The East of England
# Priorities Advisory Committee
A function of PrescQIPP

GUIDANCE STATEMENT

## FreeStyle Libre® Glucose Monitoring System

### PAC interim recommendations

1. The routine use of FreeStyle Libre® for all patients with type 1 and type 2 diabetes is not recommended.
2. FreeStyle Libre® has not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal (TA), produced and published by the National Institute for Health and Care Excellence (NICE), is not recommended for routine funding in primary care.
3. This recommendation will be reviewed in the light of new evidence to support the cost effective use of FreeStyle Libre®.

## Key points

- FreeStyle Libre® is a flash glucose monitoring (FGM) system which monitors glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing.
- It consists of a handheld reader and a sensor, which is sited on the back of the arm. When the reader unit is passed over the sensor, the reader shows a reading based on interstitial fluid glucose levels. The sensor lasts for up to 14 days and then needs to be replaced.
- The reader can show a trace for the last eight hours and displays an arrow showing the direction the glucose reading is heading. FGM is not the same as continuous glucose monitoring (CGM).
- 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.
- 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 (i.e. acute illness such as Influenza, diarrhoea and vomiting), if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings.
- FreeStyle Libre® users will still need to perform finger-prick blood tests prior to and during driving to meet current DVLA requirements, as FreeStyle Libre®, like CGM, measures interstitial fluid levels and not capillary blood glucose levels.
- There is currently limited evidence to support the use of FreeStyle Libre®.
- In an open label, randomised controlled trial involving 224 patients with type 2 diabetes, there was no difference in the change in HbA1c between intervention (FreeStyle Libre®) and control (self-monitoring of blood glucose) -3.1 ± 0.75 mmol/mol, [-0.29 ± 0.07% (mean ± SE)] and -3.4 ± 1.04 mmol/mol (-0.31 ± 0.09%) respectively; p = 0.8222. In participants younger than 65 years, the drop in HbA1c was more pronounced in the intervention group compared with controls [-5.7 ± 0.96 mmol/mol, (adjusted mean ± SE) (-0.53 ± 0.09%) and -2.2 ± 1.31 mmol/mol (-0.20 ± 0.12%), respectively; p = 0.0301]. A significant association between treatment group and age was observed for change in HbA1c (p = 0.0017).

- In a second study involving 241 individuals with type 1 diabetes, mean time in hypoglycaemia changed from 3·38 h/day at baseline to 2·03 h/day at 6 months (baseline adjusted mean change −1·39) in the intervention group, and from 3·44 h/day to 3·27 h/day in the control group (−0·14); with the between-group difference of −1·24 (SE 0·239; p<0·0001). Several secondary outcomes were also reported; HbA1c concentrations in the intervention group were essentially unchanged compared with the control group.
- There is limited data to confirm that use of FreeStyle Libre® will result in better controlled diabetes, an improvement in patient oriented outcomes such as a reduction in complications due to poorly controlled diabetes, hospitalisation rates or ambulance/GP call out rates, improvement in overall long-term diabetes control or quality of life. More data is also required to confirm effectiveness of this technology in less well controlled diabetes.
- There is limited data to support the routine use in children and young people. A small uncontrolled study has evaluated the accuracy of FreeStyle Libre® readings compared to capillary blood glucose testing strips and found the readings to be broadly comparable. However, there is insufficient data to confirm that use of FreeStyle Libre® in under 18s is associated with better disease control and associated outcomes.
- There is limited available data comparing to standalone CGM.
- Current NICE clinical guidance in relation to type 1 diabetes, recommends that finger pricking and capillary blood should be used routinely for the monitoring of glucose. FreeStyle Libre® uses interstitial fluid to monitor blood glucose and consequently does not meet the standard expected by NICE. CGM, which also uses interstitial fluid, is recommended as an option, but only in certain circumstances and should not be used routinely.
- NICE clinical guidelines recommend that monitors should have an audible alarm to alert users to potential problems with blood glucose levels. Freestyle Libre® does not have an audible alarm.
- A NICE Medtech Innovation Briefing (MIB110) on FreeStyle Libre® for glucose monitoring highlights the key uncertainty around the evidence for FreeStyle Libre® in that the randomised controlled trial of people with type 1 diabetes included only adults whose diabetes was already well controlled.
- The briefing also states that currently the resource impact is uncertain, and will depend upon the extent to which improved glucose control through the adoption of FreeStyle Libre® translates into fewer complications, reduced emergency admissions and less use of glucose test strips.
- The products are available to buy online and some patients have chosen to self-fund. The current cost of the reader and two sensors (i.e. first 28 days) is £133.29 (excluding VAT). A single sensor (14 days) is £48.29 (i.e. 28 days cost for sensor replacement is £96.58).
- The year one cost of the FreeStyle Libre® per person is approximately £1,255 (excluding VAT), based on the prices listed on the manufacturer's website. According to NICE clinical guideline NG17, the annual cost of self-monitoring blood glucose (SMBG) with single-use lancets and blood glucose strips once per day is £106; SMBG four times daily is £423 and ten times daily is £1,059.
- FreeStyle Libre® meter and sensors will be included in the Drug Tariff and available to prescribe on NHS prescription from 1st November 2017.
- At the time of writing, it is not known if the manufacturer will offer a reduced price to the NHS.
- Standalone CGM currently costs around £5,000 per year and is recommended as an option in certain clinical scenarios in patients with type 1 diabetes.
- No studies on the cost-effectiveness of FreeStyle Libre® in the UK were identified.
- Current prevalence data suggests that 432 patients per 100,000 population have type 1 diabetes. If all eligible patients were switched to FreeStyle Libre® from current standard practice, the

