

Flash Glucose Scanning System (FGS) – funding application for FGS sensors for use in children and young people age 4 up to {i.e. less than} age 19 with type 1 diabetes mellitus – Bedfordshire version 2

NOTIFICATION ONLY

Flash Glucose Scanning System (FGS) – funding application for FGS sensors for use in children and young people age 4 up to {i.e. less than} age 19 with type 1 diabetes mellitus.

Patient NHS No.		Trust		GP name	
Patient hospital number		Consultant making request		GP code/ Practice code	
Patient initials and date of birth		Consultant contact details		GP post code	

Only fully completed forms will be accepted for consideration. These should be submitted via Blueteq.

If the patient does not meet routine commissioning criteria, please consider if there are any individual exceptional clinical circumstances. If so, a full individual funding request (IFR) form will need to be completed

(http://www.gpref.bedfordshire.nhs.uk/media/146459/bccg_individualfundingrequestformdrugsonlyjuly2016.docx) and submitted to Beds.IFRrequests@nhs.net (e-mail preferred method) or telephone 01494 555530. IFR team, South, Central and West CSU, Albert House, Queen Victoria Road, High Wycombe, HP11 1AG.

NB -‘Child’ or ‘Children’ terminology outlined below is defined as ‘children or young people age 4 up to (i.e. less than) age 19’. For adult patients (19 years and over), please complete the adult proforma.

1. Confirm that the child has Type 1 diabetes and is under the care of the Paediatric Diabetes Specialist Team	Yes
	<input type="checkbox"/>
2. Confirm which indication category applies to this patient (please tick box or type X and provide details requested)	

2.1 Confirm that the child has recently developed hypoglycaemia unawareness (< 3 months' onset) with <ul style="list-style-type: none"> a score >4 on the Clarke hypoglycaemia unawareness questionnaire OR score ≥4 on the Gold hypoglycaemia unawareness Likert scale AND evidence of incidentally detected hypoglycaemic episodes/significant hypoglycaemia lasting > 15 minutes confirmed by downloaded blood glucose data or diagnostic Continuous Glucose Monitoring (CGM) that occurred during the waking day which the patients were unaware AND frequent blood glucose testing (≥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 			<input type="checkbox"/> Yes
Duration of hypo unawareness		Evidence of hypoglycaemia confirmed by	BG meter data download <input type="checkbox"/> Diagnostic CGM <input type="checkbox"/>
Baseline HbA1c Target HbA1c		Average number of blood glucose tests performed per day over the last 3 months	
Confirm hypoglycaemia scale used		Clarke <input type="checkbox"/> or Gold score <input type="checkbox"/>	actual score
2.2 Confirm that the child has disabling hypoglycaemia without loss of hypo awareness with <ul style="list-style-type: none"> evidence of frequent hypoglycaemic episodes/significant hypoglycaemia lasting > 15 minutes confirmed by downloaded blood glucose data or diagnostic Continuous Glucose Monitoring (CGM). AND persistent anxiety not resolved by psychological therapy AND frequent blood glucose testing ≥8 tests per day including night time testing confirmed by data download from blood glucose testing meter 			<input type="checkbox"/> Yes
Evidence of frequent hypoglycaemia confirmed by	BG meter data download <input type="checkbox"/> Diagnostic CGM <input type="checkbox"/>	Average number of blood glucose tests performed when the child is asleep over the last 6 months	
Average number of blood glucose tests performed during the day over the last 6 months		Baseline HbA1c Target HbA1c	
I confirm the child has had anxiety management treatment from a clinical psychologist			<input type="checkbox"/> Yes
2.3 Confirm that, for this child, 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 with <ul style="list-style-type: none"> a diagnosed behavioural or mental health disorder under the care of Child and Adolescent Mental Health services (CAMHS) or community paediatric services AND blood glucose testing occurring less than 4 times per day confirmed by data download from blood glucose testing meter AND evidence of frequent hypoglycaemia and/or DKA or HbA1c ≥ 69 mmol/mol 			<input type="checkbox"/> Yes
I confirm that the child is under the care of CAMHS/Community Health services	CAMHS <input type="checkbox"/> Community Health services <input type="checkbox"/>	Please state diagnosis of behavioural or mental health disorder	

