



Statement on prescribing FreeStyle Libre flash glucose monitoring system for type 1 and type 2 diabetes

Background

FreeStyle Libre is a flash glucose monitoring system for people with diabetes. A sensor is applied to the arm of the patient and a small mobile device reads the interstitial fluid glucose level when it is flashed over the sensor.

Patient groups have been campaigning for access to FreeStyle Libre and there could be strong demand for its use. Due to the rapid timeframe in which advice is needed to inform the launch of this product onto the Drug Tariff, it has not been possible for Health Technology Wales to undertake an appraisal of its clinical and cost effectiveness to identify patients who would benefit from it most. Instead, this Statement presents the most relevant evidence-based guidance that currently applies in NHS Wales, which comes from the National Institute for Health and Care Excellence (NICE).

Question

What evidence about the clinical and cost effectiveness of FreeStyle Libre flash glucose monitoring system is available to inform prescribing policies in Wales?

NHS availability

FreeStyle Libre disposable sensors will be placed on the NHS drug tariff from 1st November 2017, with an NHS reimbursement price of £35.00. The reader is not prescribable on the NHS and has a commercial list price (including VAT) of £57.95 (NICE 2017, Abbott 2017). It is stated that the sensor must be replaced every two weeks, but it may need to be replaced more frequently. The Haute Autorité de Santé in France has permitted reimbursement of the product but stated a limit of 26 sensors per year (2016).

Local criteria are being developed to inform prescribing policies in some of the nations of the UK. In Wales, an “All-Wales” approach is considered desirable.

Comparators

Standard care is routine self-monitoring of blood glucose through ‘finger prick’ tests. Mobile continuous glucose monitoring systems (Dexcom and Medtronic products) are used for some patients in Wales (personal communication) but are not available on the UK drug tariff.

Methods

Given the time constraints, only the HTA database and NICE website were searched in October 2017. A limited number of sources were contacted directly for further information and clarification. Relevant reports were identified and data were extracted by a single reviewer. The final statement was reviewed internally and by the Welsh Government Chief Pharmaceutical Officer.

Due to the rapid nature of this review, timelines did not allow for wider external peer review or stakeholder feedback. No attempts were made to assess the quality of the evidence. HTW does not guarantee the quality, currency, propriety, accuracy, or reasonableness of any statements, information, or conclusions contained in any third-party materials.

Evidence sources

1. NICE Medtech Innovation Briefing
2. NICE Clinical Guidelines
3. Health Services Executive (Republic of Ireland)
4. Current status in Wales

1. NICE Medtech Innovation Briefing

In 2017, NICE published a Medtech Innovation Briefing (MIB 110) on FreeStyle Libre. MIBs are intended to support decisions made by NHS commissioners by providing a description of the technology and potential role in the treatment pathway. The MIB summary for FreeStyle Libre is presented in Box 1. This presents evidence of efficacy and costs, but there is no evidence of cost effectiveness or discussion about the eligible patient population.

Box 1. Excerpt from NICE Medical Innovation Briefing 110 on FreeStyle Libre

The intended place in therapy is as an alternative to routine blood glucose monitoring in people with type1 and 2 diabetes who use insulin injections.

Five studies were summarized involving 700 people. Two of the trials were randomized, one in type1 diabetes (n=241) and the other in type2 diabetes (n=224). Three of the studies reported device accuracy compared with self-monitored blood glucose, with results ranging from 84% to 88% accuracy and from 99% to 100% clinical acceptability, using an error grid. One study reported device accuracy and acceptability of 97% to 99% compared with venous blood sampling.

The evidence suggests that using FreeStyle Libre for up to 12 months reduces time spent in hypoglycaemia compared with self-monitoring of blood glucose using finger-prick tests, and reduces the average number of finger-prick blood glucose tests needed.

A key uncertainty around the evidence is that the randomised controlled trial of people with type1 diabetes included only adults whose diabetes was well controlled.

The resource impact is uncertain, and depends 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.

2. NICE Clinical Guidelines

NICE clinical guidelines are available for management of type 1 and type 2 diabetes and include sections on self-monitoring. However, only the guideline on type 1 diabetes includes a section on continuous glucose monitoring (boxes 2 and 3). Neither guideline includes recommendations for intermittent interstitial fluid glucose monitoring.

Box 2. Excerpt from NICE clinical guideline on management of type 2 diabetes (NICE 2015)

Self-monitoring of blood glucose

1.6.12 Take the Driver and Vehicle Licensing Agency (DVLA) [At a glance guide to the current medical standards of fitness to drive](#) into account when offering self-monitoring of blood glucose levels for adults with type 2 diabetes. [new 2015]

1.6.13 Do not routinely offer self-monitoring of blood glucose levels for adults with type 2 diabetes unless:

- the person is on insulin or
- there is evidence of hypoglycaemic episodes or
- the person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery or
- the person is pregnant, or is planning to become pregnant. For more information, see the NICE guideline on [diabetes in pregnancy](#). [new 2015]

1.6.14 Consider short-term self-monitoring of blood glucose levels in adults with type 2 diabetes (and review treatment as necessary):

- when starting treatment with oral or intravenous corticosteroids or
- to confirm suspected hypoglycaemia. [new 2015]

