

ii. Flash Glucose Sensors (FreeStyle Libre®)



What are we Funding?	Highlights
<p>Extend eligibility for Flash glucose monitoring, the FreeStyle Libre® to all people with diabetes, based on clinical need.</p> <p>Budget 2022 Ask: €2.5m</p> <p>Why Fund This?</p> <p>This technology allows people using insulin to more effectively manage their blood sugar levels, and has been clinically demonstrated to reduce diabetes-related hospital admission.</p> <p>If Not Funded...</p> <p>Preventable serious diabetes complications will continue to harm those on insulin and consume HSE resources.</p>	<ol style="list-style-type: none"> 1. Adults with diabetes over age 21 cannot access Flash glucose monitoring – this is estimated to be 75% of the type 1 diabetes population. 2. People with diabetes have been calling for wider access to this device since 2016. 3. Flash Glucose monitoring allows users to see a more comprehensive profile of blood glucose levels to help people with diabetes and clinicians to make more informed diabetes management decisions which improves quality of life. 4. There is substantial body of clinical evidence demonstrating that the Flash Libre® system improves clinical outcomes for people with diabetes who intensively use insulin.

FreeStyle Libre® is a trademark of Abbott Diabetes Care, Inc.

ii. Extend eligibility for Flash Glucose Monitoring (FreeStyleLibre®) to adults with diabetes based on clinical need

Adults over age 21 years, who manage their diabetes using insulin, either by multiple daily injections MDI or an insulin pump, cannot access the only Flash Glucose Monitor available in Ireland, the FreeStyle Libre®. This flash monitor offers a more comprehensive profile of blood glucose levels to help people with diabetes and clinicians to make more informed diabetes management decisions. **We are asking that the government extend access to the Flash Glucose Monitoring (FreeStyle Libre®) to all people with diabetes on MDI or an insulin pump (Type1, Type 2, etc.) based on clinical need.**

People with diabetes have been calling for the inclusion of Flash technology (FreeStyle Libre®) on the long-term illness scheme since 2016 when the device first became available in Ireland, the evidence of this can be seen in the hundreds of parliamentary questions submitted by TDs from then up to the present day. This did happen in 2018, but only for a very small cohort of the type 1 diabetes population and the community responded by organising a community led petition signed by 19,000 people, almost one signature for every person with type 1 diabetes in Ireland. Diabetes Ireland has supported the HSE in their review of the reimbursement scheme by submitting Irish clinical research and a user experience survey completed by 300 people self-funding their flash glucose monitors and yet we are still awaiting a decision on expanding the scheme two years later.

Flash (FreeStyle Libre®) Glucose Monitoring is one of the technologies designed to replace routine 'finger-stick' self-monitoring blood glucose (SMBG) for people with diabetes aged 4 or over, including pregnant women, who use multiple daily injections (MDI) or an insulin pump to deliver their insulin. These technologies also address many barriers with 'finger-stick' monitoring and their data sharing Apps allows clinicians, as part of virtual consultations, to effectively support people with diabetes under their care. This expanded use would provide a foundation to deliver efficient diabetes care post COVID-19 which can potentially reduce the need for face-to-face appointments. A recent Irish survey by Diabetes Ireland on the acceptability of virtual consultations with patients who took part in one during COVID-19 lockdown indicated that having this data saves time and leads to a deeper more productive consultation between the clinician and patient as there is greater understanding of glucose variability on which to base clinical decision making.

Furthermore, there is now a substantial body of clinical evidence including Randomised Controlled Trials (RCT), real world and observational studies demonstrating that the FreeStyle Libre® system safely improves clinical outcomes for people with diabetes. The Association of British Clinical Diabetologists (ABCD) FreeStyle Libre® UK Nationwide Audit involving 102 UK diabetes centres contributed, with over 10,000 users' data collected, reported that FreeStyle Libre® system users had significantly less paramedic call outs, hospital admissions and episodes of severe hypoglycaemia in the 7.5 month follow up period – admissions for hypoglycaemia reduced from 120 to 45 and admissions for hyperglycaemia/ DKA reduced from 269 to 86, comparing 12 months pre-FreeStyle Libre®

initiation to 7.5 months post. **The cost of a hypoglycaemia admission in Ireland is in the region of €1000.**

Irish based clinical evidence has been provided by a number of Irish diabetes centres plus a submission to the HSE (PCRS) by Diabetes Ireland which highlighted that adult with diabetes using the technology privately showed a 66% reduction in their blood glucose strip usage. This clinical evidence along with other analytical data provided by the PCRS was to be considered by the HTAG Review Team with a decision to be made by March 2020. Covid 19 has delayed this decision.

This mounting clinical evidence on the reduced hospitalisation costs and the massive improvements in the quality of life for people with diabetes should be a considerable factor in the decision to expand access to Flash Glucose Monitors.

Diabetes Ireland propose that funding for expanding access to people with diabetes be based on clinical need and be allocated from the estimated savings generated from the HSE Medicines Management Programme (MMP) evaluation to identify preferred blood glucose test strips which are estimated to be approximately €8-10m this year alone, and from offering choice to adults qualifying for Continuous Glucose Monitoring systems CGMs which share many of the features of the Flash (FreeStyle Libre®) but cost almost twice as much.

We estimate that the updated additional cost of Flash (FreeStyle Libre®) to be approximately €622 per person per year based on the 2017 HTAG and adjusted to reflect the February 2021 reduction in blood glucose monitoring strip price.

If 4,000 adults were funded for Flash glucose monitoring in 2022 this would cost the HSE approximately €2.5 million. This does not consider any savings that could be made from potential reductions in hospitalisation for Flash (FreeStyle Libre®) users that have been seen in published clinical data.

Eligibility for Flash glucose monitor (FreeStyle Libre®)	Eligibility for Continuous Glucose Monitoring (CGM)
Patients using multiple daily injections of insulin or insulin pump therapy	3.6.23 For adults with type 1 diabetes who are having real-time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy.
Patients who have increased blood glucose testing requirements (≥8 times daily)	Hyperglycaemia (HbA1c level of 75 mmol/litre [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 3.6.11 and 3.6.12).
Frequent episodes of diabetic ketoacidosis (DKA) or hypoglycaemia which have included hospital admissions	<p>More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.</p> <p>Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.</p> <p>3.6.24 Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes.</p> <p>Complete loss of awareness of hypoglycaemia.</p> <p>Extreme fear of hypoglycaemia.</p>
Children and young adults aged 4 - 21 years	No age restriction

Table 1 - Flash/CGM Eligibility Comparison

Diabetes Ireland is calling for Flash (FreeStyle Libre®) to be made available to all people with diabetes, who use MDI or an insulin pump (Type1, Type 2, etc.) to manage their diabetes based on clinical need and is asking that savings from the blood glucose strips be earmarked for adults who are deemed to clinically require the Flash (FreeStyle Libre®) by their diabetes teams and offset by the savings from offering choice.

This will improve quality of life for the individual and further aid prevention of costly diabetes complications and make short and long-term savings for the health service.