CCGs working together

Airedale, Wharfedale and Craven CCG
Bradford City CCG
Bradford Districts CCG

Commissioning Statement

Treatment/ device	Flash Glucose Monitoring Systems (including Freestyle Libre®)
For the treatment of	Monitoring glucose levels in adults and children over 4 years of age with type 1 diabetes mellitus.
Commissioning position	Bradford district and Craven CCG commissions the use of Flash Glucose Monitoring Systems (FGS) for monitoring the level of glucose in interstitial fluid for adults and children with type 1 diabetes mellitus only in the following circumstances: •Patients with Type 1 diabetes mellitus and; •Aged four and above and; •Under specialist care and; •Using multiple daily injections of insulin, or insulin pump therapy, •Whom the specialist considers the use of the device will be cost- effective **and;** •Meets <u>one or more</u> of the following criteria: •Meet current NICE criteria for insulin pump therapy (HbA1c ≥69.4 mmol/mol (8.5%) or disabling hypoglycaemia as described in NICE TA151) where a successful trial of a FGS System may avoid the need for pump therapy •Recently developed impaired awareness of hypoglycaemia such that there is an inability to detect the onset of hypoglycaemia because of absence of warning symptoms. The individual must also demonstrate a willingness to engage with further education where applicable and a high level of engagement with glucose testing and management. (Note that for persistent hypoglycaemia unawareness, NICE recommends continuous glucose monitoring with alarms and FGS do not currently have this function). •Two or more admissions to hospital per year with diabetic ketoacidosis or hypoglycaemia •Patients or carer of a patient who have considerable difficulties in finger prick testing due to physical or mental health limitations •Patients or carer of a patient with functional impairment that impacts on their ability to interpret standard finger prick testing results ***<u>Reluctance to carry out finger prick testing (e.g. due to distress or inconvenience) alone is not considered to be criteria qualifying the use of FGS.</u>***

	The FGS System will be provided initially on a 6 month trial basis. The decision to continue will be made by the diabetes specialist team only if one or more of the following are demonstrated: •A demonstrable reduction in usage of blood glucose test strips. It is noted that patients will still continue to do extra tests to fulfil DVLA requirements. It is also noted that patients with smart meters and bolus calculators will continue to do regular blood glucose testing. However a demonstrable reduction in usage of strips will still be expected. *(Trial data showed a reduction in blood glucose testing to an average of 0.5 times per day in patients using FreeStyle Libre®; however it is acknowledged that more frequent testing may be required in certain circumstances e.g. during periods of illness).* •Significant reduction in severe/non- severe hypoglycaemia frequency •Reversal of impaired awareness of hypoglycaemia •Significant reduction in episodes of diabetic ketoacidosis •Reduction in hospital admissions •Where indication is HbA1c >70 mmol/mol then treatment goal is a reduction in HbA1c depending on pre-intervention HbA1c: Pre-FlashGM HbA1c (mmol/mol) — Goal HbA1c to continue FlashGM >100 — reduce by at least 15 mmol/mol 70-100 — reduce by at least 10 mmol/mol <70 — reduce by at least 5 mmol/mol •FGS will be provided through the hospital specialist diabetes team only as a RED drug i.e. *FreeStyle Libre®;* sensors will not be prescribed by general practitioners. All patients (or carers) must be willing to undertake training in the use of FGS Systems. They must commit to regular scans of the device demonstrating evidence of FGS use in self-management, and commit to ongoing regular follow-up and monitoring. They must also agree the expected outcomes with usage and that NHS provision of FGS will be withdrawn if one or more of the above criteria are not met. The diabetes specialist team in secondary care must gain consent from the patient (or patient representative) at the point of initiation of FGS commissioned by the NHS, to permit NHS staff to undertake an audit of data from both the specialist setting and the patient's GP Practice to enable the benefit of initiation and continuation of FGS to be assessed. Secondary care specialist teams are responsible for collecting the audit data at the end of a six month trial from primary and secondary care in order for the commissioning of FGS to continue. The CCG may require data for verification that use is in line with the commissioning policy. After a six month successful trial the ongoing use of FGS in individuals should be reviewed annually by the specialist team to ensure usage continues to be in line with the commissioning criteria.