additional investment required is likely to be between £126k and £376k per 100,000 population (based on current retail price), excluding first year set up costs.

- Until more evidence/data becomes available in relation to improvements in real patient orientated outcomes such as complication rates and hospital admissions, or a positive recommendation from a full NICE technology appraisal (TA), FreeStyle Libre® is not recommended for routine funding in either primary or secondary care.

## Background

The FreeStyle Libre® is a flash glucose monitoring (FGM) system which allows people with diabetes mellitus (DM) (age 4 and older), to monitor blood glucose levels and trends without performing capillary (finger prick) testing.[1] It was awarded CE Mark certification in August 2014. A sensor, approximately the size of a £2 coin with a microfilament 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.[1] FGM is not the same as continuous glucose monitoring (CGM) with several distinct differences.[2] FreeStyle Libre® 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.[1] The company information claims 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[1] and apps are now available for Android phones which allow the phone to act as the reader and also allows remote monitoring of the sensor by a parent or other carer.

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 (i.e. acute illness such as Influenza, diarrhoea and vomiting), or if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings. In addition, users will still need to perform finger-prick blood tests prior to and during driving to meet current DVLA requirements, as FreeStyle Libre®, like CGM, measures interstitial fluid levels and not capillary blood glucose levels.[3]

## Clinical evidence

There is currently limited evidence to support the use of FreeStyle Libre®. Two studies have been published to date which have assessed patient specific clinical parameters such as change in HbA1c or time in hypoglycaemia.[4,5] Both trials were sponsored by Abbott Diabetes Care, the manufacturer of FreeStyle Libre®.

In an open-label randomised controlled trial conducted by Haak et al,[4] 224 patients (mean age 59 years) with type 2 diabetes treated with insulin for at least six months, were randomised to either the sensor based FGM device (n=149; intervention group) or self-monitoring of blood glucose (SMBG) with blood glucose testing strips; (n=75; control group). The primary outcome was the difference in HbA1c between the intervention and control groups at six months.[4]

At six months, there was no difference in the change in HbA1c between intervention and controls -3.1 ± 0.75 mmol/mol, [-0.29 ± 0.07% (mean ± SE)] and -3.4 ± 1.04 mmol/mol (-0.31 ± 0.09%) respectively; p = 0.8222. In participants younger than 65 years, a prespecified subgroup, the drop in HbA1c was more pronounced in the intervention group compared with controls [-5.7 ± 0.96 mmol/mol, (adjusted mean ± SE) (-0.53 ± 0.09%) and -2.2 ± 1.31 mmol/mol (-0.20 ± 0.12%), respectively; p = 0.0301].[4] The number of subgroup study participants was not made available in the published details of the study.

