NHS
Cambridgeshire and Peterborough
Clinical Commissioning Group

Cambridgeshire and Peterborough CCG: Flash Glucose Scanning system (FGS) for Adults with Type 1 Diabetes

- FreeStyle Libre® is an innovative device Flash Glucose Scanning system (FGS) that has the potential to improve quality of life for patients and support self-management. However, currently there are significant limitations in available clinical trial data and economic analysis, and routine commissioning for all patients is therefore not recommended.
- Cambridgeshire and Peterborough Joint Prescribing Group (CPJPG) 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 below in line with the criteria and general funding recommendations set out in sections 2 and 3 of this document.
- 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.
- CPJPG recommends that funding is initially made available for these patient groups for a time limited period of 1 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.
- FGS should be initiated, managed and supplied by a consultant led Specialist Diabetes Team. Prescribing in Primary Care on an FP10 prescription is not recommended.
- Due to the high cost of testing strips, the use of the inbuilt FreeStyle Libre® meter for testing blood glucose or ketones is not currently recommended.

Summary for criteria recommended for funding

All recommendations apply to patients with Type 1 diabetes mellitus only unless otherwise specified (see section 3 for details).

1. Pregnancy:
   1.1. Pregnancy care for women with Type 1 diabetes
   1.2. Pregnancy care for women with preconception Type 2 diabetes on an intensive insulin regimen.
2. People with Type 1 diabetes who meet NICE TA151 criteria for Continuous Subcutaneous Insulin Infusion (CSII) and are in a recognised pathway prior to CSII.
3. People with Type 1 diabetes who have frequent hospital admissions (>2 per year) for Diabetic Ketoacidosis (DKA) with HbA1c >69 mmol/mol despite intensive clinical intervention.

1. 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 available clinical trial data and economic analysis which mean that routine use in all patients cannot be recommended.

CPJPG 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 FMS and published recommendations on its use in patients with type 1 diabetes, aged four and above, in November 2017. [1]

East of England Priorities Advisory Committee (PAC), on behalf of Cambridgeshire and Peterborough Joint Prescribing Group, have worked with East of England Diabetologists to further refine the criteria recommended by the RMOC, to identify initial patient cohorts who should be prioritised for funding. PAC will continue to work with clinicians to develop recommendations for funding for other patient groups as more information becomes available.

Audit data is to collected and these recommendations reviewed after 1 year to include new evidence on cost effectiveness, actual patient numbers and affordability.

2. General funding recommendations:

2.1. Funding for recommended patient cohorts will be provided for a maximum of 12 months (subject to a review at 6 months) unless otherwise specified in section 3, and then stopped. Continuation of funding for each criteria will be reviewed after 1 year.

2.2. FGS must be initiated, managed and supplied by a consultant led specialist Diabetes team. Prescribing on FP10 is not recommended in Primary Care.

2.3. A prior funding approval form, including treatment aims, continuation and stopping criteria, available on the CCG website and via Blueteq, must be completed and approved before FreeStyle Libre is provided to patients on the NHS in Cambridgeshire and Peterborough.

2.4. The patient should receive intensive support from an educator in carbohydrate counting and DAFNE approach before FreeStyle Libre® is considered.

2.5. Funding will be provided for a maximum of 26 sensors per patient per year

2.6. Funding is for a maximum of 6 months initially. Continued funding beyond this initial 6-month period is not automatic, and prior approval of funding beyond this time will only be granted where there is evidence of:

- Achievement of treatment goals as specified for each funding recommendation below, in comparison to baseline
  AND
- Statement of rationale from the diabetes specialist team that cessation of the FGS would reverse this benefit.

2.7. Funding for treatment should be discontinued where:

- The patient is unable to cope with sensor / manage the technology despite intensive support from the diabetic team
- The patient fails to wear the sensor >70% of the time
- Failure to perform minimum number of daily scans as agreed by the MDT (≥4 scans per day in addition to BG testing)
- Failure to achieve the treatment goals as specified for each criteria

2.8. Diabetes teams must ensure that:

- The motivation of the patient and their ability to manage the technology appropriately has been assessed before FreeStyle Libre funding is requested
- The patient has been given formal education and training masterclass on the use of FGS

2.9. Before commencing treatment, clinicians must agree a contract [see Appendix A] with the patient 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 twenty-six sensors will be provided over a twelve-month period

2.10. Patients must continue to use the most cost effective blood glucose and ketone testing meters and strips as per local policy and as directed by the specialist diabetes team. CCG use of the integral FreeStyle Libre® blood glucose and ketone testing function using Freestyle Optimum testing strips is not recommended

2.11. Teams must submit data on use of FGS to the Association of British Clinical Diabetologists (ABCD) national audit, [2] and commissioners for the purposes of audit of the use of FGS technology. http://www.diabetologists-abcd.org.uk/n3/FreeStyle_Libre_Audit.htm

3. Recommendations and Rationale

Recommendation 1:

1.1 Pregnancy care for women with type 1 diabetes
1.2 Pregnancy care for women with preconception type 2 diabetes on an intensive insulin regimen.

