

## BEDFORDSHIRE AND LUTON JOINT PRESCRIBING COMMITTEE (JPC)

June 2018

(Updated October 2018 to include  
final published PAC Bulletin)

Review: December 2019

**Bulletin 265: FreeStyle Libre ® (Flash Glucose Scanning {FGS}):- Locally agreed JPC recommendations and East of England Priorities Advisory Committee (EoEPAC) guidance for the use of FGS in children and young people with type 1 diabetes age 4 up to {i.e less than} age 19.**

The JPC agreed to support the attached EoEPAC bulletin and criteria for funding.

The JPC supported all of the PAC recommendations except for the following recommendation:-

- FGS should be initiated, managed and supplied by a consultant led specialist Diabetes team. GP prescribing is not recommended.

A locally modified version of the above recommendation was agreed as outlined below:-

- FGS should be initiated, managed and supplied as agreed by locally commissioned pathways. GP prescribing is not recommended at the current time.

**All PAC recommendations relate to the use of FGS in children and young people with type 1 diabetes age 4 to up to {i.e less than} age 19.**

**NB – the Commissioning Position of the CCGs with respect to the JPC recommendations is outlined below.**

### **BCCG Commissioning Position**

BCCG has agreed to fund (commencing 1<sup>st</sup> August 2018) in line with the JPC recommendations and criteria approved at the April 2018 meeting up to a specified maximum number of patients per annum agreed with each Trust via a CCG approval (Blueteq) process. Supply of the device/sensors will be undertaken by the Specialised Diabetes Teams at Bedford Hospital and the Luton & Dunstable Hospital with no GP prescribing, no additional activity charges and subject to audit. For patients under the care of other Trusts, GPs are asked to contact the BCCG Medicines Optimisation Team for advice.

### **LCCG Commissioning Position**

LCCG does not currently commission FreeStyle Libre ® (Flash Glucose Scanning {FGS}). The commissioning position will be reviewed in 6 months' time.

## GUIDANCE STATEMENT

Flash Glucose Scanning system (FGS) for children and young people with type 1 diabetes mellitus, age 4 to (less than) 19

### PAC interim recommendations

- Freestyle Libre® is an innovative Flash Glucose Scanning system (FGS) that has the potential to improve quality of life for patients with type 1 diabetes mellitus (T1DM) and support self-management. However, currently there are significant limitations in the available clinical trial data and economic analysis, and routine commissioning for all patients is not recommended.
- PAC supports a managed entry of FGS to allow real world data on use and outcomes to be collected in order to inform future policy.
- These recommendations are not a commissioning directive and individual commissioners should consider this advice considering affordability and local priorities. PAC will continue to work with clinicians to develop recommendations for funding for other patient groups as more information becomes available.
- FGS is recommended as an option for the patient groups outlined below in line with the criteria and general funding recommendations set out in this document.
- PAC recommends that funding is initially made available for these patient groups for a time limited period of one year. It is recommended that audit data is collected and that funding recommendations are reviewed to include new evidence on cost effectiveness, actual patient numbers and affordability.
- Routine funding for any other indication is currently considered a low priority and is not recommended.
- Funding for patients who are currently self-funding who do not fulfil the criteria is not recommended.
- FGS should be initiated, managed and supplied by a consultant led specialist diabetes team. GP prescribing is not recommended.
- The use of FreeStyle Libre® blood glucose testing strips using the inbuilt meter should be considered locally.
- Due to the high cost of testing strips the use of the inbuilt FreeStyle Libre® meter for testing ketones is not currently recommended.

#### Summary of criteria recommended for funding

All recommendations apply to patients with type 1 diabetes mellitus (T1DM) only unless otherwise specified (see section on recommended criteria for commissioning on page 3 for details).

1. Children who have recently developed hypoglycaemia unawareness (< 3 months onset).
2. Children who have disabling hypoglycaemia without loss of hypoglycaemia awareness  
Disabling hypoglycaemia is defined as the repeated and unpredictable hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life and is manifested by one or more of the following features:

