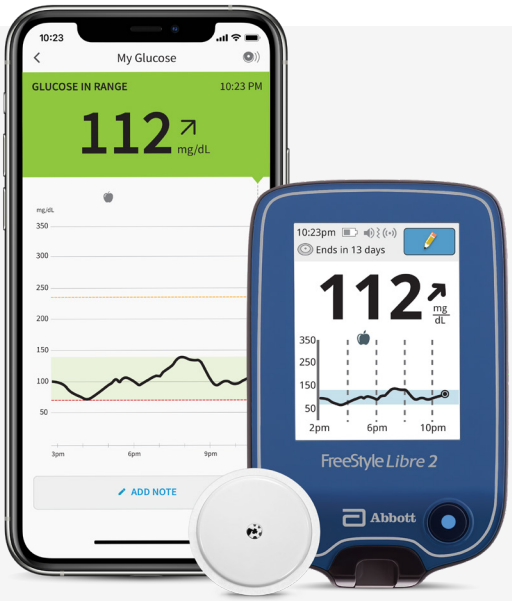
FreeStyle Libre 2

Formulary Kit

FreeStyle Libre 2 System



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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.

Medicare coverage is available for the FreeStyle Libre 2 system if a smartphone with the FreeStyle Libre 2 app is used in conjunction with the FreeStyle Libre 2 reader to review glucose data. Medicare coverage is not available if a patient never uses the FreeStyle Libre 2 reader, and patients must meet other applicable coverage criteria. See Local Coverage Determination: Glucose Monitors (L33822), July 2021 and Local Coverage Article: Glucose Monitors (A52464), Jan 2020. As a courtesy to its customers, Abbott provides the most up-to-date information available, but it is subject to change and interpretation. The customer is ultimately responsible for determining the appropriate codes, coverage, and payment policies for individual patients. Abbott does not guarantee third party coverage of payment for our products or reimburse customers for claims that are denied by third party payors.

FreeStyle Libre 2

September 2021

Dear Health Plan Administrator,

The FreeStyle Libre 2 system is a continuous glucose monitoring (CGM) device with real time alarms capability* indicated for the management of diabetes in persons age 4 and older.

This FreeStyle Libre 2 System Formulary Kit contains more information about the following:

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

The FreeStyle Libre 2 system has unsurpassed 14 day accuracy[1] for adults and children (age 4 and older), and offers real-time glucose alarms* with readings every minute[1].
The FreeStyle Libre Family of Personal CGMs is the #1 CGM in the US† and Worldwide‡.

Best regards,
Peter Johns
General Manager, Market Access

* Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device. You must have Critical Alerts enabled to receive alarms and alerts on your smartphone.

† Data based on the number of patients assigned to each manufacturer based on last filled prescription in US Retail Pharmacy and DME.

‡ Data based on the number of users worldwide for FreeStyle Libre family of personal CGMs compared to the number of users for other leading personal CGM brands and based on CGM sales dollars compared to other leading personal CGM brands.

Reference: 1. FreeStyle Libre 2 User's Manual.

FreeStyle Libre 2

Important Safety Information

FreeStyle Libre 2 system

Important Safety Information

Failure to use FreeStyle Libre 2 system 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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Product Information

System Components

The FreeStyle Libre 2 system has two main parts: a handheld reader and a disposable sensor that patients wear on their bodies. They use the 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 system is the easiest iCGM to apply* with no in-person patient training required[1].

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. It measures 95mm x 60mm x 16mm. 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).

FreeStyle Libre 2 sensor

The sensor measures and stores glucose readings when worn on the body. It initially comes in two parts: one part is in the sensor pack and the other part is in the sensor applicator. By following the instructions, patients prepare and apply the sensor on the back of the upper arm. The sensor has a small, flexible tip that is inserted just under the skin. The sensor can be worn for up to 14 days.

* Based on a comparison to Dexcom G6.

Reference: 1. Data on File. Abbott Diabetes Care.

FreeStyle Libre 2

Product Information

Alarms

The FreeStyle Libre 2 system provides 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 reader and that low or high glucose alarms will not be received

The FreeStyle Libre 2 app† also has a mandatory Urgent Low Glucose Alarm that lets users know when their glucose value is below 55mg/dL.

