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
REF: PS212 FINAL
APC BOARD DATE: 23 MAY 2018

NHS Pan Mersey Area Prescribing Committee

FLASH GLUCOSE MONITOR (FreeStyle Libre®)

AMBER

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

FOLLOWING SPECIALIST INITIATION

Freestyle Libre® should only be used for people with type 1 diabetes, ≥ 4 years of age, attending specialist care using multiple daily injections or insulin pump therapy, 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:

1. Patients / carers who undertake intensive blood glucose monitoring ≥ 8 times daily including those on insulin pump.
2. Those who meet the current NICE criteria for insulin pump therapy (and this would be considered a viable option for them) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy.
3. Those who have recently developed impaired awareness of hypoglycaemia (potentially short-term use). However, it is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre® does not currently have that function.
4. Frequent hospital admissions (>2 per year) with diabetic ketoacidosis (DKA) or hypoglycaemia but only where use of Freestyle Libre® would be likely to prevent this in future.
5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible.

In addition, all users must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring. Data from all patients must be included in the national Association of British Clinical Diabetologists (ABCD) audit on flash glucose monitoring (unless patient declines consent). Pregnant women fitting the above criteria may be considered for Freestyle Libre for the duration of pregnancy. Patients who drive may not be suitable, as measurement of interstitial glucose by Freestyle Libre® does not comply with DVLA regulations for driving which require measurement of blood glucose.

Patients not fulfilling above criteria should not be prescribed Freestyle Libre® on the NHS. Patients currently self-funding will not receive FreeStyle Libre® on the NHS unless they fulfil the above criteria.

If no improvement is demonstrated in one or more of the following:

- reduction in severe/non-severe hypoglycaemia,
- reversal of impaired awareness of hypoglycaemia,
- episodes of DKA,
- hospital admissions,
- improvements in HbA1c,
- decreased blood testing strip usage,
- quality of life changes using validated rating scales,
- Commitment to regular scans and their use in self-management

over a maximum (depending on response) 6-month trial, then the use of Freestyle Libre® should be discontinued and an alternative method of monitoring used.

Potential financial implication: Use within the above criteria has the potential to be cost-saving in the majority of individual patients (e.g. cost reduction compared to patient otherwise requiring treatment with insulin pump or CGM is approximately £2,300 per patient per year).

The criteria in this statement are based on Regional Medicines Optimisation Committee recommendations

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.

FLASH GLUCOSE MONITOR (FreeStyle Libre®)

EFFECTIVENESS

Mean time in hypoglycaemia (<3·9mmol/L) in 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 FreeStyle Libre® shows hypoglycaemia or impending hypoglycaemia
- when symptoms do not match the system readings
- to fulfil DVLA requirements to assess fitness to drive.

COST per year (Drug Tariff Nov. 2017)

		£10/ 50 strips	£13/ 50 strips
Blood glucose monitor (BGM)*:	4 x daily	£350	£438
	7 x daily	£613	£767
	10 x daily	£876	£1095
Freestyle Libre® + BGM**	3 x week £913 + £56		£969
Insulin pump (NICE) + BGM	10 x daily		£3445
Continuous glucose monitoring (CGM)			£3240

Assuming 10,720 people with T1 diabetes in Pan Mersey area, 60% on multiple daily injections (6432 patients) with 50% using BGM 4 x daily and 50% using 7 x daily, estimated current cost of BGM strips in Pan Mersey is £3.1million annually (of total BGM strip cost of £4.8million annually). If all the patients using BGM 7 x daily switched to Freestyle Libre® this would cost an additional £0.65million* annually. If 50% of patients switched but were split 50:50 between the 4 x daily and the 7 x daily users this would cost an additional £1.2million* annually. Assuming 10% of all patients were using BGM 10 x daily and all switch to Freestyle Libre® this would cost an additional £60,000 annually. Manufacturer estimates £60/patient/year savings on hospital admissions, emergency department visits and ambulance attendances (based on unpublished data).

*£13/ 50 strips **£16/ 50 strips (all assume £0.04 per lancet)

PATIENT FACTORS

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

PRESCRIBING INFORMATION: Initial sensor and reader supply **t**o be made by specialist diabetes clinics (reader not available on prescription). Primary care prescribers should only be asked to prescribe sensors by specialist, and should only agree to prescribe, if specialist confirms patient meets criteria overleaf (see link) and confirms they continue to meet criteria at 6 months (see link). Patients to be informed that if they do not continue to meet criteria then prescribing will be stopped (see link). BG strips will still need to be prescribed; consider use of separate low-cost BG/ketone strip meter as Pan Mersey guideline.

IMPLEMENTATION NOTES: Users require support and training from specialist in FreeStyle Libre® use[6]. Ongoing use should be assessed at 6 months and annually thereafter as described overleaf. Patients should have completed a structured diabetes education programme and been educated to make sure they can best use the information the system provides[7]. Data from all patients must 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.