- » High frequency of blood glucose testing during night that disturbs sleep.
  - » Persistent efforts to maintain high blood glucose levels in excess of the recommended maximum target in order to avoid hypoglycaemic episodes, that adversely affect metabolic control.
3. Children where adequate frequency of blood glucose monitoring is unachievable due to diagnosed behavioural or mental health disorders where there are significant concerns about the safety of the individual, and poor metabolic control
  4. Children with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity resulting in marked fluctuations of blood glucose levels that make diabetes management very difficult. This applies to patients with anorexia nervosa, PEG feeding, and children with cystic-fibrosis related diabetes.
  5. Frequent hospital admissions (>2 per year) with diabetic ketoacidosis (DKA) and HbA1c  $\geq$  69 mmol/mol despite intensive clinical intervention.
  6. Children who meet the current NICE criteria for insulin pump therapy who are on the pump pathway, where a successful trial of FGS may avoid the need for insulin pump therapy if clinically appropriate.
  7. Children with extreme phobia towards a finger prick blood test which adversely affects metabolic control, this is defined as:
    - » Children who have good concordance with insulin treatment but who have significant needle phobia despite psychological/play therapy interventions, and who are blood glucose testing <5 times a day resulting in poor metabolic control (HbA1c  $\geq$ 69 mmol/mol).
  8. Children who are unable to achieve the HbA1c target of <58 mmol/mol despite intensive clinical intervention to optimise therapy and persistent (>6 months) intensive blood glucose monitoring (blood glucose tests  $\geq$ 8/day that is clinically appropriate, on the recommendation of the diabetes specialist team).

## Key points

Flash Glucose Scanning (FGS) systems such as FreeStyle Libre® have the potential to improve quality of life for patients by reducing the burden of invasive finger prick blood glucose (BG) testing, and by supporting self-management. However, currently there are significant limitations in the available clinical trial data and economic analysis which mean that routine use in all patients cannot be recommended.

PAC supports a managed entry of FGS to allow real world data on use and outcomes to be collected in order to inform future policy. The Regional Medicines Optimisation Committee (RMOC) (North) reviewed the use of FGS and published recommendations on its use in patients with type 1 diabetes, aged four and above, in November 2017.<sup>1</sup> PAC have worked with clinicians from the Eastern Paediatric Diabetes Network (EPDN) to further refine the criteria recommended by the RMOC to identify initial patient cohorts who should be prioritised for funding by Clinical Commissioning Groups (CCGs). These recommendations are not a commissioning directive and individual commissioners should consider this advice considering affordability and local priorities. PAC will continue to work with clinicians to develop recommendations for funding for other patient groups as more information becomes available.

It is not possible to accurately estimate patient numbers for each patient cohort, and cost impact assessments presented in this document are indicative only. It is recommended that audit data is collected and these recommendations reviewed after one year to include new evidence on cost effectiveness, actual patient numbers and affordability.

## General funding recommendations

- Funding for recommended patient cohorts should be provided for a maximum of 12 months (subject to a review at six months) unless otherwise specified in the section on recommended criteria for

commissioning on page 3. Continuation of funding for each criteria will be reviewed after one year.

- FGS must be initiated, managed and supplied by a consultant led specialist diabetes team.
- GP prescribing is not recommended.
- Prior funding approval including treatment aims, continuation and stopping criteria must be agreed with the commissioner before commencement of treatment – see individual criteria below.
- Funding should be provided for a maximum of 26 sensors per patient per year.
- Funding should be reviewed after six months, and annually thereafter.
- Continued funding beyond this initial six months is not automatic, and prior approval of funding beyond this time will only be granted where there is evidence of:
  - » Achievement of treatment goals specified for each criteria below

AND

- » Statement of rationale from diabetologist that cessation of FGS would reverse this benefit.
- Funding for treatment should be discontinued where:
  - » Patient/carers are unable to cope with sensor/ managing technology despite intensive support by the diabetic team.
  - » Failure to wear the sensor >70% of the time.
  - » Failure to perform the minimum number of daily scans as agreed by the multidisciplinary team (MDT) (≥4 scans per day in addition to BG testing).
  - » Failure to achieve treatment goals specified for each criteria.
- Funding for FreeStyle Libre® will be reviewed at age 19. Funding will be stopped if the patient does not fulfil the agreed criteria for funding in people aged 19 or older. See PAC document for recommendations on funding FGS in adults with type 1 diabetes.
- Diabetes teams must ensure that:
  - » The motivation of children and their carers and their ability to manage the technology appropriately has been assessed.
  - » Children and their carers have been given a formal education and training masterclass on the use of FGS in a format approved by the Eastern Paediatric Diabetes Network (EPDN).
- Before commencing treatment, clinicians must agree a contract with the child/parent/carer agreeing the treatment aims and terms of use, e.g. agree to use the sensors for at least 70% of the time, and confirming that they understand that:
  - » Funding for treatment will be withdrawn if treatment aims are not met or the technology is not used as per the agreed treatment plan.
  - » Funding will be provided for a time limited period only as specified in the patient contract, and that sensors will no longer be provided after this time.
  - » A maximum number of 26 sensors will be provided over a 12 month period.
- Funding for FreeStyle Libre® will be reviewed and stopped at age 19 if the patient does not fulfil the agreed criteria for funding in people aged 19 or older.
- Patients must continue to use the most cost effective blood glucose and ketone testing meters and strips as per local policy. The use of FreeStyle Libre® blood glucose testing strips using the inbuilt meter should be considered locally. Due to the high cost of testing strips the use of the inbuilt FreeStyle Libre® meter for testing ketones is not currently recommended
- Teams must submit data on use of FGS to the Association of British Clinical Diabetologists (ABCD) national audit,<sup>2</sup> the EPDN and commissioners for the purposes of audit of the use of FGS technology.

