NHS
Coventry and Warwickshire
Integrated Care Board

Commissioning Policy

Flash Glucose Monitoring

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
Version:	Version 1.0
Name of responsible Committee and date approved or recommended to Integrated Care Board Board:	Audit Committee
Date approved by the Integrated Care Board (if applicable):	1 July 2022
Next Review Date:	1 April 2024
Expiry Date:	1 October 2024
Name of author and title:	Altaz Dhanani, ICB
Name of reviewer and title:	Angela Brady, Chief Medical Officer, ICB
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

Treatment	Flash Glucose Monitoring
Indication	All people with Type 1 diabetes, over the age of 4years old All people treated with insulin for Type 1 or 2 diabetes, who are living with a learning disability and which is recorded on their GP Learning Disability register
Background	The NHS Long Term Plan made a commitment to "ensure that, in line with clinical guidelines, patients with type 1 diabetes benefit from life changing Flash Glucose Monitors from April 2019, ending the variation patients in some parts of the country are facing." The original roll out of Flash only applied to select patients with Type 1 diabetes. Many people with diabetes and a learning disability have Type 2 diabetes. The NHS has now extended the use of Flash Glucose Monitor to all patients with a learning disability and diabetes and who use insulin to manage their condition. In 2019 a third of deaths of people with a learning disability were shown to have been due to treatable causes, compared with 8% in the general population. A recommendation specific to diabetes from the Learning Disabilities Mortality Review (LeDeR) Programme reviews related to appropriate provision of support for people with diabetes, particularly in community settings. Flash technology should ultimately help people with a learning disability achieve better health outcomes. The benefits for patients include: • Not having to do finger-prick checks • Making it easier to check glucose levels, so action can be taken earlier • Giving patients, their families and carers more confidence in managing the condition This Commissioning Policy outlines the patient eligibility criteria for funding of Flash Glucose monitoring; • for people with Type 1 diabetes in line with the NHS England publication: ***NHSE Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients*** (March 2019) and • for people treated with insulin for their diabetes and are living with a learning disability which is recorded on their GP Learning Disability register are eligible for, in line with the NHSE publication above and NHSE communication of this additional cohort (05/11/2020). Flash uses a sensor that is placed on the back of the upper arm and worn externally by the user, allowing glucose information to be monitored using a mobile app. This information helps the user and their clinical team to identify what changes are needed to insulin administration to achieve optimal glucose control, and therefore reducing the risk of adverse outcomes.

	Freestyle Libre® is currently the only Flash Glucose Monitoring device listed in the NHS drug tariff. This guidance will be applicable to any other flash glucose monitoring device added to the NHS drug tariff in the future.
Criteria	The following eligibility criteria must be met, for people defined in the above to qualify for treatment; 1. People with Type 1 diabetes **OR** with any form of diabetes on haemodialysis and on insulin treatment Who, in either of the above, are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months. **OR** 2. People with diabetes associated with cystic fibrosis on insulin treatment **OR** 3. Pregnant women with Type 1 diabetes – 12 months in total inclusive of post-delivery (should funding be required post the 12-month period, then a further review against the eligibility criteria will be required) **OR** 4. People with Type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carer to support glucose monitoring and insulin management **OR** 5. People with Type 1 diabetes for whom the specialist MDT determines have occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6-month trial of Flash Glucose Monitoring with appropriate adjunct support **OR** 6. Previous self-funders of Flash Glucose Monitoring with Type 1 diabetes where those with clinical responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of these criteria prior to them commencing use of Flash Glucose Monitoring had these criteria been in place prior to April 2019 **AND** has shown improvement in HbA1c since self-funding.

OR

7. For those with Type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes and their clinician consider that a Flash Glucose Monitoring system would be more appropriate for the individual's specific situation, then this can be considered.

