NHS Bedfordshire Clinical Commissioning Group

NHS Luton Clinical Commissioning Group

BEDFORDSHIRE AND LUTON JOINT PRESCRIBING COMMITTEE (JPC)

June 2018

(Updated October 2018 to include final published PAC Bulletin)

Review: December 2019

Bulletin 266: 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 adults (age 19 and older) with type 1 diabetes.
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. **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 1st 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.

The East of England
Priorities Advisory Committee
A function of PrescQIPP

GUIDANCE STATEMENT

Flash Glucose Scanning system (FGS) for adults (age 19 and older) with type 1 diabetes

PAC interim recommendations

- Freestyle Libre® is an innovative 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 the available clinical trial data and economic analysis, and routine commissioning for all patients is therefore 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.
- 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.
- PAC recommends that funding is initially made available for eligible 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.
- FGS should be initiated, managed and supplied by a consultant led specialist Diabetes team. GP prescribing 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 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. Pregnancy
   - 1.1 Pre Pregnancy Care (PPC) for women with type 1 diabetes in a recognised PPC pathway.
   - 1.2 Pre Pregnancy Care (PPC) for women with type 2 diabetes on an intensive insulin regime, in a recognised PPC pathway.
   - 1.3 Pregnancy care for women with type 1 diabetes.
   - 1.4 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 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 people with cystic-fibrosis related diabetes.
4. Frequent hospital admissions (>2 per year) with diabetic ketoacidosis (DKA) with HbA1c ≥69 mmol/mol despite intensive clinical intervention.

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.[1] PAC 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 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 section on recommended criteria for commissioning on page 3 for details. 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 the diabetologist that cessation of FGS would reverse this benefit.
- Funding for treatment should be discontinued where:
  - Patients are unable to cope with the sensor/managing technology despite intensive support by the diabetic team.
  - Failure 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 treatment goals specified for each criteria.
- Diabetes teams must ensure that:
  - The patient has received intensive support from nurse educators in carbohydrate counting and DAFNE approach.
  - The motivation of the patient and their ability to manage the technology appropriately has been assessed.
  - The patient has been given formal education and training on the use of FGS.
- Before commencing treatment, clinicians must agree a contract 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 26 sensors will be provided over a 12 month period.
- Patients must continue to use the most cost effective blood glucose and ketone testing meters and strips as per local policy. Use of the integral FreeStyle Libre® blood glucose and ketone testing function using Freestyle Optimum testing strips is not recommended.
- 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.

Recommended criteria for commissioning

Cost impact calculations in this section are based on patient number estimates for each cohort provided by East of England Diabetologists, and on both the cost of the most cost effective BG testing strips and the average cost of BG testing strips in use in the region. See cost impact section, page 8, for further details.

Recommendation 1	• Pre Pregnancy Care (PPC) for women with type 1 diabetes in a recognised PPC pathway.
	• Pre Pregnancy Care (PPC) for women with type 2 diabetes on an intensive insulin regime, in a recognised PPC pathway.
	• Pregnancy care for women with type 1 diabetes.
	• 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.

There is more evidence on the benefits of Continuous Glucose Monitoring (CGM) in pregnancy and this is the preferred option, where available, for improved pregnancy outcomes as the main end point. However, the high cost of CGM means that it is not routinely available to pregnant patients.

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.

Entry criteria

- Women with type 1 diabetes or preconception type 2 diabetes on an intensive insulin regime who are in a recognised PPC pathway or
- Pregnant women with type 1 diabetes, OR with preconception type 2 diabetes on an intensive insulin regimen.

Review and stopping criteria

- For patients who are pregnant/become pregnant: once initiated, funding should be continued six months post-partum then stopped.
- Funding should stop if the patient is no longer in a recognised PPC pathway.