Several secondary outcomes were also reported. Time in hypoglycaemia (<3.9 mmol/L or 70 mg/dL) reduced by 0.47 ± 0.13 h/day [mean ± SE (p = 0.0006)], and (<3.1 mmol/L (55 mg/dL) reduced by 0.22

± 0.07 h/day (p = 0.0014) for intervention participants compared with controls; reductions of 43% and 53%, respectively. SMBG frequency, similar at baseline, decreased in intervention participants from 3.8 ± 1.4 tests/day (mean ± SD) to 0.3 ± 0.7, remaining unchanged in controls. Treatment satisfaction measured using the Diabetes Treatment Satisfaction Questionnaire (DTSQ) score was higher in intervention participants compared with controls [13.1 ± 0.50 (mean ± SE) and 9.0 ± 0.72, respectively; p<0.0001]. No serious adverse events or severe hypoglycaemic events were reported related to sensor data use. Forty-two serious events [16 (10.7%) intervention participants, 12 (16.0%) controls] were not device-related. Six intervention participants reported nine adverse events for sensor-wear reactions (two severe, six moderate, one mild).[4]

In the second study, a multi-centre, non-masked, randomised controlled trial by Bolinder et al,[5] 241 adult patients (aged 33-57) with well controlled type 1 diabetes (HbA1c≤58mmol/mol) were either randomly assigned to the intervention group (FreeStyle Libre®; n=120) or to the control group (SBMG; n=121). The primary outcome was change in time in hypoglycaemia (<3.9 mmol/L) between baseline and six months. Mean time in hypoglycaemia changed from 3.38 h/day at baseline to 2.03 h/day at six months (baseline adjusted mean change −1.39) in the intervention group, and from 3.44 h/day to 3.27 h/day in the control group (−0.14); with the between-group difference of −1.24 (SE 0.239; p<0·0001). Several secondary outcomes were also reported. HbA1c concentrations in the intervention group were essentially unchanged compared with the control group. Time in hyperglycaemia was also reduced in the intervention group.[5]

Overall patient satisfaction improved in the intervention group, however there was no difference in diabetes distress, hypoglycaemia fear behaviour or worry scores. No device-related hypoglycaemia or safety issues were reported. 13 adverse events were reported by ten participants related to the sensor—four of allergy events (one severe, three moderate); one itching (mild); one rash (mild); four insertion-site symptom (severe); two erythema (one severe, one mild); and one oedema (moderate). There were ten serious adverse events (five in each group) reported by nine participants; none were considered by the study investigators to be related to the device.[5]

Of the 241 subjects, 19 were aged 18-24.[5] At six months, there was no significant association of age of treatment group with the primary end point of time in hypoglycaemia <3.9 mmol/L (70 mg/dL). The overall reduction in time in hypoglycaemia was significantly reduced by 38.0% (mean difference -1.24+/-0.239 hours per day [mean+/- SE]; p<0.0001). Further analysis of sensor glucose data at six months demonstrates that young adults had significantly increased time in range (TIR) (sensor glucose 3.9-10.0mmol/L [70-180mg/dL]) by 2.9+/-0.89 hours per day (mean+/-SE); p=0.0055. Adults aged 25 or over also significantly increased TIR by 0.9 +/-0.31 hours per day (mean+/-SE); p=0.0073. Time in hyperglycaemia was also significantly improved in young adults, i.e. young adults had sugnificantly hours/day >10.0 mmol/L (180 mg/dL) reduced by 2.40+/-0.834 hours per day (mean+/-SE); p=0.0113. Similarly, hours per day >13.3 mmol/L (240 mg/dL) reduced by 2.34+/-0.486 hours per day (mean+/-SE); p=0.0002.[5]

There is limited evidence to support the routine use of FreeStyle Libre®, in children and young people. Studies to date are limited to establishing the accuracy of blood glucose readings in children and young people.

