This policy statement is approved by Halton, Knowsley, Liverpool, Southport and Formby, South Sefton, St Helens, Warrington and Wirral CCGs

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PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
FIRST APC BOARD DATE: 23 MAY 2018
LAST APC BOARD DATE: 23 JUNE 2021

NHS Pan Mersey Area Prescribing Committee

FLASH GLUCOSE MONITOR (FreeStyle Libre® / Libre 2®)

AMBER

The Pan Mersey Area Prescribing Committee recommends the prescribing on the NHS of flash glucose monitor sensors (FreeStyle Libre® / Libre 2®) only within the criteria outlined below.

FOLLOWING SPECIALIST INITIATION

Flash glucose monitoring should only be used for people who have been assessed by the specialist clinician (including specialist diabetes nurses in hospital or community specialist diabetes service) and deemed to meet one or more of the following criteria:

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 with diabetes associated with cystic fibrosis on insulin treatment.
2. Pregnant women with type 1 diabetes - 12 months in total inclusive of post-delivery period.
3. People with Type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management.
4. People with type 1 diabetes for whom the specialist diabetes MDT determines have occupational circumstances (working in insufficiently hygienic conditions to safely facilitate finger-prick testing or where it is highly impractical to conduct finger-prick testing due to the practical requirements of their occupation) OR for people with type 1 diabetes transitioning between paediatric and adult services with psychosocial circumstances that warrant up to a 6-month trial of flash glucose monitoring with appropriate adjunct support **from a formal service** that manages these issues.
5. People with diabetes and a learning disability and recorded on their GP Learning Disability register who use insulin to treat their diabetes.
6. Previous self-funders of flash glucose monitors 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 have shown improvement in HbA1c since self-funding.
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/ TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes has recurrent severe hypoglycaemia or a Gold hypoglycaemia awareness score of between 3–5 (see “Patient Factors” section overleaf) 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.

In addition, all users must undertake training in the use of flash glucose monitoring, previous or future attendance at a structured diabetes education programme, agree to scan glucose levels ≥8 times per day and commit to ongoing regular follow-up and monitoring. It is recommended data from all people treated be included in the national Association of British Clinical Diabetologists (ABCD) audit on flash glucose monitoring (unless user declines consent).

People with diabetes not fulfilling the above criteria should not be prescribed flash glucose monitoring on the NHS.

If no improvement is demonstrated in one or more of the following - improvement of HbA1c or time-in-range; improvement in symptoms such as DKA or hypoglycaemia; or improvement in psycho-social wellbeing over a maximum of up to 6-month trial (trial duration depending on response), then the use of flash glucose monitoring should be discontinued and an alternative method of monitoring used. Patients should be informed of this possibility via issue of a personal contract. The criteria in this statement are based on NHS England criteria recommendations

Reduction in finger prick testing: The specialist must inform the person that frequency of finger prick testing will be reduced and inform them how often they should carry it out when using flash glucose monitoring. The specialist must also inform the person’s GP. **Unnecessary continuation of finger prick testing will greatly increase costs.**

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

SUPPORTING INFORMATION

FLASH GLUCOSE MONITOR (FreeStyle Libre® / Libre 2®)

EFFECTIVENESS

Mean time in hypoglycaemia (<3·9mmol/L) in stable T1 diabetics changed from 3·38 hr/day at baseline to 2·03 hr/day at 6 months (baseline adjusted mean change -1·39) in the flash monitoring group, a reduction of 1·24 hr/day compared to control, a 38% reduction. Time in hypoglycaemia <3.1mmol/L was reduced from 1.59h/day to 0.8h/day (difference between groups 0.82h, 50% reduction). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%)[1]. Time in hypoglycaemia <3.9mmol/L in T2 diabetics reduced by 0.47 hr/day and hypoglycaemia <3.1mmol/L reduced by 0.22 hr/day; reductions of 43% and 53%, respectively [2]. Clinical significance: the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) consider glucose levels below 3 mmol/L as clinically important[3]. A 30% reduction in hypoglycemia is considered to be clinically significant [4]. No differences were found in HbA1c [1,2]. Blood glucose strip usage was reduced from 5.5 to 0.5 per day in one study [1] and from 3.9 to 0.2 per day in another[2]. Patient satisfaction was higher by 6.1 points on an 18-point scale in T1 diabetes [1] and by 4.1 points in T2 diabetes[2] with flash monitoring but overall, Diabetes QOL Questionnaire score was not significantly different.