	Treatment outcomes must be audited in all patients started on FGS by specialist teams. This audit data will be reviewed regularly by the CCGs and will inform the review of this recommendation twelve months following publication. Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced. Use of FGS in patients with Type 2 diabetes mellitus is not currently licensed or commissioned. Patients who are self-funding FGS who do not meet the above criteria for initiation OR continuation will not be entitled to NHS prescriptions. Patients who are self-funding who did meet the criteria for FGS and where it can be demonstrated by their diabetes team that they achieved the criteria for continuation at 6 months will be entitled to receive FGS on an NHS prescription. A clinician can make an Individual Funding Request (IFR) for treatment when a patient does not meet the stated criteria for funding. Funding can only be approved if a case of "exceptional clinical need" has been demonstrated. See individual CCG websites for IFR policies. North Kirklees CCG/Bradford City CCG/Bradford Districts CCG/Greater Huddersfield CCG/Wakefield CCG/Calderdale CCG/Airedale Wharfedale and Craven CCG
Date effective from	02.08.2018
Policy to be reviewed by	02.08.2019 (to be reviewed earlier if NICE issues guidance at an earlier date)
Background information	The FGS consists of a sensor worn on the upper arm that measures interstitial glucose every minute and a reader device that is scanned over the sensor to get a result. It can produce a near continuous record of measurements which can be accessed on demand. It can also indicate glucose level trends over time. The FGS is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The product is classified as a device and received European CE mark certification in August 2014. The sensors may also be read with an appropriate application on a Smart phone which has near-field communication. This new technology helps to reduce the burden of finger prick blood tests but there is not any evidence available as yet as to whether it reduces complications and long-term outcomes for diabetic patients. There is no NICE directive for CCGs to fund this new technology but NICE has undertaken a Medtech innovation briefing [1].

Summary of evidence/ rationale	The main points from the evidence are from 5 studies involving 700 people [1]. This includes 2 randomised controlled trials; one that includes people with type 1 diabetes (n=241; the IMPACT study) and the other including people with type 2 diabetes (n=224; the REPLACE study) [1]. Three of the studies reported device accuracy compared with self-monitored blood glucose, with results ranging from 84% to 88% accuracy and from 99% to 100% clinical acceptability, using an error grid. One study reported device accuracy and acceptability of 97% to 99% compared with venous blood sampling [1]. Patients using FreeStyle Libre® experienced less time in hypoglycaemia than patients using SMBG, averaging 1.24 hours per day (SE 0.24) or 38% less time ($p<0.0001$) in hypoglycaemia and 1 hour more per day in euglycaemia ($p=0.0006$). The number of hypoglycaemic events per day reduced by mean of 0.45 (by over 25%; $p<0.0001$) [1]. The limited data available suggests that using FreeStyle Libre® for up to 12 months reduces time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick tests, and reduces the average number of finger-prick blood glucose tests needed [1] There is limited safety data available on the use of the FGS. The only published study carried out by Bailey et al reported there were no unexpected adverse device effects reported during the clinical study. Finger prick capillary blood glucose monitoring is still advised during periods of rapidly changing levels of interstitial glucose when interstitial glucose levels may not accurately reflect blood glucose levels, if hypoglycaemia or impending hypoglycaemia is reported, or the patient's symptoms do not match the system readings. Three of the studies reported device accuracy compared with self-monitored blood glucose. The investigators concluded that interstitial glucose measurements via the FreeStyle Libre® system were accurate compared with capillary blood glucose reference values, and this accuracy was maintained over 14 days lifespan of the Freestyle Libre® sensor.

Cost effectiveness / resource impact:

There is currently no UK cost-effectiveness data available for FGS to be able to determine whether this new technology is cost-effective for the NHS.

The resource impact depends upon the extent to which improved glucose control through the adoption of FGS translates into fewer complications (hypoglycaemia and the longer term microvascular and macrovascular complications of hyperglycaemia), reduced admissions and reduced use of blood glucose test strips.

Impact upon the individual CCGs test strip expenditure will be evaluated further after 12 months.

A year's cost of sensors is £910 per patient. The FGS reader is not available on prescription and will be provided free of charge by the manufacturer.

Cost of Freestyle Libre (FL) sensors per annum	**£910**
Cost of Cost effective(£9.95 for 50) Blood Glucose Test Strip (BGTS) - 8/day	**£581.08**
Cost of more expensive(£16 for 50) BGTS 8/day	**£934.40**
If T1 patient and also using ketone strips	**£10-£20 / 10 strips**

If a patient is currently using more expensive strips and tests ketones once per week at £20 per box the annual cost is £1035.

Therefore, FGS would be cost neutral if testing not more than once per month on ketones and no more than once per day on BGTS and could be cost effective if it reduced BGTS and Ketone strips usage further.

However, for a patient using cost effective BGT strips and cost effective ketone strips once per week the cost is £631 – FGS would never be cost neutral without additionality.

	References 1.) FreeStyle Libre for glucose monitoring; Medtech innovation briefing [MIB110] Published date: July 2017. Accessed: 13.06.2018 https://www.nice.org.uk/advice/mib110 **Other references used in the development of the policy** Regional Medicines Optimisation Committee FreeStyle Libre Position Statement 1st November 2018: Accessed: 13.06.2018 https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/ NHS Vale of York and NHS Scarborough and Ryedale CCGs Accessed: 13.06.2018 http://www.valeofyorkccg.nhs.uk/rss/data/uploads/procedures-not-routinely-commissioned/ys-position-statement-freestyle-libre-march-2018-final-01-03-2018.pdf NHS Bath and North East Summerset CCG; NHS Swindon CCG; NHS Wiltshire CCG Accessed: 13.06.2018 http://test.bathandnortheastsomersetccg.nhs.uk/assets/uploads/2018/05/Freestyle-Libre-Flash-Glucose-Monitoring-CBA.pdf
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