A small uncontrolled study, involving 87 paediatric subjects (aged 4-17 years) with type 1 diabetes, has been conducted, to confirm the comparable accuracy of FreeStyle Libre® and SMBG with blood glucose testing strips.[7] Subjects wore a sensor (on the back of their upper arm) for up to 14 days and throughout this home-use period were asked to perform four capillary blood glucose (BG) tests daily using the BG strip-port on the reader (FreeStyle Optium®), immediately followed by an interstitial glucose measurement with the FreeStyle Libre® reader. Sensor data was masked to subjects until the final clinic visit where the device was unmasked for subjects to experience all functionality. A total of 5,493 interstitial glucose results with paired BG results demonstrated; 83.8% of interstitial glucose results in Zone A (clinically accurate), > 99% of results in Zones A&B (clinically acceptable) and 81.2% of results within +/- 1.1mmol/L [20mg/dL] /20% of BG values. Clinically accurate results were obtained

across all three age groups: 4-7, 8-12, 13-17 years. Mean absolute relative difference (MARD) was 13.9%. Regression analysis demonstrated high correlation to BG (r = 0.95, slope = 1.03, intercept = -0.23mmol/L [- 4.12mg/ dL]). User satisfaction questionnaires indicated high levels of acceptance for sensor wear and ease of use of the device.[7]

In a similar study, 24 children with type 1 diabetes aged 4.7-15.9 years compared their usual blood glucose (BG) meter [Accu-Chek Mobile (ACM), Contour Next Link (CNL) or OneTouch Verio IQ (OTV)], followed by a FreeStyle Libre®.[8] After 14 days subjects were asked to fill in a questionnaire on the usability of the FreeStyle Libre®. 938 interstitial glucose readings had higher paired blood glucose results (mean reading 170 +/- 94 mg/dl for interstitial blood glucose result vs 156 +/- 82 mg/ dl for BG; p < 0.001). 74.20% of the data pairs were in the no risk zone; 24.20% in the slight risk zone and 1.60% in the moderate risk zone; Correlation coefficient (r= 0.957; p < 0.001), and there was an overall tendency for interstitial readings to overestimate blood glucose for very high or low blood glucose values. Overall MARD was 16.5% and varied with BG meter: CNL 16.3%, ACM 21.4%, OTV 10.7% (p<0.001). 14 patients (58%) reported sensor problems, mainly early detachment of the sensor. Nonetheless, the usability questionnaire indicated high levels of patient satisfaction.[8]

Data published, by Helm et al (n=37; aged between 7-18) as a conference abstract, suggests possible improved perception and frequency of glucose monitoring in children and young people, which may lead to improved HbA1c and diabetes control. However, further data from larger and better controlled studies are required to confirm effectiveness in under 18s.[9]

There is limited data comparing FGM to CGM, including the DEXCOM monitor (DG4P). It is unknown whether FreeStyle Libre® is a realistic alternative to current standalone CGM. FreeStyle Libre® has no audible alarm and relies on screen trend arrows to convey potential hypoglycaemia or hyperglycaemic events to the patient or carer and consequently it does not comply with current NICE recommendations which confirm that monitors should have an audible alarm to alert users to potential problems with blood glucose levels.[10-13]

Data from a very small group of outpatients with type 1 diabetes (n=8), compared the FreeStyle Libre® (FSL) and DG4P for up to 14 days.[14] FSL and DG4P recordings were aligned to obtain paired glucose measures. Comparison with SMBG was also performed. Patients varied in terms of age, diabetes duration, and HbA1c (from 5.9 to 9.6%). The pooled analysis of 10,020 paired values reported a MARD = 18.1 +/- 14.8%; r2 = 0.76; but with wide variability among patients. The MARD was significantly higher during days 11-14, than in days 1-10, and during hypoglycaemia (19%) than in normoglycaemia (16%) or hyperglycaemia (13%). Average glucose profiles and MARD versus SMBG were similar between the two sensors. Time spent in normo-, hyper-, or hypoglycaemia, and indexes of glucose variability were similarly estimated by the two sensors. The study authors concluded that there was good agreement between the FSL and DG4P readings in outpatients with type-1 diabetes.[14] More data is required to establish place in therapy of FreeStyle Libre® in relation to standalone CGM.

