

Freestyle Libre Glucose Monitoring System

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Introduction

In September 2016, the U.S. Food and Drug Administration (FDA) approved the Freestyle Libre Pro Glucose Monitoring System, a continuous glucose monitoring (CGM) system for blinded professional use in clinics. In September 2017, the FDA approved a Freestyle Libre for personal use by patients (1). The system's disposable sensor is applied to the back of a patient's arm and can be worn for 10 days with the personal device and up to 14 days with the Pro version. Providers and patients use a handheld device to download the blood glucose information stored in the sensor. The retrospective information then can be used by providers to make therapy changes to improve patients' glycemic control (2). Alternatively, patients can use the data in daily life to get on-demand glucose readings without having to perform a fingerstick to obtain blood for use with a glucose meter.

Indications

The Freestyle Libre Pro is indicated for professional use only. It is intended to be used by health care professionals to detect blood glucose trends and patterns in patients ≥ 18 years of age with type 1 or type 2 diabetes (2). The Freestyle Libre can be used by patients ≥ 18 years of age with type 1 or type 2 diabetes.

Limitations of Use

Freestyle Libre Pro and Freestyle Libre are not approved in children < 18 years of age or for patients who are pregnant, on dialysis, or critically ill.

Patients who are dehydrated or have high levels of vitamin C or salicylic acid may not get accurate readings with the system (2).

Mechanism of Action

Freestyle Libre Pro and Freestyle Libre use subcutaneous, wired enzyme glucose sensing technology to detect glucose levels in interstitial fluid (3). They automatically measure glucose every minute, and readings are stored in 15-minute intervals. The Libre Reader is held near the sensor when a glucose reading is needed. The reader device will then display the past 8 hours of glucose information, including current glucose, a trend graph, and a trend arrow. The arrow indicates the direction and velocity of the patient's current glucose level. This technology is factory-calibrated, and patients do not have to calibrate with blood sample glucose meter readings (2).

Potential Advantages

The Freestyle Libre has several potential advantages. For the Pro version, the initial cost to the clinic is minimal. Only disposable portions of the system are sent home with patients. There are no reusable parts that must be sanitized between patients. The handheld device for reading the sensor stays with the health care professional and is used for all patients. The downloading and reporting software, LibreView, is also free to the clinic.

The Freestyle Libre is available to patients through retail pharmacies. Unlike other CGMs on the market,

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Libre will not need authorizations through specialty distributors. The time from a patient's decision to wear a CGM device to the first delivery can often take months with other CGM systems.

The Freestyle Libre is also the only CGM system on the market with no acetaminophen interference. Dexcom and Medtronic CGM systems give falsely high glucose readings when a patient takes acetaminophen (2).

The sensor does not need to be calibrated with blood glucose meter readings to maintain accuracy. Freestyle Libre allows valuable glucose data to be collected even if patients are inconsistent with their blood glucose monitoring.

The Freestyle Libre Pro can be an effective tool to coordinate care in virtually any health care setting. Fourteen days after placement at a provider's office, patients can remove the sensor and send it back to the health care provider. Appropriate therapeutic changes can then be made over the phone or through the electronic medical record/patient portal.

The sensor is small and discreet, measuring approximately the size of a quarter. Thus, patients can wear it for 10–14 days with minimal disturbance of their activities of daily living.

Potential Disadvantages

The FDA has identified inaccuracies of the system at lower glucose levels, as seen in the clinical trials of the system. In 40% of instances in which the device indicated that a patient's glucose was <60 mg/dL, the patient's glucose was actually in range (81–160 mg/dL). Although CGM devices in general tend to lose accuracy at lower blood glucose numbers, the Freestyle Libre is less accurate than previously approved CGM systems (2).

Freestyle Libre does not have any alert functions for high or low glucose levels. Other CGM systems provide programmable limits that alert patients if they are approaching hypoglycemia or hyperglycemia. This feature serves as a safety net for many patients but is not available with the Freestyle Libre.

Freestyle Libre is not linked to phone apps and does not provide a means for real-time sharing of glucose data. Other CGM systems have apps that allow for sharing glucose data with friends, family members, and health care providers.

Cost

The handheld device for the Freestyle Libre Pro, used by the clinic to read the sensor, costs \$65. It is used on all patients and stays with the health care provider. Each disposable sensor costs \$60. The clinic can bill for both the insertion of the sensor and interpretation of the data using existing billing codes (4). The Freestyle Libre for personal use is not yet available in the marketplace. Insurance coverage is unknown at this time but anticipated to be comparable to coverage for using the Pro edition.

Commentary

With the publication of the DIAMOND (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) randomized, controlled trial (5) in January 2017, the Centers for Medicare & Medicaid Services (CMS) published a new ruling on the coverage for "therapeutic CGM" systems (6). Currently, Dexcom's CGM system is the only one that falls in that CMS-defined category. Although the Freestyle Libre was not approved as a "therapeutic CGM" system, it could replace blood glucose meters and test strips and thus be eligible for alternative coverage.

Clinical Implications

The Freestyle Libre Pro offers an alternative to other professional-use CGM options. It offers added financial benefits to clinics and ease of use for patients. The Freestyle Libre for personal use adds another option for patients to monitor their glucose. It can replace a glucose meter and eliminate the need for multiple fingersticks, allowing patients to receive glucose information on demand. Although it may not be for everyone, it will give patients and providers another option.

Duality of Interest

No potential conflicts of interest relevant to this article were reported.

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