Estimated patient numbers and cost impact

Estimated % diabetes population	1.8% T1DM and 0.07% T2DM		
No. patients per 100,000 total population (all ages)	9		
Additional cost per 100,000 total population, per year using FGS and continuing to BG test four times per day		If currently using most cost effective strips	If currently using average cost strips
	Excluding VAT	£3,618	£2,682
	Including VAT	£5,256	£4,320

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.[3]

Rationale

Flash monitoring provides detailed information on glucose trends allowing optimisation of insulin delivery to reduce hypoglycaemic 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. NB: Funding for FGS will be reviewed and stopped on initiation of pump therapy.

Estimated patient numbers and cost impact

Estimated % diabetes population	1.2% – 3.8% of T1DM population		
No. patients per 100,000 total population (all ages) using upper end of estimate 3.8%	16		
Additional cost per 100,000 total population per year using FGS and continuing to BG test four times per day (upper end of estimate 3.8%)		If currently using most cost effective strips	If currently using average cost strips
	Excluding VAT	£6,432	£4,768
	Including VAT	£9,344	£7,680

Recommendation 3	People 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 people with the following co-morbidities:
	• Anorexia nervosa (receiving concomitant psychological therapy)
	• PEG feeding
	• People with cystic fibrosis related diabetes

Rationale

This group of patients are difficult to control using conventional blood glucose testing and will test blood glucose frequently (≥ 8 tests per day). Flash monitoring provides detailed information on glucose trends allowing optimisation of insulin delivery to reduce hypoglycaemic events and improve 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

- Patients 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 ≥ 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 downloaded from blood glucose testing meter.

Review and stopping criteria

Discontinue if:

- No reduction in the number of hypo glycaemic events and/or no improvement in HbA1C defined as:
  - » Failure to achieve a ≥ 5 mmol/mol (0.5%) reduction in HbA1c.

OR

  - » No longer diagnosed with a qualifying co-morbidity.

Estimated patient numbers and cost impact

Estimated % diabetes population	0.5% of T1DM population		
No. patients per 100,000 total population (all ages)	2		
Additional cost per 100,000 total population, per year using FGS and continuing to BG test four times per day		If currently using most cost effective strips	If currently using average cost strips
	Excluding VAT	£804	£596
	Including VAT	£1,168	£960

Recommendation 4	Frequent (>2 per year) hospital admissions (inpatient episodes) with diabetic ketoacidosis (DKA) with HbA1c ≥69 mmol/mol despite intensive clinical intervention.

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 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

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 six 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 % diabetes population	0.5% of T1DM population		
No. patients per 100,000 total population (all ages)	2		
Additional cost per 100,000 total population, per year using FGS with no change to baseline BG testing frequency		*If currently using most cost effective strips	*If currently using average cost strips
	Excluding VAT	£1,820	£1,820
	Including VAT	£2,184	£2,184

*Note that cost impact for this cohort of patients has been estimated to be the same regardless of the cost of BG strip being used, as there is no anticipated change in blood glucose testing frequency.

Background

The 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.[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 eight 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 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.[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 on the frequency of BG testing is yet to be fully evaluated. Current NICE guidelines advise adults with type 1 diabetes to routinely perform at least four 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 two 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 four BG tests per day will continue to be advocated in FGS users in line with NICE guidelines.

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®:[1]

- 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.

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 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.

Cost impact calculations by the Association of British Clinical Diabetologists and Hellmund et al 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.

The average cost of blood glucose testing across the East of England over the three month period from August to October 2017 was £12.37 for 50 blood glucose testing strips (£0.25 per test strip), and £3.29 for 100 lancets (£0.03 per lancet).[11] Many CCGs have initiatives in place to ensure patients are using the most cost effective blood glucose testing strips and are moving to use strips costing less than £10 for 50 strips (£0.20 per test strip). A summary of current costs for blood glucose testing can be seen in table 1.

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 Optium 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. These 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 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 four 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.

The cost of FreeStyle Libre® vs. blood glucose testing[11,12]

Table 1:

Cost of blood glucose testing	Most cost effective strips	Average EoE cost per strip
Cost per pack	£9.99 for 50	£12.37
Cost per strip	£0.20	£0.25
Cost per lancet	£0.03	£0.03
Total cost per test	£0.23	£0.28

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 East of England diabetologists.