Or

8. Insulin treated people with diabetes (either Type 1 or Type 2) who are living with a learning disability which is recorded on their GP Learning Disability register

Flash glucose monitoring devices should not be routinely offered to people with type 2 diabetes, using insulin, who **DO NOT** have a record of a learning disability

Current Self-Funders
Patients who have obtained a Flash Continuous Glucose Monitoring System through clinical trials; private treatment; or who have been self-funding and are now seeking an NHS prescription, will be required to demonstrate that they:

- Satisfied the prescribing criteria and
- Have shown improvement in HbA1c since self-funding

Other Requirements

Patients diabetes are central in developing and agreeing their personalised care and support plan including deciding who is involved in the process.

They should be supported to have proactive, personalised conversations which focus on what matters to them, paying attention to their diabetes needs and wider health & wellbeing.

The patient or their family or their carer must meet the following requirements to qualify for Flash Glucose Monitoring;

1. Education on Flash Glucose Monitoring has been provided (online or in person);

2. The patient/carer agrees to scan glucose levels no less than 8 times per day and use the sensor >70% of the time. If scanning of glucose levels is not clinically required 8 times a day a lower number can be agreed with the clinical prescribing team with the expectation that the patient/carer scans a minimum of 4 times per day;

	3. Agree, as a minimum, to attend their 6-month review with the clinical team who initiated Flash Glucose Monitoring, to review continued use based on the policy criteria; 4. Previous attendance, or due consideration given to future attendance, at a diabetes structured education programme appropriate to the individual. 5. Agree to the patient contract in using the device (see appendix 1 for copy). *If a person lacks capacity to sign the patient contract, the family member or carer will be asked to sign the contract.*
Initiation	Initiation of Flash Glucose Monitoring will be undertaken by hospital diabetes specialist nurses GP's within primary care should not initiate Flash Glucose Monitoring, but should identify patients who are eligible and who may benefit from this approach Flash Glucose Monitoring will initially be provided on a 6-month trial basis, with a review at 6-months to determine if Flash Glucose Monitoring should be continued. There is a requirement for the diabetes team to complete a Blueteq form at initiation of Flash and at every 6-month review thereafter. Although prior approval is not required, the completion of this form will support the monitoring of Flash initiation. At six months, patients will be required to attend for a diabetes review, which includes a HbA1c blood test, to ensure that flash glucose monitoring is still appropriate as per the policy criteria Following the initial prescription of one set of 2 sensors (4-week supply), patients will be asked to return to primary care for their ongoing prescriptions. A confirmation letter will be sent to the patient's GP Practice to confirm this. It is also expected that the frequency of current blood glucose monitoring using test strips and subsequent quantities prescribed, will significantly reduce and prescriptions should be adjusted accordingly on initiation and reviewed regularly.
Review	Patients who meet the criteria for Flash should be initially prescribed for a maximum 6-month period during which time data should be collected on the indicators below. 1. Reductions in severe/non-severe hypoglycaemia 2. Reversal of impaired awareness of hypoglycaemia 3. Episodes of diabetic ketoacidosis 4. Admissions to hospital 5. Changes in HbA1c 6. Testing strip usage 7. Quality of Life changes using validated rating scales.

	8. Commitment to regular scans and their use in self-management. A review should take place with the responsible clinician at the end of the initial trial period. If there is demonstrable improvement in one or more of the indicators above, the use of Flash should be continued. If there is no improvement, then an alternative method of blood glucose monitoring should be used. Expectations regarding patient compliance and continuation criteria should be made clear to the patient before initiation of the trial period. **NHS funding for Flash Glucose Monitoring will be withdrawn if the patient fails to meet the policy criteria and patients, family and carers should be made aware of this at initiation.** A confirmation letter will be sent to the patient's GP Practice following the review, outlining outcomes from the trial and if there is to be a continuation of prescribing Flash sensors. The diabetes team will complete the Bluteq form if FGM is to continue to be prescribed. **It is the responsibility of responsible clinician to inform the patient's Primary Care clinician if Flash Glucose Monitoring is to be withdrawn at any time.**
Reference	NHSE Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients – March 2019.
Equality Analysis	See below

Appendix One – Patient Contract

Example of Patient Contract – Freestyle Libre
Name……
Hospital/NHS #.....
GP……
Patient Contract – Freestyle Libre

You have been assessed as meeting the criteria for use of NHS funded Libre® in line with accepted pathways set out by the Integrated Care Board and its area prescribing committee.