There is limited data to confirm that use of FreeStyle Libre® will result in better controlled diabetes, an improvement in patient oriented outcomes, such as a reduction in complications due to poorly controlled diabetes and hospitalisation rates, ambulance/GP call out rates, overall long-term diabetes control or quality of life. More data is also required to confirm effectiveness of this technology in less well controlled diabetes.

NICE Guidance NG17 type 1 Diabetes in adults; diagnosis and management, specifically states that monitoring blood glucose from sites other than fingertips cannot be routinely recommended instead of conventional blood glucose monitoring at the present time (i.e. monitoring via interstitial fluid should not be used routinely) and also recommends that CGM is not routinely offered and should only be considered when standard management of blood glucose levels has not worked or been difficult.[10-13]

A NICE Medtech Innovation Briefing (MIB110) FreeStyle Libre® for glucose monitoring was published in July 2017 which confirms the key evidence uncertainty with FreeStyle Libre® in relation to the inclusion of well controlled type 1 adults in the main randomised clinical trials.[15] A full NICE Technology Appraisal is not on the current NICE workplan.

## Cost impact and cost effectiveness

At present it is standard practice for patients to be issued with the most cost-effective blood glucose testing meter which tests for glucose only, along with a separate meter which is used to test for ketones only, as this is less expensive then issuing a combined glucose and ketone meter. FreeStyle Libre® does not test for ketones, so all diabetic patients who are injecting insulin will still require a ketone testing meter as well.

FreeStyle Libre® meter and sensors will be included in the Drug Tariff and available to prescribe on NHS prescription from 1st November 2017. FreeStyle Libre® is available to buy online and some patients have chosen to self-fund.

The current costs for FreeStyle Libre® are shown in table 1.

**Table 1. FreeStyle Libre®**

| Free Style Libra Evaluation | Including VAT | Excluding VAT |
|---|---|---|
| Starter pack (Reader plus two sensors) | £159.95 | £133.29 |
| Sensors x 1 (14 days) | £57.95 | £48.29 |
| 1 day cost (sensors only) | £4.14 | £3.45 |
| 28 day cost (sensors only) | £115.90 | £96.58 |
| First year costs (sensors only) | £1,390.80 | £1,158.96 |
| First year costs (Reader plus Sensors) | £1,550.75 | £1,292.25 |
| Second year costs (sensors only) | £1,506.70 | £1,255.54 |
| **Cost per 100,000 population for one year (sensors only)** | £650,894.40 | £542,393.28 |

**Notes for table 1**

- Costs shown are the costs for members of the public to purchase directly from the manufacturer and were current at the time of writing. It is not yet known if the manufacturer will offer a reduced price to the NHS.
- First reader set up costs include cost of reader and two sensors only. Costs of associated clinician time for consultation and training have not been included and will need to be considered locally, based on local knowledge.
- When prescribed on FP10 prescription, the cost to the NHS will exclude VAT.

Comparative costs are shown in table 2, appendix 1, page 10.

Current prevalence data suggests that 432 patients per 100,000 population have type 1 diabetes.[17] If all eligible patients were switched to FreeStyle Libre® from current standard practice, the additional investment required is likely to be between £126k and £376k per 100,000 patient population, excluding first year set up costs. FreeStyle Libre® may be more cost effective than current standard practice in a very small sub-group of type 1 diabetes patients who are using the most expensive combined glucose and ketone meters and test strips, and are testing blood glucose levels more than 8-10 times per day.