Rationale:
Pregnancies associated with diabetes have high maternal and fetal risks, especially if metabolic control is suboptimal. Flash monitoring provides detailed information on glucose trends allowing optimisation of insulin delivery to improve metabolic control to reduce hypoglycaemic events, and a reduction in the number of blood glucose tests required to achieve good control.
Note: This group does not include patients who develop Gestational Diabetes Mellitus.

Treatment aims:
- Achievement and maintenance of good glycaemic control
- Reduction in the number of blood glucose tests (average reduction from 10 tests per day to 4 tests per day)

Entry criteria:
- Pregnant women with type 1 diabetes, OR with preconception type 2 diabetes on an intensive insulin regimen

Review and stopping criteria:
Once initiated, funding should be continued 6 months' post-partum then stopped

Recommendation 2:

People with type 1 diabetes who meet NICE TA151 criteria for Continuous Subcutaneous Insulin Infusion CSII), and who are in a recognised pre pump pathway, where a successful trial of FreeStyle Libre® may avoid the need for insulin pump therapy if clinically appropriate.

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 TA 151.

Review and stopping criteria:

- Six-month trial.
- Improvement in metabolic control: Continue treatment.
- No improvement in metabolic control: Progress to pump therapy in line with Cambridgeshire and Peterborough CCG commissioning policy. NB: Funding for FGS will be reviewed and stopped on initiation of pump therapy.

Recommendation 3:

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

Rationale:

These patients are heterogeneous and very poorly controlled despite intensive clinical intervention. Flash glucose monitoring, if tolerated, provides data of blood glucose levels to patients and 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
- Poor metabolic control: HbA1c >69 mmol/mol despite intensive clinical intervention.

Review and stopping criteria:

- Review after 6 months and against treatment aims and compliance criteria

Discontinue if:

- No improvement in HbA1c defined as:
  Failure to achieve a ≥ 5 mmol/mol (0.5%) reduction in HbA1c
- An increase in DKA attendances from baseline at any time

  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 Diabetic Ketoacidosis (DKA) at 18 months after initiation.

4. Background

The FreeStyle Libre® is a flash glucose scanning (FGS) system which allows people, with diabetes mellitus (DM) (age four and older), to monitor glucose levels and trends without performing capillary (finger prick) testing. [4] 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 8 hours and displays an arrow showing the direction the glucose reading is heading. FGS is not the same as Continuous Glucose Monitoring (CGM) with several distinct differences. [5] 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 8 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. [4]

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 is yet to be fully evaluated. Current NICE guidelines advises adults with type 1 diabetes to routinely perform at least 4 capillary blood glucose tests per day including before each meal and before bed. Blood glucose tests are advised before each meal to calculate bolus insulin doses, and before bed. [6]

Additional BG tests will be required during illness and if hypoglycaemia is suspected, and there is a legal requirement to perform a blood glucose test prior to driving and every 2 hours whilst driving, to meet DVLA requirements. [7]

The IMPACT study found that BG testing in adults using FGS reduced to an average of 0.5 tests per day. [8] However, it is assumed that a minimum number of 4 BG tests per day will continue to be advocated in FGS users in line with NICE guidelines.

5. 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.

- 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 Continuous Glucose Monitoring
- Limited or no data of use in unstable patients, pregnancy, young people and children

6. 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.

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 starter packs containing a reader and one sensor to patients free of charge. No information is currently available on how long this arrangement will be honoured by Abbott.

The cost calculation for a flash glucose monitoring system for UK adults with type 1 diabetes mellitus receiving intensive insulin treatment.

ABCD and Hellmund et al cost impact calculations both use a cost of £0.29 per test strip and lancet cost of £0.04, total cost £0.33 per test, based on the average weighted cost of top 10 suppliers. [9,10], However these costs do not reflect the current cost of blood glucose testing in the East of England. Cambridgeshire and Peterborough CCG recommends strips costing less than £10 for 50 strips (£0.20 per test strip).

The FreeStyle Libre® device comes with an inbuilt FreeStyle Optium blood glucose and ketone meter which is capable of calculating bolus insulin doses for patients who are carbohydrate counting. The cost of FreeStyle Optimum blood glucose testing strips for use in the Libre reader is currently £16.00 for 50 strips, and the FreeStyle Optium ß-Ketone Test Strips currently cost £21.53, and are significantly more expensive than other more cost effective products currently in use in the East of England. [12] Due to the high cost of testing strips, the use of the inbuilt FreeStyle Libre® meter for testing blood glucose or ketones is not currently recommended.