## Recommended criteria for commissioning

Cost impact calculations in this section are based on patient number estimates for each cohort provided by the EPDN, and the cost of Aviva BG testing strips which are used by the majority of children with type 1 diabetes in the East of England. See section on cost impact for further details.

<b>Recommendation 1</b>	<p>Children who have recently developed hypoglycaemia unawareness (&lt; 3 months onset) defined as:</p> <p>Score &gt;4 on the Clarke hypoglycaemia unawareness questionnaire</p> <p>OR</p> <p>Score <math>\geq</math>4 on the Gold hypoglycaemia unawareness Likert scale</p> <p>AND</p> <p>Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose data/significant hypoglycaemia lasting &gt;15 minutes confirmed by diagnostic Continuous Glucose Monitoring (CGM) or downloaded blood glucose data, that occurred during the waking day which the patients were unaware of.<sup>3</sup></p>
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## Rationale

Hypoglycaemia unawareness in a previously hypoglycaemia aware patient suggests that a patient is experiencing unpredictable and/or frequent hypoglycaemia. Although there is variability in individual's ability to identify and recognise hypoglycaemia, a significant drop in glucose levels is usually needed to trigger symptoms that can be detected. Hypoglycaemia unawareness often occurs as a result of improved glycaemic control because as blood glucose levels are maintained at lower levels, the drop to hypoglycaemic levels is not sufficient to trigger symptoms of hypoglycaemia.

The frequent episodes of hypoglycaemia and hypoglycaemia unawareness put these patients at a very high risk of developing severe hypoglycaemia.<sup>4</sup>

FGS will provide data on glucose trends which will allow the patient and MDT to optimise care (including insulin and carbohydrate dose adjusting) to reduce risks of severe hypoglycaemia episodes without loss of glycaemic control, and to improve hypoglycaemia awareness. It is anticipated that use of FGS in this group of patients may reduce the occurrence of severe hypoglycaemia episodes and/or persistent loss of hypoglycaemia awareness which would otherwise require management with CGM.

## Treatment aims

- Improvement in hypoglycaemia awareness through the reduction in the number of episodes of hypoglycaemia from baseline without loss of glycaemic control.
- Achievement and maintenance of target HbA1c agreed by the MDT.
- Reduction in blood glucose variability.
- Reduction in number of blood glucose tests.
- Improve quality of life.

## Entry criteria

- Evidence of incidentally detected hypoglycaemia episodes from downloaded blood glucose data/significant hypoglycaemia lasting >15 minutes confirmed by diagnostic CGM or downloaded blood glucose data, that occurred during the waking day which the patients were unaware of

AND

- Score >4 on the Clarke hypoglycaemia unawareness questionnaire or score  $\geq$ 4 on the Gold hypoglycaemia unawareness Likert scale

AND

- Frequent blood glucose testing ( $\geq$ 8 times per day) that is clinically appropriate on the recommendation of the diabetes specialist team, confirmed by data download from blood glucose testing meter.

## Review and stopping criteria

Discontinue if:

- Hypoglycaemia awareness improved (score <4 on the Clarke hypoglycaemia unawareness questionnaire/score ≤4 on the Gold hypoglycaemia unawareness Likert scale)

OR

- No improvement in hypoglycaemia awareness.

## Estimated patient numbers and cost impact

Estimated % paediatric caseload	2%	
No. patients per 100,000 total population (all ages)	1.2	
Additional cost per 100,000 total population per year using FGS and continuing to BG test five times per day	Exc. VAT	£317
	Inc. VAT	£535

<b>Recommendation 2</b>	Children who have disabling hypoglycaemia without loss of hypoglycaemia awareness.
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## Rationale

Disabling hypoglycaemia is defined as the repeated and unpredictable hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.<sup>5</sup> Children/carers of children with disabling hypoglycaemia often test blood glucose frequently (≥ 8 tests per day), including testing during the night.

In order to avoid hypoglycaemic episodes, blood glucose levels are maintained in excess of the recommended maximum target for sustained periods, adversely affecting metabolic control. Frequent hypoglycaemia episodes, its treatment and the consequent anxiety considerably affect day to day functioning of children.

24-hour glucose profile from FGS provides detailed information on the glucose trends allowing optimisation of insulin delivery to reduce hypoglycaemia events and improve metabolic control and allows a reduction in the number of blood glucose tests, and improved quality of life.

All patients must have had anxiety management treatment from a clinical psychologist prior to starting FGS.