You will be enrolled onto a 6 month programme managed through the specialist team which will consist of a group session to educate you on how to insert the Libre® and how to use the data effectively in improving your diabetes care.

As part of the programme you are required to sign up to the following criteria to avail maximum benefit from the Libre® and therefore warrant continued NHS funding at the end of the 6 month programme. If you have been self-funding Libre® and now applicable to receive NHS funding, you will still be required to agree to the following stipulations.

1. Attendance at the initial session (online and/or face to face) which provides instructions and structured education on Libre® use and using glucose data for self-care of diabetes
2. Agree to scan the Libre® a minimum of 4 times/day and at intervals of no more than 8-10 hours a majority of the time.
3. Agree to attend all follow-up sessions (minimum of 1,3 & 6 months post initiation) some of which may be telephone based and some face-to-face and to download and share Libre® data on a regular basis.
4. Agree to regular blood tests for HbA1c to monitor diabetes at follow-up sessions.
5. Understand that further funding beyond the first 6 months will be dependent on adherence to agreed criteria and achieving relevant outcomes laid out below. This will be reviewed at 3 and 6 months post initiation.
6. Agree to abide by the rules (applicable/not applicable) around diabetes & driving which currently stipulate the use of finger-prick glucose checks at times relevant to driving.

Selection for Libre® is on the following basis: (To be filled in by HCP)	**At the end of 6 months achieving one or more of the following will be expected (HCP to complete)**

I (name) have read and understood the information above and agree to this contract prior to starting/continuing on Freestyle Libre® through NHS funding

Signature _____

Date _____

Frequently Asked Questions

What Happens Next?

We will send you details of the next available course and you will be started on the Freestyle Libre®. We will provide you with a detailed information leaflet regarding the Freestyle Libre® Flash glucose monitoring device and the Freestyle Academy.

How will I get my prescriptions?

The diabetes team will give you a sensor for Libre® to cover the initial 2 weeks. Further ongoing prescriptions will be provided for you by the GP.

What about blood glucose monitoring?

You will get more details when you attend the education session. We expect you to use less finger-prick glucose checks but in certain circumstances you are advised to check with a finger-prick (eg hypoglycaemia, unexpected high reading etc). We have written to your GP to continue to supply you with glucose monitoring strips.

What happens if my Libre® sensor is faulty before it is fully used?

Please contact the Libre® help-line on 0800 612 3006 and provide details to receive a replacement sensor. Please remember that the faulty sensor will need to be sent back to the company. Please note that a replacement will not be available if there is inappropriate handling or misuse of the sensor leading to fault.

What happens after 6 months?

You should be reviewed by your consultant or Specialist at the Hospital Diabetes Centre and if you have progressed as expected, NHS funding will continue. If you are not meeting the criteria then a decision will be made to revert to finger-prick glucose monitoring and Libre® NHS funding will cease. In either case, you will continue to receive support and review thereafter. Please do not hesitate to contact a member of the team if more information is required or any clinical queries arise.

The Diabetes Team,

Diabetes Centre

Address XXX

Centre Phone: XXX

Equality Impact Assessment (EIA)

Policy/Service	Flash Glucose Monitoring Policy	**Person completing EIA**	Natasha Jacques
Date of EIA	January 2020	**Accountable ICB Lead**	Alison Walshe (ICB) Andrew Harkness (ICB)

Aim of Work	The Public Sector Equality Duty (PSED) requires us to eliminate discrimination, advance equality of opportunity, and foster good relations with protected groups. This EIA assesses the impact of the policy on protected groups.

Protected Group	Likely to be a differential impact?	Protected Group	Likely to be a differential impact?
Age	No	**Race**	No
Disability	No	**Religion or belief**	No
Gender reassignment	No	**Sex**	No
Marriage and civil partnership	No	**Sexual orientation**	No