The effect of using FGS on the frequency of BG testing is yet to be fully evaluated. The IMPACT study found that BG testing in adults using FGS reduced to an average of 0.5 tests per day. [8] However, it is assumed that a minimum number of 4 BG tests per day will continue to be performed by patients using FGS in line with NICE guidelines, and additional tests to meet DVLA requirements.

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

<u>Cost impact of FreeStyle Libre®</u>

It is not possible to accurately estimate the number of patients that will be eligible for each of the proposed criteria.

Based on feedback from clinicians, we have assumed people 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 4 tests per day as per current NICE recommendations. Impact of reducing BG testing to 0.5 tests per day is shown for comparative purposes.

Cost per patient per year

	Most cost effective strips
10 BG tests per day	£847
4 BG tests per day	£339
0.5 BG tests per day using	£42
Including VAT	
FreeStyle Libre® (sensors only)	£1,092
FreeStyle Libre® (sensors only) and BG testing 4 times per day	£1,431
Additional cost of using FreeStyle Libre® and BG testing 4 times per day vs BG testing 10 times per day	£584
FreeStyle Libre® (sensors only) and BG testing 0.5 times per day	£1,134
Additional cost of using FreeStyle Libre® and BG testing 0.5 per day vs BG testing 10 times per day	£287

Notes on cost calculations:

- BG testing (strips and lancets) costs based on average cost from ePACT data:
- Using most cost effective BG testing strip and lancet: £0.2327 per test
- VAT would not be added if supplied on FP10 prescription however an unknown handling fee may be levied by community pharmacies increasing the overall cost
- Supplies made via secondary care would be subject to 20% VAT

References:

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2. Association of British Clinical Diabetologists nationwide FreeStyle Libre® audit https://abcd.care/launch-abcd-nationwide-freestyle-libre-audit
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4. Company Website FreeStyle Libre® Commercial Website. Abbott Diabetes Care https://www.freestylelibre.co.uk/libre/products.html
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7. DVLA Guidance: Diabetes mellitus: assessing fitness to drive Last updated March 2016. Accessed Feb 2017 via https://www.gov.uk/guidance/diabetes-mellitus-assessing-fitness-to-drive
8. Bolinder J, et al. (2016) Novel glucose sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. The Lancet. Nov 11;388 (10057):2254-63. https://www.ncbi.nlm.nih.gov/pubmed/27634581
9. Association of British Clinical Diabetologists Information to help a formulary case https://abcd.care/getting-freestyle-libre-your-formulary

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11. NHSBSA ePACT2 https://www.nhsbsa.nhs.uk/information-services-portal-isp
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Approved by Cambridgeshire and Peterborough Joint Prescribing Group, July 2018
Version 1.0
Adapted from the East of England Priorities Advisory Committee document 'Flash Glucose Scanning system (FGS) for adults with Type 1 diabetes

Appendix A

Flash Glucose Scanning system (Freestyle Libre®) Agreement (Adults)

This form should be completed jointly by patient and NHS diabetes specialist

Patients name		Unit number	
Consultant		Diabetes specialist nurse	

Whilst using FreeStyle Libre®, the *insert team name* Diabetes Team expect you to take responsibility for using the technology appropriately to improve your diabetes care.

Patient responsibilities

I agree to:

- Discuss education events and tools with my specialist team, to support me in managing my diabetes.
- Attend locally approved training on use of Freestyle Libre® and how to interpret and act on readings.
- Commit to using Freestyle Libre® at least 70% of the time and perform at least 4 scans per day, in addition to blood glucose testing as advised by my specialist team
- Follow advice from the diabetes team on how to interpret Freestyle Libre® readings and take appropriate action

I understand that:

Funding will be stopped and sensors will no longer be provided if:

- I do not wear the sensors for 70% of the time and/or scan less than 4 times per day.
- I do not take appropriate action in response to readings as advised by the diabetes team.
- Freestyle Libre® will be reviewed after 6 months and will be discontinued it its use has not resulted in: (delete as appropriate)
    - Improved hypo awareness
    - A reduction in the number of hypoglycaemic events
    - A reduction in frequency of blood glucose testing
    - A reduction in Diabetic Ketoacidosis
    - An improvement in HbA1c ≥ 5 mmol/mol (0.5%)

- A maximum number of 26 sensors will be provided over a 12 month period.
- Funding for sensors is for a time limited period (initially for 6 month). Freestyle Libre® is a developing technology. As such, the current funding agreement will be reviewed regularly
- I understand that funding of this treatment is not indefinite and may be stopped in the future in line with local policies.

Patient Agreement

Signed.....(Patient) Date.....

Signed.....(DSN/Consultant) Date.....