## Treatment aims

- Reduction in the number of unpredicted hypoglycaemic events.
- Prevent loss of hypoglycaemia awareness.
- Improvement in metabolic control.
- Reduce blood glucose variability.
- Reduction in number of blood glucose tests.
- Reduction in the number of night time blood glucose tests.
- Reduce anxiety and improve quality of life.

## Entry criteria

- Evidence of frequent hypoglycaemic episodes from downloaded blood glucose data/significant hypoglycaemia lasting > 15 minutes confirmed by diagnostic CGM or downloaded blood glucose data

AND

- Persistent anxiety not resolved by psychological therapy

AND

- Frequent blood glucose testing  $\geq 8$  tests per day including night time testing confirmed by data downloaded from blood glucose testing meter.

### Review and stopping criteria

No reduction in the number of hypoglycaemic events

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	5%	
No. patients per 100,000 total population (all ages)	3	
Additional cost per 100,000 total population per year using FGS and continuing to BG test five times per day	Exc. VAT	£792
	Inc. VAT	£1,338

### Recommendation 3

Children where adequate frequency of blood glucose monitoring is unachievable due to diagnosed behavioural or mental health disorders, where there are significant concerns about the safety of the individual, and poor metabolic control.

### Rationale

This group of children are characterised by behavioural or mental health disorders and often require significant involvement/support by multiple agencies/services (e.g. social service, education, psychiatry/psychology). In some of these children there are concerns about inadequate blood glucose testing either in the form of persistent or intermittent poor monitoring often leading to raised significant concerns for the safety of individuals by the multidisciplinary team. The concerns are mainly related to the risk of severe short-term complications such as severe hypoglycaemia or diabetes ketoacidosis. Flash glucose monitoring if tolerated, provides data of blood glucose levels to patients/parents or carers and the health professionals to help to prevent these complications.

### Treatment aims

- Avoiding/reducing severe hypoglycaemia or DKA
- Improving glycaemic control

### Entry criteria

- Children with diagnosed behavioural or mental health disorders under the care of Child and Adolescent Mental Health services (CAMHS) or community paediatric services.

AND

- Blood glucose testing less than four times per day confirmed by data downloaded from blood glucose testing meter.

AND

- Evidence of frequent hypoglycaemia and/or DKA or HbA1c  $\geq 69$  mmol/mol.

### Review and stopping criteria

Discontinue if:

- No reduction in the number of hypoglycaemic events

OR

- No reduction in DKA

OR

- No improvement in HbA1c defined as:
  - » Failure to achieve a  $\geq 5$  mmol/mol (0.5%) reduction in HbA1c.

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	1%	
No. patients per 100,000 total population (all ages)	0.6	
Additional cost per 100,000 total population per year using FGS with no change to baseline BG testing frequency	Exc. VAT	£546
	Inc. VAT	£655

<b>Recommendation 4</b>	<p>Children with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity resulting in marked fluctuations of blood glucose levels that make diabetes management very difficult. This applies to children with the following co-morbidities:</p> <ul style="list-style-type: none"> <li>• Anorexia nervosa (receiving concomitant psychological therapy)</li> <li>• PEG feeding</li> <li>• Children with cystic fibrosis related diabetes</li> </ul>
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### Rationale

This group of patients are difficult to control using conventional blood glucose testing and will test blood glucose frequently ( $\geq 8$  tests per day). Flash monitoring provides detailed information on glucose trends allowing optimisation of insulin delivery to reduce hypoglycaemia events and optimise metabolic control, and a reduction in the number of blood glucose tests required.

### Treatment aims

- Reduction in number of blood glucose tests.
- Achievement and maintenance of good glycaemic control.

### Entry criteria

- Children with anorexia nervosa (receiving concomitant psychological therapy) or PEG feeding or cystic fibrosis related diabetes

AND

- Evidence of hypoglycaemia episodes from downloaded blood glucose data/ significant hypoglycaemia lasting  $>15$  minutes confirmed by diagnostic CGM or downloaded blood glucose data and/or HbA1c  $\geq 58$  mmol/mol

AND

- Frequent blood glucose testing ( $\geq 8$  times per day) that is clinically appropriate on the recommendation of the diabetes specialist team confirmed by data downloaded from blood glucose testing meter.

### Review and stopping criteria

Discontinue if:

- No reduction in the number of hypoglycaemic events and/or no improvement in HbA1c defined as:

- » Failure to achieve a  $\geq 5$  mmol/mol (0.5%) reduction in HbA1c

OR

- No longer diagnosed with a qualifying co-morbidity.