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 ten 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 ten tests per day to four 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	Average EoE cost per strip
10 BG tests per day		£847	£1,020
4 BG tests per day		£339	£408
0.5 BG tests per day using		£42	£51
Excluding VAT	FreeStyle Libre® (sensors only)	£910	
	FreeStyle Libre® (sensors only) and BG testing 4 times per day	£1,249	£1,318
	Additional cost of using FreeStyle Libre® and BG testing 4 times per day vs. BG testing 10 times per day	£402	£298
	FreeStyle Libre® (sensors only) and BG testing 0.5 times per day	£952	£961
	Additional cost of using FreeStyle Libre® and BG testing 0.5 per day vs. BG testing 10 times per day	£105	-£59
Including VAT	FreeStyle Libre® (sensors only)	£1,092	
	FreeStyle Libre® (sensors only) and BG testing 4 times per day	£1,431	£1,500
	Additional cost of using FreeStyle Libre® and BG testing 4 times per day vs. BG testing 10 times per day	£584	£480
	FreeStyle Libre® (sensors only) and BG testing 0.5 times per day	£1,134	£1,143
	Additional cost of using FreeStyle Libre® and BG testing 0.5 per day vs. BG testing 10 times per day	£287	£123

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

Average EoE cost per BG testing strip and lancet: £0.2803 per test

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 also 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.[13]

Document history

PAC approval date	12th March 2018
Version	2
Consultation process	East of England clinicians/PAC members
QA process	Katie Smith, Director Clinical Quality, PrescQIPP, 21st June 2018

References

1. Regional Medicines Optimisation Committee. FreeStyle Libre Position Statement. Published 1st November 2017, updated 8th January 2018. https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/
2. Association of British Clinical Diabetologists Nationwide FreeStyle Libre Audit. https://abcd.care/launch-abcd-nationwide-freestyle-libre-audit
3. NICE Technology Appraisal guidance 151. Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Published 23 July 2008. https://www.nice.org.uk/guidance/ta151
4. FreeStyle Libre® Commercial Website. Abbott Diabetes Care. Accessed December 2017. https://www.freestylelibre.co.uk/libre/products.html
5. Heinemann L, Freckmann G. CGM versus FGM; or Continuous Glucose Monitoring Is Not Flash Glucose Monitoring. Diabetes Sci Technol 2015; 9(5): 947–950. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4667350/
6. NICE guideline [NG17]. type 1 diabetes in adults: diagnosis and management. Published August 2015, last updated July 2016. https://www.nice.org.uk/guidance/ng17
7. DVLA Guidance. Diabetes mellitus: assessing fitness to drive. Last updated March 2016. Accessed Feb 2018 via https://www.gov.uk/guidance/diabetes-mellitus-assessing-fitness-to-drive
8. Bolinder J, et al. Novel glucose sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. The Lancet 2916;388:2254-63. 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

10. Hellmund R, Weitgasser R, Blissett D. Cost calculation for a flash glucose monitoring system for UK adults with type 1 diabetes mellitus receiving intensive insulin treatment. Diabetes Res Clin Pract 2018;138:193-20. https://www.ncbi.nlm.nih.gov/pubmed/29410149
11. NHSBSA ePACT2 Accessed December 2018 https://www.nhsbsa.nhs.uk/information-services-portal-isp
12. NHS Business Services Authority. Drug Tariff. February 2018. Accessed 20/02/2018 via http:// www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx
13. Personal communication, Abbott Ltd. 28th March 2018

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 therefore 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 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.

PAC 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. GP prescribing 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.

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 NG17, which recommends that finger pricking of capillary blood should be used routinely. FreeStyle Libre® monitors blood glucose via interstitial fluid.

NICE does not routinely recommend monitoring of glucose in patients with type 2 diabetes managed by

diet and oral medications alone.

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

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, which may offset the additional cost.