No published studies on the cost-effectiveness in the UK of FreeStyle Libre® were identified. Several cost-effectiveness analyses in other European Union countries have been published as conference abstracts, however no cost-effectiveness data specifically in relation to the UK were included.[18-20] Whilst these studies seem to suggest that FreeStyle Libre® could be cost effective, it is not possible to fully assess the applicability of the results, as there is limited information available from these conference abstracts in relation to the included studies, methodology used and comparative systems/technologies. More data on the cost-effectiveness of FreeStyle Libre®, specifically in relation to the UK is required.

The NICE Medtech Innovation Briefing (MIB110) Freestyle Libre® for glucose monitoring states that the resource impact is currently uncertain, and will depend upon the extent to which improved glucose control through the adoption of FreeStyle Libre® translates into fewer complications, reduced emergency admissions and less use of blood glucose test strips.[15] In the absence of a positive decision from NICE, FreeStyle Libre® is not considered to be cost-effective and is not recommended for funding.

**Author: Vicky Gibson on behalf of East of England Priorities Advisory Committee (PAC)**

## Document history

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| **PAC approval date** | September 2017 |
| **Version** | v1 |
| **Consultation process** | PAC members |
| **QA process** | Sue Smith. Senior Clinical Pharmacist, PrescQIPP, 3 August 2017 |

## References


1. Company Website FreeStyle Libre® Commercial Website. Abbott Diabetes Care https://www.freestylelibre.co.uk/ Accessed 19/01/2017
2. Heinemann L, Freckmann G. CGM versus FGM; or Continuous Glucose Monitoring Is Not Flash Glucose Monitoring. Diabetes Sci Technol. 2015 September; 9(5): 947–950. Accessed via http://europepmc.org/articles/PMC4667350;jsessionid=2B41F95398EA769AFE223C9EA6685334
3. 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
4. Haak T, Hanaire H et al. Flash Glucose Sensing Technology as a replacement for blood glucose monitoring for the management of insulin treated type 2 diabetes: a multicentre open-label randomised controlled trial. Diabetes Therapy 2016; doi:10.1007/s13300-016-0223-6. Published online 20 December 2016. Accessed 10/02/2017 at http://link.springer.com/article/10.1007/s13300-016-0223-6
5. Bolinder J, Antuna R et al. Novel glucose sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet 2016; 388: 2254-2262.
6. Bolinder J.; Antuna R et al. Using novel flash glucose-sensing technology for 6 months results in a high rate of concordance by young adults with type 1 diabetes. Diabetologia; Aug 2016; vol. 59 (no. 1) Conference Abstract
7. Edge J, Acerini C et al. An alternative sensor based method for glucose monitoring in children and young people with diabetes. Archives of Diseases of Childhood 2017; 0 1-7: DOI: 10:10.1136/archdischild-2016-311530. http://adc.bmj.com/content/archdischild/early/2017/01/30/archdischild-2016-311530.full.pdf
8. Gys I.; Op'T Eyndt A.; Evaluation of the FreeStyle Libre® Flash glucose monitoring system in children and adolescents with type 1 diabetes. Paediatric Diabetes 2016; 17; 85-86.
9. Helm N.; De Mendonca et al. Flash glucose monitoring improves perception and frequency of glucose monitoring leading to improved glucose control. Paediatric Diabetes; 2016; 17: 115.
10. NICE Type 1 Diabetes in adults; management (NG17). August 2015. Available at https://www.nice.org.uk/guidance/ng17
11. NICE. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. (NG18). August 2015. https://www.nice.org.uk/guidance/ng18
12. NICE. Type 2 Diabetes in adults Management (NG28) December 2015. Available at https://www.nice.org.uk/guidance/ng28
13. NICE Technology Appraisal TA151. Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. NICE July 2008. Available at https://www.nice.org.uk/guidance/ta151