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	1%	
No. patients per 100,000 total population (all ages)	0.6	
Additional cost per 100,000 total population per year using FGS and continuing to BG test five times per day	Exc. VAT	£158
	Inc. VAT	£268

<b>Recommendation 5</b>	Frequent (>2 per year) hospital admissions (inpatient episodes) with DKA with HbA1c $\geq 69$ mmol/mol despite intensive clinical intervention.
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### Rationale

These patients are heterogenous and very poorly controlled despite intensive clinical intervention. Flash glucose monitoring, if tolerated, provides data of blood glucose levels to patients/ parents or carers and the health professionals to assist in optimising treatment to reduce incidence of DKA and improve metabolic control.

### Treatment aims

- Reduction in the number of hospital admissions with DKA
- Improvement in glycaemic control

### Entry criteria

- Hospital admissions (>2 per year) with DKA with a blood pH <7.3.<sup>6</sup>
- Poor metabolic control: HbA1c  $\geq 69$  mmol/mol despite intensive clinical intervention.

### Review and stopping criteria

Discontinue if:

- No improvement in HbA1c defined as:
  - » Failure to achieve a  $\geq 5$  mmol/mol (0.5%) reduction in HbA1c.
- If reduction in HbA1c is demonstrated at 6 months, continue treatment and reassess 18 months after initiation. Discontinue if no reduction in the number of hospital admissions with DKA at 18 months after initiation.

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	1%	
No. patients per 100,000 total population (all ages)	0.6	
Additional cost per 100,000 total population per year using FGS with no change to baseline BG testing frequency	Exc. VAT	£546
	Inc. VAT	£655

<b>Recommendation 6</b>	Children who meet the current NICE criteria for Continuous Subcutaneous Insulin Infusion (CSII) therapy and who are on recognised insulin pump pathway, where a successful trial of FreeStyle Libre® may avoid the need for pump therapy if clinically appropriate. <sup>5</sup>
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### Rationale

Flash monitoring provides detailed information on glucose trends allowing optimisation of insulin delivery to reduce hypo events and improve metabolic control, which may avoid the need for progression to pump therapy.

### Treatment aims

- Improvement in glycaemic control.
- Avoidance of the need for pump therapy.

### Entry criteria

Patients who fulfil criteria for CSII who are on a recognised pump pathway in line with criteria specified in NICE TA151.

### Review and stopping criteria

- Six month trial
- Improvement in metabolic control: continue treatment
- No improvement in metabolic control: progress to pump therapy. NB: Funding for FGS will be reviewed and stopped on initiation of pump therapy.

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	2%	
No. patients per 100,000 total population (all ages)	1.2	
Additional cost per 100,000 total population per year using FGS with no change to baseline BG testing frequency	Exc. VAT	£317
	Inc. VAT	£535

<b>Recommendation 7</b>	<p>Children with extreme phobia towards finger prick blood test which adversely affects metabolic control defined as:</p> <ul style="list-style-type: none"> <li>• Children who have good concordance with insulin treatment but who have significant needle phobia despite psychological/play therapy interventions, and who are BG testing &lt;5 times a day resulting in poor metabolic control (HbA1c ≥ 69 mmol/mol).</li> </ul>
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### Rationale

This group of children are currently inadequately managed with infrequent blood glucose testing resulting in poor metabolic control.

### Treatment aims

- Avoiding/reducing hypoglycaemia
- Improving glycaemic control

- Achievement and maintenance of good glycaemic control

### Entry criteria

- Significant needle phobia despite psychological/play therapy interventions

AND

- Blood glucose testing <5 times a day

AND

- Poor metabolic control (HbA1c  $\geq$  69 mmol/mol).

AND

- Good concordance with insulin treatment.

### Review and stopping criteria

Discontinue if:

- No improvement in HbA1c defined as:
  - » Failure to achieve a 5 mmol/mol (0.5%) reduction in HbA1c

OR

- No longer fulfil this criteria for FGS funding.

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	2%	
No. patients per 100,000 total population (all ages)	1.2	
Additional cost per 100,000 total population per year using FGS with no change to baseline BG testing frequency	Exc. VAT	£1,092
	Inc. VAT	£1,310

<b>Recommendation 8</b>	Children who are unable to achieve an HbA1c target of <58 mmol/mol despite intensive clinical intervention to optimise therapy and persistent (>6 months) intensive blood glucose monitoring (blood glucose tests $\geq$ 8/ day).
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### Rationale

NICE guidelines currently state that patients should aim to achieve an HbA1c of <48 mmol/mol in order to reduce long-term complications.<sup>6</sup> However, only a small proportion of patients (10-15%) achieve this target. There is a distinct cohort of highly motivated patients/parents or carers of children with type 1 diabetes who intensively manage diabetes but do not achieve this target. These patients/parents or carers of children have very good self-management skills and use the regularly (weekly or fortnightly) downloaded data from glucose meter of insulin pump to optimise treatment. They test blood glucose very frequently including while the child is asleep and treat any high blood glucose levels by intermittent correction doses of insulin including while the child is asleep. This intensive management causes significant disruption of day to day life adversely affecting the quality of life of children and parents/ carers. Regular downloads (weekly to fortnightly) from FGS which provide 24-hour glucose profiles and the recent retrospective trends of glucose levels are extremely useful tools to optimise insulin delivery and improve metabolic control. Furthermore, FGS helps to monitor the levels frequently during day time and while children are asleep with minimum disruption day to day activities and sleep and improve the overall quality of life. The cost of FGS may be offset by a reduced number of finger prick blood tests, as BG levels in between the meals are not needed.