Baseline HbA1c Target HbA1c		Average number of blood glucose tests performed per day over the last 6 months	
Tick all that apply	Frequent hypoglycaemia <input type="checkbox"/>	Frequent DKA <input type="checkbox"/>	HbA1c ≥ 69 mmol/mol <input type="checkbox"/>
<p>2.4 Confirm that the child has co-morbidities (This applies to Anorexia nervosa (receiving concomitant psychological therapy), PEG feeding or People with cystic fibrosis related diabetes) or is on treatments which are associated with changes in nutrient intake or insulin sensitivity resulting in marked fluctuations of blood glucose levels with</p> <ul style="list-style-type: none"> evidence of frequent hypoglycaemic episodes/significant hypoglycaemia lasting > 15 minutes confirmed by downloaded blood glucose data or diagnostic Continuous Glucose Monitoring (CGM) AND/OR HbA1c ≥ 58 mmol/mol AND frequent blood glucose testing (≥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. <p>Please select the relevant co-morbidity, if applicable:</p> <ul style="list-style-type: none"> Anorexia nervosa (receiving concomitant psychological therapy) PEG feeding People with cystic fibrosis related diabetes 			<input type="checkbox"/> Yes <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
Baseline HbA1c Target HbA1c		Average number of blood glucose tests performed per day over the last 6 months	
Evidence of frequent hypoglycaemia confirmed BG meter data download <input type="checkbox"/> OR diagnostic CGM <input type="checkbox"/> AND/OR Poor glycaemic control (HbA1c ≥58 mmol/mol) <input type="checkbox"/>			
Average number of hypoglycaemic events per week AND/OR Evidence of significant hypos >15 minutes <input type="checkbox"/>			
<p>2.5 Confirm that the child has frequent (>2 per year) hospital admissions (inpatient episodes) with Diabetic Ketoacidosis (DKA) and HbA1c ≥ 69 mmol/mol despite intensive clinical intervention.</p>			<input type="checkbox"/> Yes
Number of hospital admissions with DKA blood pH <7.3 over the last year		Average number of blood glucose tests performed per day over the last 6 months	
Baseline HbA1c	Target HbA1c		
<p>2.6 Confirm that the child meets the current NICE criteria for Continuous Subcutaneous Insulin Infusion (CSII) and is on the recognised insulin pump pathway, where a successful trial of FGS may avoid the need for insulin pump therapy if clinically appropriate.</p>			<input type="checkbox"/> Yes

Average number of blood glucose tests performed per day over the last 6 months		Baseline HbA1c Target HbA1c	
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I confirm that the child is currently on an insulin pump pathway in line with NICE TA151 Yes

Please confirm the indication for pump therapy:

Is ≥ 12 years of age and attempts to achieve target HbA1c levels with multiple daily injections (MDIs) has resulted in disabling hypoglycaemia **OR**
 Is ≥ 12 years of age and HbA1c levels ≥ 69 mmol/mol on MDI therapy including, if appropriate, the use of long-acting insulin analogues, despite a high level of care. **OR**
 Is under 12 years of age and MDI therapy is considered to be impractical or inappropriate

2.7 Confirm that the child has extreme phobia towards finger prick blood test which adversely affect metabolic control with

- good concordance with insulin treatment **AND**
- significant needle phobia despite psychological/play therapy interventions **AND**
- BG testing is occurring <5 times a day resulting in poor metabolic control (HbA1c ≥ 69 mmol/mol).

