



Health Technology Review	
Technology Ref.:	HTA23081
Technology Name/Version/Model:	FreeStyle Libre 2, Version 2
Approvals by International Bodies:	CE mark, FDA and MoHaP
Company name:	Abbott Laboratories GmbH – Diabetes Care Division
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Short Description of the Technology:	<p>FreeStyle Libre 2 system is a continuous glucose monitoring device with sensor-based technology. The sensor is applied on the arm of diabetes patients to continuously monitor in real-time glucose levels every single minute, sent automatically to the patients' smartphone (via Freestyle LibreLink App). It also has an optional alarm system that notifies patients the minute their glucose levels are too low or too high.</p> <p>All the collected patient glucose readings are collated into intuitive reports (via LibreView Platform) that are shared with treating physicians providing them the option to effectively manage their patients whether in face-to-face consultations or virtual ones with individualized frequency depending on the need and the severity of patients' conditions. LibreView reports have follow international guidelines for clinical targets such as the Ambulatory Glucose Profiles and Time in Range.</p> <p>In addition to the system existing offerings, a new clinic pathway is proposed to include educational interventions via educators that will be following up with patients over the course of 90 days through 6 touchpoints (virtual & face-to-face) to ensure proper education and improved glycaemic outcomes are achieved.</p>
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Health Technology Assessment Team Recommendation:

Approve

Summary of Review:

The FreeStyle Libre glucose monitoring system is typically self-administered by the individual with diabetes. Users apply the sensor to their body and use the reader or a compatible mobile device to scan and monitor their glucose levels. It's designed for ease of use so individuals can manage their diabetes more independently.

Advantages	Disadvantages
Approvals by International Bodies: CE mark, FDA and MoHaP.	Sensors need replacing every two weeks, and improper maintenance can reduce this lifespan.
Considered as safe and efficient system for the patients. As it's Adhere to regulations with applicable regulatory standards and requirements to ensure its safety and effectiveness.	The system may be expensive, especially for those uninsured or under-insured.
Eliminates the need for constant finger pricking, making glucose testing less painful.	The Libre 2 Reader is only compatible with Freestyle Precision Neo Test Strips.
The system is user-friendly, with simple and painless sensor application.	Some users may experience skin sensitivity where the sensor is applied
Offers real-time readings, tracking glucose trends over eight hours.	
Comes with an app that provides valuable health information and allows for alarms and trend viewing.	
The sensors are small and discreet, and the system is lightweight and water-resistant, making it suitable for on-the-go lifestyles.	

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. FreeStyle Libre 2 Version 2.
2. Recommended for patients of pre-diabetic and uncontrolled diabetic patients with an A1c >7% regardless of their medication.
3. The technology may only be used after being prescribed by a healthcare professional.
4. Using the technology may only be started after completion of the required training from a qualified instructor.
5. Follow the instructions provided by the manufacturer for the users.
6. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
7. Provision of regular updates and reports outcome about the product to DOH upon request.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image



Population, setting and intended user for Technology “FreeStyle Libre 2”

- **Population/ Intended User;**
 - Individuals with diabetes who require regular monitoring and management of their blood glucose levels.
 - Recommended for patients of pre-diabetic and uncontrolled diabetic patients with an A1c >7% regardless of their medication
- **To be performed by:**
 - Healthcare professionals
 - Trained individual with diabetes
 - Trained parents whose children have diabetes
- **Clinical Setting:**
 - Hospitals
 - Clean environment
- **Condition of use:**
 - As per manufacturer instructions.
- **Exclusion criteria:**
 - People who are not able to be in regular contact with their healthcare professional.
 - People with skin that does not tolerate adhesive pads.
 - People who are not able to notice alarms because of physical limitations.