Accuracy

The FreeStyle Libre 2 system has unsurpassed 14 day accuracy[1] for adults and children (age 4 and older). Accuracy of the system was measured by comparing paired system glucose measurement (CGM) and Yellow Springs Instrument (YSI) analyzer blood glucose values. The percentage of total system readings that were within 20 mg/dL for YSI blood glucose values <70 mg/dL or 20% of YSI for blood glucose values ≥70 mg/dL is displayed in the table below. The mean absolute relative difference (MARD) gives an indication of the average percent disagreement between the CGM and the reference. For example, in the Adult study, 92.4% of the readings fell within ±20 mg/dL of YSI blood glucose values <70 mg/dL and within ±20% of YSI blood glucose values ≥70 mg/dL. The total number of data pairs considered in the analysis was 18,735. In the Adult study, the MARD was 9.2% for the comparison with YSI reference. In the Pediatric study, the MARD was 9.7% for the comparison with YSI reference.

Overall Accuracy to YSI

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	18735	144	92.4	87.5	81.7	9.2
Children (age 6-17)	6546	129	91.6	84.1	80.3	9.7
Children (age 4-5)[a]	341	8	85.9	87.9	90.9	11.8

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Reference: 1. FreeStyle Libre 2 User's Manual.

FreeStyle Libre 2

Digital Health Tools

FreeStyle Libre 2 app* — *for the patient*

The FreeStyle Libre 2 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 sensor. The FreeStyle Libre 2 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 FreeStyle Libre 2 app.

The FreeStyle Libre 2 app is not compatible with FreeStyle Libre 14 day sensors.

LibreLinkUp§ — *for the caregivers*

LibreLinkUp is designed to be used by family, friends, and other caregivers of patients using the FreeStyle Libre 2 app. This app allows users to follow up to 20 different connections. LibreLinkUp users receive glucose readings on their smartphone‖ whenever their connection scans their FreeStyle Libre 2 sensor with the FreeStyle Libre 2 app.

LibreView¶ — *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. Uploaded glucose data are 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 with diabetes.

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† Fingersticks are required if your glucose alarms and readings do not match symptoms or when you see Check Blood Glucose symbol during the first 12 hours.

‡ Notifications will only be received when alarms are turned on and the sensor is within 20 feet of the reading device. You must have Critical Alerts enabled to receive alarms and alerts on your smartphone.

§ The FreeStyle LibreLink app is only compatible with certain mobile devices and operating systems. Please check the website for more information about device compatibility before using the app. Use of the FreeStyle LibreLink app 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.

¶ 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.

\# Data from this study was collected with the outside US version of the FreeStyle Libre 14 day system. FreeStyle Libre 2 system has the same features as FreeStyle Libre 14 days system with optional real-time glucose alarms. Therefore, the study data is applicable to both products.

Reference: 1. Unger, J. Postgraduate Medicine (2020): https://doi.org/10.1080/00325481.2020.1744393

FreeStyle Libre 2

Clinical Outcomes: Highlights

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

Reduced HbA1c across multiple groups of patients[1-5*]

- ↓ **0.55%** HbA1c reduction observed among patients with T1D/T2D in a meta-analysis[1*†]
- ↓ **0.4%** HbA1c reduction among children and teenagers (4-17 years) with T1D[2*]
- ↓ **0.6%** HbA1c reduction among patients with T1D[3*]
- ↓ **0.9%** HbA1c reduction among patients with T2D on intensive insulin regimens[4*]
- ↓ **1.1%** HbA1c reduction among patients with T2D on basal insulin[5*]
- ↓ **1.6%** HbA1c reduction among patients with T2D on non-insulin therapies[5*]

Reduced number of serious hypoglycemic events (<55 mg/dL)[6,7*]

- ↓ **41%** reduction in number of serious hypoglycemic events among patients with T1D[6*]
- ↓ **44%** reduction in number of serious hypoglycemic events among patients with T2D on intensive insulin regimens[7*]

Reduced resource utilization[8,9*]

- ↓ **85%** in diabetes-related hospital admissions among patients with T1D[8*]
- ↓ **61%** reduction in acute diabetes events among patients with T2D on intensive insulin regimens[9*‡]
- ↓ **32%** reduction in all-cause hospitalizations among patients with T2D on intensive insulin regimens[9*‡]