The number of patients currently unable to achieve the NICE recommended target of HbA1c of <48 mmol/mol is unknown but is likely to be in excess of 10% of the paediatric diabetes population. Due to the lack of accurate information on patient numbers, cost impact and long term outcomes, PAC agreed to recommend targeting funding for this group of patients to those who are unable to achieve an HbA1c of <58 mmol/mol despite intensive clinical intervention.

### Treatment aim

- Improvement in HbA1c  $\geq$  5 mmol/mol.
- Reduction in number of blood glucose tests.
- Reduction in night time testing.

### Entry criteria

- HbA1c of  $\geq$  58 mmol/mol despite intensive clinical intervention to optimise therapy

AND

- $\geq$  6 months intensive blood glucose monitoring ( $\geq$ 8 times per day) that is clinically appropriate and on the recommendation of the diabetes specialist team, confirmed by data downloaded from blood glucose testing meter.

### Review and stopping criteria

Discontinue if:

- No improvement in HbA1c defined as:
  - » Failure to achieve a  $\geq$  5.5 mmol/ml (0.5%) reduction in HbA1c.

### Estimated patient numbers and cost impact

Estimated % paediatric caseload	3%	
No. patients per 100,000 total population (all ages)	1.7	
Additional cost per 100,000 total population per year using FGS and continuing to BG test five times per day	Exc. VAT	£449
	Inc. VAT	£758

## Background

FreeStyle Libre® is a flash glucose scanning (FGS) system which allows people, with diabetes mellitus (DM) (age 4 and older), to monitor glucose levels and trends without performing capillary (finger prick) testing.<sup>7</sup> A sensor approximately the size of a £2 coin with a microfilament which is sited in the skin, is placed on the back of the arm and when the reader unit passes over the sensor, the reader display shows a reading based on interstitial fluid glucose levels. Results can be obtained through clothing. The reader can show a trace for the last eight hours and displays an arrow showing the direction the glucose reading is heading. FGS is not the same as CGM with several distinct differences.<sup>8</sup> FreeStyle Libre® does not have an alarm and does not notify the user of adverse events such as hypoglycaemia as they happen.

The sensor lasts for up to 14 days before it needs to be replaced and can tolerate immersion in water up to 1 metre for up to 30 minutes. The company information states that scanning of the sensor at least every eight hours provides the user with a 24-hour continuous blood glucose profile. The reader can store 90 days of data and apps are now available for smart phones which allow the phone to act as the reader and also allow remote monitoring of the sensor, by a parent or other carer.<sup>7</sup>

The FreeStyle Libre® is calibrated as part of the production process and so does not require calibration using finger-prick testing, unlike CGM systems which do. However, a finger-prick test using a blood glucose meter is still required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels (e.g. acute illness such as influenza,

diarrhoea and vomiting), if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings.

The effect of using FGS on the frequency of BG testing in children is yet to be fully evaluated. Current NICE guidelines advise children and young people with type 1 diabetes and their family members or carers (as appropriate) to routinely perform at least five capillary blood glucose tests per day.<sup>6</sup> Blood glucose tests are advised before each meal to calculate bolus insulin doses before bedtime and one random test per day as well as additional tests during times of illness.

The IMPACT study found that BG testing in adults using FGS reduced to an average of 0.5 tests per day.<sup>9</sup> Data for children is not yet available but clinical experience of using FGS indicates that patients will in practice, perform less BG tests than the minimum recommended five tests per day, sometimes only testing to confirm FGS readings that indicate hypoglycaemia. However, it should be noted that the advice of local diabetologists is that FGS cannot currently replace pre-meal glucose testing in patients who are carbohydrate counting and that these patients will continue to require finger prick testing a minimum of four times daily in order to calculate their required insulin dose.

Young people who drive will still need to perform a blood glucose test prior to driving and every two hours whilst driving, to meet DVLA requirements.<sup>10</sup>

## Clinical evidence

There is currently limited evidence to support the use of FreeStyle Libre®.

The Regional Medicines Optimisation Committee review and recommendations notes the following concerns with regard to the clinical evidence and costing information supplied for FreeStyle Libre®:<sup>1</sup>

- Trials contain only small numbers (n=700) of patients with well controlled type 1 diabetes.
- Limited trial duration (6-12 months only).
- Limited data comparing to CGM.
- Limited or no data of use in unstable patients, pregnancy, young people and children.