14. Bonora B.; Maran A. et al Head-to-head comparison between flash and continuous glucose monitoring systems in outpatients with type 1 diabetes. Journal of Endocrinological Investigation; Dec 2016; 39 1391-1399
15. NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110
16. NHS Business Services Authority. Drug Tariff. February 2017. Accessed 15/02/2017 via http://www.nhsbsa.nhs.uk/PrescriptionServices/4940.aspx
17. Diabetes UK. Diabetes Facts and Stats Version 4 Revised October 2016. Accessed 17/02/2017 via https://www.diabetes.org.uk/Documents/Position%20statements/DiabetesUK_Facts_Stats_Oct16.pdf
18. Hellmund R. Budget impact analysis of a flash glucose monitoring system for patients with diabetes who are using intensive insulin. Value in Health; Nov 2016; vol. 19 (no. 7). Conference Abstract
19. Li H.; Bilir S.P et al. Cost effectiveness analysis of a flash glucose monitoring system for type 2 diabetes (T2DM) patients receiving intensive insulin treatment in Europe. Value in Health; Nov 2016; vol. 19 (no. 7): : Conference Abstract
20. Bilir S.P.; Munakata J et al. Cost effectiveness analysis of a flash glucose monitoring system for type 1 diabetes (T1DM) patients receiving intensive insulin treatment in Europe and Australia. Value in Health; Nov 2016; vol. 19 (no. 7): Conference Abstract.
21. Monitor and NHS England Statutory guidance. NHS National Tariff Payment System 2016/17 23rd March 2016 Accessed 04/07/2016 via https://www.gov.uk/government/publications/nhs-national-tariff-payment-system-201617

## Assessment against ethical and commissioning principles

| Treatment assessed | FreeStyle Libre® |
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| East of England Priorities Advisory Committee recommendation | The routine use of FreeStyle Libre® for all patients with type 1 and type 2 diabetes is not supported.<br><br>FreeStyle Libre® is not been demonstrated to be cost-effective and in the absence of a positive recommendation from a full technology appraisal conducted by the National Institute for Health and Care Excellence is not recommended for funding in primary care. |
| 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. In an open label, randomised controlled trial involving 224 patients with type 2 diabetes, there was no difference in the change in HbA1c between intervention ((FreeStyle Libre®) and controls (self-monitoring of blood glucose) -3.1 ± 0.75 mmol/mol, [-0.29 ± 0.07% (mean ± SE)] and -3.4 ± 1.04 mmol/mol (-0.31 ± 0.09%) respectively; p = 0.8222. In participants, younger than 65 years, the drop in HbA1c was more pronounced in the intervention group compared with controls [-5.7 ± 0.96 mmol/mol, (adjusted mean ± SE) (-0.53 ± 0.09%) and -2.2 ± 1.31 mmol/mol (-0.20 ± 0.12%), respectively; p = 0.0301]. A significant interaction between treatment group and age was observed for change in HbA1c (p = 0.0017).<br><br>In a second study involving 241 individuals with type 1 diabetes, mean time in hypoglycaemia changed from 3·38 h/day at baseline to 2·03 h/day at 6 months (baseline adjusted mean change −1·39) in the intervention group, and from 3·44 h/day to 3·27 h/day in the control group (−0·14); with the between-group difference of −1·24 (SE 0·239; p<0·0001). Several secondary outcomes were also reported. HbA1c concentrations in the intervention group were essentially unchanged compared with the control group. |
| Cost effectiveness | No studies on the cost-effectiveness in the UK of FreeStyle Libre® were identified Several cost-effectiveness analyses in other European Union countries have been published as conference abstracts. Whilst these studies seem to suggest that FreeStyle Libre® could be cost-effective, it is not possible to fully assess the applicability of the results, as there is limited information available from these conference abstracts in relation to the included studies, methodology used and comparative systems/technologies. More data on the cost-effectiveness of Freestyle Libre®, specifically in relation to the UK is required.<br><br>Prevalence data suggests that 432 patients per 100,000 population have type 1 diabetes. If all eligible patients were switched to FreeStyle Libre® from current standard practice, the additional investment required is likely to be between £126k and £376k per 100,000 patient population, excluding first year set up costs. |
| Equity | No issues identified. |