SAFETY

The flash glucose monitor measures glucose in interstitial fluid. Finger-prick blood glucose testing is still required[6]:

- during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels*
- if flash glucose monitoring shows hypoglycaemia or impending hypoglycaemia*
- when symptoms do not match the system readings

* not necessary with Freestyle Libre 2®

Driving: Group 1 drivers may now use flash glucose monitoring for driving. However they must get a confirmatory finger prick blood glucose level in certain circumstances (see DVLA guidance). Group 2 drivers must continue to use finger prick testing for driving. Flash glucose monitoring systems are not legally permitted for Group 2 driving.

COST per year (Drug Tariff May. 2019) £10/ £13 per 50 strips

Blood glucose monitor (BGM)*	4 x daily	£350 / £438	
	8 x daily	£701 / £876	
	10 x daily	£876 / £1095	
Freestyle Libre 2® + BGM**	3 x week	£913 + £56	£969
Insulin pump (NICE) + BGM	10 x daily		£3445
Continuous glucose monitoring (CGM)			£3240

Use has the potential to be cost-saving in people requiring treatment with insulin pump and CGM (cost reduction approximately £2,300 per person per year) or those using finger-prick testing more than 8-10 times per day. However, use in other circumstances will increase costs compared to finger-prick testing.

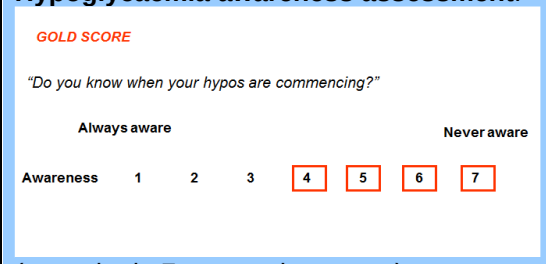
It is estimated that 50% of people with type 1 diabetes will fit the criteria on the previous page for flash glucose monitoring. This might cost approximately £134,000 per 100,000 population annually.

*all costs assume £0.04 per lancet **£16/ 50 strips

PATIENT FACTORS

Should not be used where person has completely and irreversibly lost their hypoglycaemia awareness[7].

Hypoglycaemia awareness assessment:



(see criteria 7. on previous page)

PRESCRIBING INFORMATION: Initial sensor and reader supply **t**o be made by specialist diabetes clinics (reader not available on prescription). Phone app may be used as alternative to reader. Primary care prescribers should only be asked to prescribe sensors by specialist, and should only agree to prescribe, if specialist confirms person meets criteria overleaf (see link) and confirms they continue to meet criteria at up to 6 months (see link). People to be informed via a personal contract that if they do not continue to meet criteria then prescribing will be stopped (see link). BG strips will still need to be prescribed but in reduced quantity; use a separate low-cost BG/ketone strip meter as per Pan Mersey guideline. Sensors: Prescribe only 2 sensors per month (some clinical systems describe as a "kit" as each contains 1 sensor, 1 applicator and wipe). Please note if a person experiences problems with the sensor falling off or it is faulty, they should contact the manufacturer on 0800 170 1177 in the first instance to resolve the issue and receive replacement sensor(s). **Freestyle Libre 2®:** Available January 2021 at same cost as original Libre® sensors. All new users should be initiated on Freestyle Libre 2® sensors and reader/ app. Original Libre® sensors currently remain available. However, users of original Freestyle Libre® may be switched to Freestyle Libre 2® by their GP or specialist (who must inform GP - see link) when current sensors used up – for further details see link. Patient instruction / information on Freestyle Libre 2® is available from manufacturer here. Information for healthcare professionals is available here.

IMPLEMENTATION NOTES: Users require support and training from specialist in flash glucose monitoring use[6]. Ongoing use should be assessed at 6 months or earlier and annually thereafter as described overleaf. People must have completed a structured diabetes education programme and been educated to make sure they can best use the information the system provides[7]. It is recommended data from all users be included in the national Association of British Clinical Diabetologists (ABCD) audit on flash glucose monitoring.

REFERENCES

1. Bolinder J et al. Lancet 2016; 388: 2254-2262.
2. Haak T. et al. Diabetes Ther (2017) 8:55-73
3. International Hypoglycaemia Study Group. Diabetalogia. 2017; 60:3–6.
4. American Diabetes Association Workgroup on Hypoglycemia. Diabetes Care. 2005; 28:1245–9
5. East of England Prescribing Advisory Committee Guidance Statement, FreeStyle Libre® Glucose Monitoring System, Sept. 2017
6. NICE Medtech innovation briefing 110. FreeStyle Libre® for glucose monitoring. July 2017
7. Diabetes U.K. Consensus Guideline for Flash Glucose Monitoring, Sept. 2017.