## Cost effectiveness and cost impact

### Cost effectiveness

The short and long term impacts of using FGS which may offset the additional cost have yet to be fully evaluated.

Anticipated short term benefits include a reduction in the number of ambulance call outs and/or hospital admissions for hypoglycaemia/DKA which may offset the additional cost of FGS.

The following are indicative costs of acute hospital care for children admitted with DKA or hypoglycaemia.<sup>11</sup>

Admission for DKA	£980
Admission for hypoglycaemia	£719

### Cost impact

FreeStyle Libre® Sensor discs were included in the Drug Tariff from 1st November 2017. The Freestyle Reader is not currently available to prescribe on FP10 prescription and the manufacturers, Abbott, are currently supplying the devices to patients free of charge. No information is currently available on how long this arrangement will be honoured by Abbott.

Currently the majority of children with type 1 diabetes in the East of England use “smart” glucose meters which can calculate bolus doses and have the ability to transmit data remotely to diabetes teams via a system such as Diasend. These meters use glucose testing strips at the higher end of the price range (e.g. Aviva test strips).

The FreeStyle Libre® device comes with an inbuilt FreeStyle Optium blood glucose and ketone meter. The inbuilt blood glucose meter has a facility to calculate bolus doses for patients who are carbohydrate counting, however it has been designed for adult use, and does not have small enough increments for it to be suitable for use by young children. In practice, many patients who have self-funded FGS have used the inbuilt meter, as it is more convenient than carrying an additional meter.

The cost of FreeStyle Optium blood glucose testing strips for use in the FreeStyle Libre® reader is currently £16.00 for 50 strips, broadly in line with Aviva strips currently used by the majority of paediatric patients in the region. Provision of BG testing strips and meters varies across the region, and it is recommended that a local decision is made on whether to support the use of FreeStyle Libre® device/ strips for BG testing in children.

The FreeStyle Optium  $\beta$ -Ketone Test Strips currently cost £21.53 and are significantly more expensive than other more cost effective products.<sup>12</sup> Due to the high cost of testing strips the use of the inbuilt FreeStyle Libre® meter for testing ketones is not currently recommended.

The frequency of BG testing in children using FGS is not yet known. EPDN clinicians have confirmed that they will not be advocating the use of flash monitoring readings to replace blood glucose testing when calculating bolus doses of insulin, or where hypoglycaemia is suspected.

For the purposes of estimating cost impact, it has been assumed that the minimum number of daily blood glucose tests recommended by NICE (five tests per day) will continue to be performed. In clinical practice, the number of daily BG tests performed may be less, further offsetting the cost of FGS provision. The impact of reducing to an average of 0.5 tests per day as reported in the IMPACT study in adults, is shown for comparative purposes only.

This assumption will be reviewed in the light of evidence from audit and/or a change in national recommendations on capillary blood glucose monitoring.

The cost of FreeStyle Libre® vs. blood glucose testing using Aviva strips and standard lancets is shown in the tables below.<sup>12,13</sup>

Cost of blood glucose testing using Aviva test strips	Per pack	Per test
Aviva Test strips	£16.09 for 50	£0.32
Lancets (average cost East of England CCGs)	£3.29 for 100	£0.03
Average cost per test		£0.35

FreeStyle Libre® costs	Excluding VAT	Including VAT
Sensor x 1 (14 days)	£35	£42
1 year cost (sensors only)	£910	£1,092

### Cost impact of FreeStyle Libre®

It is not possible to accurately estimate the number of patients that will be eligible for each of the proposed criteria. Cost impact estimates are based on estimated patient numbers provided by the EPDN.

To estimate patient numbers in each cohort, we have estimated an approximate prevalence of 244 children with type 1 diabetes per 100,000 children under the age of 19. This equates to approximately 58 children per 100,000 of the general population of all ages.<sup>14,15</sup>

Based on clinical experience from the EPDN, we have assumed children who are testing BG frequently, e.g. because of disabling hypoglycaemia, are testing an average of 10 times per day. Where a reduction in blood glucose testing is expected as a result of using FreeStyle Libre®, we have assumed an average reduction from 10 tests per day to 5 tests per day as per current NICE recommendations. Impact of reducing BG testing to 0.5 tests per day is shown for comparative purposes only.