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† A meta-analysis of RCTs and single arm studies (in addition to 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, et al. *Diabetes Therapy.* 2020. https://doi.org/10.1007/s13300-019-00720-0 **2.** Campbell F, et al. *Pediatric Diabetes.* 2018. https://doi.org/10.1111/pedi.12735 **3.** Tyndall V, et al. *Diabetologia.* 2019. https://doi.org/10.1007/s00125-019-4894-1 **4.** Kroger J, et al. *Diabetes Ther.* 2020. https://doi.org/10.1007/s13300-019-00741-9 **5.** Wright E, *Diabetes Spectrum* 2021. https://doi.org/10.2337/ds20-0069 **6.** Bolinder J, et al. *Lancet.* 2016. https://doi.org/10.1016/S0140-6736(16)31535-5 **7.** Haak T, et al. *Diabetes Ther.* 2017. https://dx.doi.org/10.1007%2Fs13300-016-0223-6 **8.** Fokkert M, et al. *BMJ Open Diabetes Research and Care.* 2019. https://doi.org/10.1136/bmjdrc-2019-000809 **9.** Bergenstal R, et al. *J Endocrine Society.* 2021. https://doi.org/10.1210/jendso/bvab013

FreeStyle Libre 2

Pricing Information

FreeStyle Libre 2 System

Reader Kit

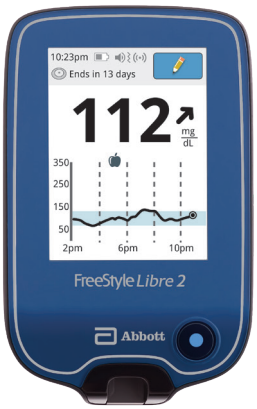
Sensor Kit

	Reader Kit	Sensor Kit
Package Size	1	1
Unit Price	$70.00	$57.70
NDC	57599-0803-00	57599-0800-00
UPC	357599803001	357599800000

Reference: Data on File. Abbott Diabetes Care.

FreeStyle Libre 2

Prescribing Information



1 Reader

Required for new prescriptions
(NDC# 57599-0803-00)

2 Sensors

28-day supply, filled monthly
(NDC# 57599-0800-00)

Refills: PRN or 12 fills annually

How to get the FreeStyle Libre 2 app

Once your member receives their FreeStyle Libre 2 system prescription, they can download the app to their compatible smart device*.

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Highlights of clinical guidelines for the use of CGM

Several clinical organizations including the ADA and AACE have published guidelines for the use of CGM in the management of diabetes[1-3].

American Diabetes Association (ADA)

The ADA published diabetes treatment guidelines as part of the 2021 Standards of Medical Care in Diabetes[1], making the following clinical and access recommendations specific to FreeStyle Libre Personal CGMs:

- When used properly, continuous glucose monitors in conjunction with multiple daily injections and continuous subcutaneous insulin infusion and other forms of insulin therapy can be useful and may lower A1c levels and/or reduce hypoglycemia in adults and youth with diabetes to replace self-monitoring of blood glucose[1]
- CGMs can be helpful in identifying and correcting patterns of hyper- and hypoglycemia and improving A1c levels in people with diabetes on non-insulin as well as basal insulin regimens[1]
- People who have been using CGMs should have continued access through third-party payers[1]

American Association of Clinical Endocrinology (AACE)

The AACE published recommendations in 2021[2], regarding the use of CGMs in the management of people with diabetes. The following recommendations were highlighted with respect to continuous glucose monitoring:

- CGMs are strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump[2]
- CGMs are recommended for all individuals with problematic hypoglycemia (frequent/severe hypoglycemia, nocturnal hypoglycemia, hypoglycemia unawareness[2])

CGM Metrics: Recommendations from ADA and AACE

- Two metrics, %TIR (Time in Range) and %TBR (Time Below Range), should be used as a starting point for the assessment of quality of glycemic control and as the basis for therapy adjustment, with emphasis on reducing %TBR when the percentages of CGM values falling below 54 mg/dL or 70 mg/dL are close to or exceed targets[2]
- Time in Range (TIR) is associated with the risk of microvascular complications, should be an acceptable end point for clinical trials moving forward, and can be used for assessment of glycemic control[3]

References: 1. American Diabetes Association. *Diabetes Care* (2021). https://doi.org/10.2337/dc21-S007 **2.** Grunberger G, et al. *Endocrine Practice* (2021). https://doi.org/10.1016/j.eprac.2021.04.008 **3.** American Diabetes Association. *Diabetes Care* (2021). https://doi.org/10.2337/dc21-S006

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Resources

Sign up to learn more: Payer.FreeStyle.Abbott

Website for providers: Provider.MyFreeStyle.com

Website for members: FreeStyle.Abbott

MORE PATIENTS CAN DO IT WITHOUT FINGERSTICKS*

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