*4]		**↓44%** fewer severe hypoglycemia admissions among patients with T2D[*13]	**↓25%** reduction in acute diabetes event rates among patients with T2D on non-insulin therapies[*‡5]
↓0.9-1.6% reduction in HbA1c among people with T2D[*5-8]			**↓75% fewer** DKA-related hospital admissions among patients with T2D[*9]
↓2.4% reduction in HbA1c when used in combination with a GLP-1 RA among patients with T2D[*9]			

* Study was performed with the outside US version of the FreeStyle Libre 14 day system. Data is applicable to FreeStyle Libre 2 system, as feature sets are similar as FreeStyle Libre 14 day system, excluding alarms. † 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* (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 **11.** Wada E, et al. *BMJ Open Diabetes Res Care* (2020): http://dx.doi.org/10.1136/bmjdrc-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/bmjdrc-2019-000809

FreeStyle Libre 2 system

	FreeStyle Libre 2 Plus Sensor	**FreeStyle Libre 2 Reader**
SKU #	78747-01	71953-01
Quantity	1 sensor	1 reader
Unit Price	$77.31 ea	$70
NRC	57599-0805-00	57599-0804-00
UPC	30357599836017	30357599804016
Unit Pkg. Weight	0.214 lb	0.865 lb
Storage Temperature	36°F to 82°F (2.22°C to 27.78°C)	-4°F to 140°F (-20°C to 60°C)
Storage Humidity	10% to 90%	10% to 90%
Contains Battery	Yes	Yes

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Pharmacy

Commercially insured / cash-pay patients

FreeStyle Libre 2 system Rx includes:

- The Libre app*
- FreeStyle Libre 2 Plus sensor
  - Quantity: 2 sensors/month, NRC # 57599-0805-00
 - 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 insurer for eligibility criteria

2. FreeStyle Libre DME Supplier Grid provides options to select 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 supplier

How to get the Libre app*

Once your member receives their prescription for the FreeStyle Libre 2 system, they can download the Libre app to their compatible smartphone at no cost.
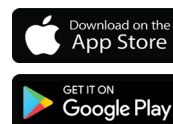
Download on the App Store

GET IT ON Google Play

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* The FreeStyle Libre systems apps are only compatible with certain mobile devices and operating systems. Please check the Support section of our website for more information about device compatibility before using the apps. Use of the FreeStyle Libre systems apps may require registration with LibreView. † 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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