Cost per patient per year		
10 BG tests per day using Aviva test strips	£1,291	
5 BG tests per day using Aviva test strips	£646	
0.5 BG tests per day using Aviva test strips	£65	
	Excluding VAT*	Including VAT**
FreeStyle Libre® (sensors only) and BG testing 5 times per day	£910	£1,092
FreeStyle Libre® (sensors only) and BG testing 5 times per day	£1,556	£1,092
Additional cost of using FreeStyle Libre® and BG testing 5 times per day vs BG testing 10 times per day	£264	£446
FreeStyle Libre® (sensors only) and BG testing 0.5 times per day	£975	£1,157
Cost saving of using FreeStyle Libre® and BG testing 0.5 per day vs. BG testing 10 times per day	-£317	-£135

\*VAT would not be added if supplied on FP10 prescription. \*\*Supplies made via secondary care would be subject to 20% VAT.

## Commissioning considerations

Until place in therapy is more established, it is recommended that the use of FGS is initiated, supplied and monitored by diabetes specialists only. CCGs should define which specialist services will be responsible for managing FGS in line with their local arrangements for service provision.

All sensors supplied via a secondary care route will be subject to VAT increasing the cost of sensors from £910 per year to £1,092 per patient per year.

Currently sensors are only available to community pharmacies direct from Abbott and not via wholesalers.

Abbott have been approached by the East of England Procurement Hub, however there is currently little scope for contract or price negotiations due to a lack of alternative similar technology and alternative suppliers, and Abbott do not currently wish to enter into further negotiations on a contract price for secondary care trusts.

Abbott have been approached to discuss the possibility of supply direct to patients via a "Homecare" type arrangement, on request from diabetes specialist teams, however they have confirmed that they are currently not able to offer this service, as their business model has been built on the assumption that supply would be to individual pharmacies rather than to individual patients.<sup>16</sup>

## Document history

PAC approval date	12th March 2018
Version	2.1 - Version 2 revised to include details of recommendations 7 and 8 in recommendations summary box on page 2.
Consultation process	East of England clinicians PAC members
QA process	Katie Smith, Director Clinical Quality, PrescQIPP. 21st June 2018

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## Appendix 1: Assessment against Ethical and Commissioning Principles

### Treatment assessed

Flash Glucose Scanning system (FGS) FreeStyle Libre®

Currently there are significant limitations in the available clinical trial data and economic analysis, and routine commissioning for all patients is not recommended.

PAC supports a managed entry of FGS to allow real world data on use and outcomes to be collected in order to inform future policy.

FGS is recommended for the patient groups outlined in this document in line with the criteria and general funding recommendations set out in sections 2 and 3 of this document.

PAC recommends that funding is initially made available for these patient groups for a time limited period of one year. It is recommended that audit data is collected and that funding recommendations are reviewed to include new evidence on cost effectiveness, actual patient numbers and affordability.

Routine funding for any other indication is currently considered a low priority and is not recommended.

Funding for patients who are currently self-funding who do not fulfil the criteria is not recommended.

FGS should be initiated, managed and supplied by a consultant led specialist diabetes team. GP prescribing is not recommended.

The use of FreeStyle Libre® blood glucose testing strips using the inbuilt meter should be considered locally.

Due to the high cost of testing strips, the use of the inbuilt FreeStyle Libre® meter for testing ketones is not currently recommended.

### Clinical effectiveness

There is limited evidence of effectiveness. Studies to date have investigated the accuracy of FreeStyle Libre® as well as changes in clinical parameters associated with diabetes management (i.e. change in HbA1c and time in hypoglycaemia), as surrogate markers for improvement in disease control.

### Cost effectiveness

Cost effectiveness of the use of FGS has yet to be established. More data on the cost-effectiveness of Freestyle Libre® is required.

### Equity

No issues identified.

### Needs of the community

The needs of the community are considered to be low as well established and accurate alternatives exist which comply with the requirements of current NICE Guidance for type 1 diabetes.

FreeStyle Libre® does not currently meet the standards for monitoring of blood glucose in type 1 diabetics as specified by NICE Clinical Guideline NG18, which recommends that finger pricking of capillary blood should be used routinely. FreeStyle Libre® monitors blood glucose via interstitial fluid.

### Need for healthcare (incorporates patient choice and exceptional need)

This is a new technology which no longer involves multiple finger prick testing which are disliked by patients and can be problematic for carers of small children with diabetes and there is considerable support from patient groups and discussion groups advocating this new technology.

### Policy drivers

NICE guidance in relation to diabetes does not currently support the routine use of interstitial fluid to monitor blood glucose and recommends that finger pricking and capillary blood should be used routinely

until more evidence is available. Continuous Glucose Monitoring, which also uses interstitial fluid is recommended as an option in certain circumstances, but is not recommended for routine use. NICE have not made any specific recommendations in relation to the use of FGS. The Regional Medicines Optimisation Committee (RMOC) (North) reviewed the use of FGS and published recommendations on its use in patients with type 1 diabetes, aged four and above, in November 2017.<sup>1</sup>

### **Disinvestment**

More data is required to evaluate if use of FreeStyle Libre® is associated with fewer complications, reduced emergency admissions and less use of blood glucose test strips.