APPENDIX 1



Policy statement:	Flash Glucose Scanning
Status:	Group (Notification) / Individual Prior Approval

Flash Glucose Scanning systems monitor blood glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing. It consists of a handheld reader and a sensor, which is sited on the arm. When the reader unit is passed over the sensor, the reader shows a reading based on interstitial fluid glucose levels. The sensor lasts for up to 14 days and then needs to be replaced. The reader can show a trace for the last 8 hours and displays an arrow showing the direction the glucose reading is heading.

Flash Glucose Scanning is not the same as continuous glucose monitoring (CGM).

At present there is only one product where prescribing on the NHS is supported- FreeStyle Libre®. The following policy therefore applies only to this product and funding for any other flash glucose scanning products is not currently available.

Group Prior Approval

M&SECCGs commission use of FreeStyle Libre[®] on a restricted basis, and only for people with diabetes on insulin, aged 4 and above, attending specialist care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist diabetes clinician and deemed to meet one or more of the following criteria:

- Patients with Type 1 diabetes with poorly controlled Hba1c (>8.5% or >69 mmol/mol) requiring self-monitoring blood glucose testing nine times or more daily to achieve safe control as demonstrated on a meter download/review over the past 3 months and determined by those with clinical responsibility for their diabetes care and where they are satisfied that the patient's clinical history support this (supported by NICE TA151, NG17 & NG18)
- Patients with Type 1 diabetes with multiple episodes of diabetic ketoacidosis (DKA) and/ or severe hypoglycaemic episodes (i.e. needing external support) and/ or multiple admissions due to poor glycaemic control, requiring self-monitoring blood glucose testing nine times or more daily (supported by NICE TA151, NG17 & NG18)
- Patients with Type 1 or Type 2 diabetes on haemodialysis and on insulin with poorly controlled Hba1c (>8.5% or >69 mmol/mol) requiring self-monitoring blood glucose testing nine times or more daily as demonstrated on a meter download/review over the past 3 months
- Diabetes associated with cystic fibrosis on insulin treatment
- Pregnant women with Type 1 or Type 2 diabetes requiring insulin this will only be funded for 12 months in total inclusive of post-delivery period
- Patients with Type 1 diabetes who the specialist diabetes multi-disciplinary team



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 FreeStyle Libre® with appropriate adjunct support.

- Patients with Type 1 unable to routinely self-monitor blood glucose at home due to severe mental or physical disability. Evidence must be provided that they require carers to directly support glucose monitoring and insulin management, and that these carers struggle to manage simple blood glucose monitoring.
- Patients with Type 1 diabetes previously self-funding Flash Glucose Scanning 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 the above criteria prior to them commencing use of Flash Glucose Scanning had these criteria been in place prior to April 2019

AND

 has shown improvement in HbA1c over a period of 6 months since using the selffunded sensors.

Additional Requirements

In addition all patients (or carers) must be willing to:

- undertake training in the use of FreeStyle Libre[®]
- agree to scan glucose levels no less than 8 times a day and use the sensor for more than 70% time
- o agree to regular reviews with the local specialist clinical team
- complete a Type 1 diabetes structured education programme (DAFNE, BERTIE or equivalent). Previously completed approved courses will be recognised.

The decision to start FreeStyle Libre® will only be made by the diabetes specialist team and will initially be for a 6 month trial period.

Use will only be continued at the discretion of the diabetes specialist if there is sustained benefit in patient outcomes whilst they are using the device as demonstrated by one or more of the following:

- Reduction in severe / non-severe hypoglycaemia episodes
- Reduction in HbA1c of 0.5%/5mmol/mol or more within 6 months
- Agreed reduction in use of self-monitoring blood glucose test strips
- Reduction in episodes of DKA
- Reductions in admission to hospital
- In severe disability to ensure clear benefit to the carer support for the patient

If there has not been sufficient improvement in one or more of the above areas over a 6 month period then the use of FreeStyle Libre® under NHS prescription will be discontinued and an alternative method of monitoring should be used.



Individual Prior Approval

Patients with Type 1 Diabetes with recurrent severe loss of hypoglycaemia awareness or impaired awareness of hypoglycemia may be considered for Flash Glucose Scanning on a case by case basis. These patients ideally do not need FreeStyle Libre® but will need a different Continuous Glucose Monitoring system with an alarm component - requested on a named patient basis- see VBCP- **Continuous Glucose Monitoring**

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. (supported by NICE TA151, NG17 & NG18)

Any patient individually approved for FreeStyle Libre® must also meet the **additional requirements** listed in section above.

Patients not meeting the above criteria will only be funded where there are exceptional clinical circumstances.

Further information on applying for funding in exceptional clinical circumstances can be found by clicking the link below.

Value Based Commissioning Policies

Additional Information

Under national criteria and this policy the following groups do not currently meet the criteria for NHS funding:

- Any Type 2 diabetes patient unless on insulin and pregnant or on haemodialysis requiring more than 8 tests daily, or fulfils the severe disability criteria
- Otherwise well Type 1 diabetes patients with no major disabling symptoms, recurrent hospital admissions, psychosocial issues, severe disabilities, poor Hba1c or any other of the criteria stated above
- Poor engagement or compliance with glucose testing- no evidence use of FreeStyle Libre® solves this

Patients who by choice self-fund FreeStyle Libre® will continue to be supported (and data viewed) in routine NHS clinics.

References

Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients Issued by NHS England March 2019

https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/

Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus July 2008 https://www.nice.org.uk/guidance/ta151

Type 1 diabetes in adults: diagnosis and management July 2016 https://www.nice.org.uk/guidance/ng17

Diabetes (type 1 and type 2) in children and young people: diagnosis and management November 2016 https://www.nice.org.uk/guidance/ng18