Yes

Baseline HbA1c Target HbA1c		Average number of blood glucose tests performed per day over the last 6 months	
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2.8 Confirm that the child is unable to achieve the HbA1c target of <58 mmol/mol despite intensive clinical intervention to optimise therapy with

- *HbA1c of ≥ 58 mmol/mol despite intensive clinical intervention to optimise therapy **AND***
- *≥ 6 months intensive blood glucose monitoring (≥ 8 times per day) that is clinically appropriate and on the recommendation of the diabetes specialist team, confirmed by data download from blood glucose testing meter.*

Yes

Baseline HbA1c Target HbA1c		Average number of blood glucose tests performed per day over the last 6 months	
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3. Confirm that the patient has received approved training in the use of FGS, and that they/parents/carers have been assessed as able to use the device, interpret readings and take appropriate action (please tick box or type X) Yes

4. Confirm that a patient contract has been completed and that the patient is aware that if they do not use the technology appropriately it will not be continued, and that funding policy will be subject to review and that may be stopped in the future (please tick box or type X) Yes

<p>5. Confirm that the patient has been entered into the Association of British Clinical Diabetologists (ABCD) national audit. (please tick box or type X)</p>	<input type="checkbox"/> Yes
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<p>6. Continuation of funding</p> <p>Funding will initially be provided for a 6 month period.</p> <p>Funding will be provided for continuation of treatment where there is clear evidence of an initial and ongoing adequate response to treatment. This information should be submitted via a follow-up form on Blueteq which will require Prior Approval</p>
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<p>7. Please provide any other relevant information</p>
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<p>8. I confirm that the patient (or in the case of a minor or vulnerable adult where the parent/guardian or legal carer) has given consent for the patient identifiable data on this form to be shared with the CCG Medicines Management / Optimisation or Contracts Team. This data may then be used 1. In the interests of the care of the patient 2. For clinical audit purposes 3. To validate against subsequent invoices.</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No
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Form completed by		Date:	
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I confirm that the patient meets the criteria for the technology: Consultant/Specialist Diabetes Nurse/Dietician signature*		Date	
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Trust Chief Pharmacist (or nominated deputy) signature*		Date	
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*Electronic signatures are acceptable

Summary of PAC recommendations:

NB. All recommendations apply to patients with Type 1 diabetes mellitus (T1DM) only unless otherwise stated. See bulletin for full details.

Recommendation 1:

Children who have recently developed hypoglycaemia unawareness (< 3 months onset) defined as:

Score >4 on the Clarke hypoglycaemia unawareness questionnaire

OR

Score \geq 4 on the Gold hypoglycaemia unawareness Likert scale

AND

Evidence of incidentally detected hypo episodes from downloaded blood glucose data/ significant hypoglycaemia lasting >15 minutes confirmed by diagnostic Continuous Glucose Monitoring (CGM) or diagnostic FGS provided by the diabetes specialist team, that occurred during the waking day which the patients were unaware.

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.

Recommendation 2:

Children who have disabling hypoglycaemia without loss of hypo awareness.

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 ≥ 8 tests per day including night time testing confirmed by data download from blood glucose testing meter.

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.

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 4 times per day confirmed by data download from blood glucose testing meter.
and
Evidence of frequent hypoglycaemia and/or DKA or HbA1c ≥ 69 mmol/mol

Recommendation 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 the diabetes management difficult. This applies to children with the following co-morbidities:

- Anorexia nervosa (receiving concomitant psychological therapy)
- PEG feeding
- Children with Cystic-fibrosis related diabetes

Entry criteria:

- Children with co-morbidities or who are on treatments which are associated with changes in nutrient intake or insulin sensitivity
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 download from blood glucose testing meter.

Recommendation 5:

Frequent (>2 per year) hospital admissions (inpatient episodes) with Diabetic Ketoacidosis (DKA) with HbA1c \geq 69 mmol/mol despite intensive clinical intervention.

Entry criteria:

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

Recommendation 6:

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.

Entry criteria:

- Patients who fulfil criteria for CSII who are on a recognised pump pathway in line with criteria specified in NICE TA 151

Recommendation 7:

Children with extreme phobia towards finger prick blood test which adversely affect metabolic control defined as:

Children who have good concordance with insulin treatment but who have significant needle phobia despite psychological/play therapy interventions, and who are BG testing <5 times a day resulting in poor metabolic control (HbA1c \geq 69 mmol/mol).

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

Recommendation 8:

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).

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 download from blood glucose testing meter.