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| **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.<br><br>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.<br><br>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. A NICE Medtech innovation briefing has made no specific recommendation in relation to FreeStyle Libre®. |
| **Disinvestment** | This technology could potentially be used by clinicians to investigate poorly controlled diabetes as well as patient non-compliance with management, rather than the more costly standalone continuous glucose monitors. However, there is currently only very limited comparative evidence available. 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. |

## Appendix 1: Table 2: Comparative costs of blood glucose test strips and FreeStyle Libre®

| | | Blood glucose test strips (BGTS) | | Lancets | | Lancets + BGTS (cost range) | | Cost impact versus Libre* | BGTS strips for combined glucose/ ketone meters | | BGTS strips for combined glucose/ ketone meters + lancets (cost range) | | Cost impact versus Libre* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | min | max | min | max | min | max | | min | max | min | max | |
| Cost per pack | | £7.75 | £9.99 | £3.00 | £6.50 | £10.75 | £16.49 | | £13.95 | £15.71 | £16.95 | £22.21 | |
| Cost per test | | £0.16 | £0.20 | £0.03 | £0.07 | £0.19 | £0.26 | | £0.28 | £0.31 | £0.31 | £0.38 | |
| 4 tests per day | 1-day cost | £0.62 | £0.80 | £0.12 | £0.26 | £0.74 | £1.06 | | £1.12 | £1.26 | £1.24 | £1.52 | |
| | 28-day cost | £17.36 | £22.38 | £3.36 | £7.28 | £20.72 | £29.66 | | £31.25 | £35.19 | £34.61 | £42.47 | |
| | 1-year cost | £225.68 | £290.91 | £43.68 | £94.64 | £269.36 | £385.55 | | £406.22 | £457.48 | £449.90 | £552.12 | |
| Cost per 100,000 population | 1-year cost | £97,494 | £125,673 | £18,870 | £40,884 | £116,364 | £166,557 | £375,836 | £175,489 | £197,629 | £194,359 | £238,514 | £303,880 |
| 10 tests per day | 1-day cost | £1.55 | £2.00 | £0.30 | £0.65 | £1.85 | £2.65 | | £2.79 | £3.14 | £3.09 | £3.79 | |
| | 28-day cost | £43.40 | £55.94 | £8.40 | £18.20 | £51.80 | £74.14 | | £78.12 | £87.98 | £86.52 | £106.18 | |
| | 1-year cost | £564.20 | £727.27 | £109.20 | £236.60 | £673.40 | £963.87 | | £1,015.56 | £1,143.69 | £1,124.76 | £1,380.29 | |
| Cost per 100,000 population | 1-year cost | £243,734 | £314,182 | £47,174 | £102,211 | £290,909 | £416,393 | £126,001 | £438,722 | £494,073 | £485,896 | £596,284 | -£53,891 |

* £542,393 per 100,000 population per year.

### Notes

1. It is current standard practice across England to issue seperate meters for both glucose and ketone testing as the strips for the combined meters are currently more expensive than using two seperate meters and strips. BGTS prices used for the calculation are based on current most cost effective glucose only meters recommended by CCGs. Type 1 diabetics are also issued with a separate meter to test for ketones only, which would still be needed with the FreeStyle Libre® as well. The cost of this meter and testing strips would need to also considered/included in the one year and subsequent costs with FreeStyle Libre® costs.

2. Lancets based on prices indicated in PrescQIPP bulletin.
3. Number of testing strips used per day, based on recommendations in NICE NG17 Adults and NG18 children and young people which indicates a minimum of five tests per day routinely. Frequency of testing is increased during periods of stress or acute illness.
4. All costs shown in pounds unless otherwise stated and are indicative only; the VAT excluded price has been used for the cost comparision and cost impact calculation as per likely cost FP10 prescription supply, but does not include the initial cost of the reader.
5. Current prevalence data suggests that 432 patients per 100,000 population have type 1 diabetes.