1.6.15 Be aware that adults with type 2 diabetes who have acute intercurrent illness are at risk of worsening hyperglycaemia. Review treatment as necessary. [new 2015]

1.6.16 If adults with type 2 diabetes are self-monitoring their blood glucose levels, carry out a structured assessment at least annually. The assessment should include:

- the person's self-monitoring skills
- the quality and frequency of testing
- checking that the person knows how to interpret the blood glucose results and what action to take
- the impact on the person's quality of life
- the continued benefit to the person
- the equipment used. [2015]

Box 3. Excerpt from NICE clinical guideline on diagnosis and management of type 1 diabetes (NICE 2015)

Self-monitoring of blood glucose

Frequency of self-monitoring of blood glucose

1.6.10 Advise routine self-monitoring of blood glucose levels for all adults with type 1 diabetes, and recommend testing at least 4 times a day, including before each meal and before bed. [new 2015]

1.6.11 Support adults with type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply:

- the desired target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not achieved
- the frequency of hypoglycaemic episodes increases
- there is a legal requirement to do so (such as before driving, in line with the Driver and Vehicle Licensing Agency [DVLA] [At a glance guide to the current medical standards of fitness to drive](#))
- during periods of illness
- before, during and after sport
- when planning pregnancy, during pregnancy and while breastfeeding (see the NICE guideline on [diabetes in pregnancy](#))
- if there is a need to know blood glucose levels more than 4 times a day for other reasons (for example, impaired awareness of hypoglycaemia, high-risk activities). [new 2015]

1.6.12 Enable additional blood glucose testing (more than 10 times a day) for adults with type 1 diabetes if this is necessary because of the person's lifestyle (for example, driving for a long period of time, undertaking high-risk activity or occupation, travel) or if the person has impaired awareness of hypoglycaemia. [new 2015]

Blood glucose targets

1.6.13 Advise adults with type 1 diabetes to aim for:

- a fasting plasma glucose level of 5-7 mmol/litre on waking and
- a plasma glucose level of 4-7 mmol/litre before meals at other times of the day. [new 2015]

1.6.14 Advise adults with type 1 diabetes who choose to test after meals to aim for a plasma glucose level of 5-9 mmol/litre at least 90 minutes after eating. (This timing may be different in pregnancy - for guidance on plasma glucose targets in pregnancy, see the NICE guideline on [diabetes in pregnancy](#).) [new 2015]

1.6.15 Agree bedtime target plasma glucose levels with each adult with type 1 diabetes that take into account timing of the last meal and its related insulin dose, and are consistent with the recommended fasting level on waking (see recommendation 1.6.13). [new 2015]

Empowering people to self-monitor blood glucose

1.6.16 Teach self-monitoring skills at the time of diagnosis and initiation of insulin therapy. [2004, amended 2015]

1.6.17 When choosing blood glucose meters:

- take the needs of the adult with type 1 diabetes into account
- ensure that meters meet current ISO standards. [new 2015]

1.6.18 Educate adults with type 1 diabetes about how to measure their blood glucose level, interpret the results and know what action to take. Review these skills at least annually. [new 2015]

1.6.19 Support adults with type 1 diabetes to make the best use of data from self-monitoring of blood glucose through structured education (see [recommendations 1.3.1 and 1.3.2](#)). [new 2015]

Sites for self-monitoring of blood glucose

1.6.20 Monitoring blood glucose using sites other than the fingertips cannot be recommended as a routine alternative to conventional self-monitoring of blood glucose. [2004, amended 2015]

Continuous glucose monitoring

1.6.21 Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes. [new 2015]

1.6.22 Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring:

- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Complete loss of awareness of hypoglycaemia.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more. [new 2015]

1.6.23 For adults with type 1 diabetes who are having real-time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous subcutaneous insulin infusion (CSII or insulin pump) therapy. [new 2015]

1.6.24 Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes. [new 2015]

3. Health Service Executive (Republic of Ireland)

The Health Technology Assessment Group in the Health Service Executive in Ireland is evaluating a mini-HTA and Budget Impact Analysis of FreeStyle Libre in patients with diabetes who require multiple daily injections of insulin. The associated Advice Note is planned for publication in November 2017.

4. Current status in Wales

In Wales, a clinical consensus statement has been developed (Box 4) for an interim period to inform health board policies until evidence based guidance can be produced by Health Technology Wales. Procurement uptake will be monitored over the coming months.

Box 4. Clinical consensus statement (Wales)

Consider Freestlye Libre Flash Glucose Testing as an option for patients testing eight or more times a day on a regular basis*. In this patient group, confirm that the frequency of blood glucose testing is appropriate (initiation should be limited to specialist hospital diabetes team). Patients must agree to undergo appropriate training on the use of Flash Glucose Testing:

In particular, for adults, consider the following groups and factors when despite optimised use of insulin therapy and conventional blood glucose monitoring:

- More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.
- Extreme fear of hypoglycaemia.
- Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. Continue only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more.

In particular, for children and young people, consider the following groups despite optimised use of insulin therapy and conventional blood glucose monitoring:

- Children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level).
- Children and young people who have co-morbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.
- Children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.
- Should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. The responsible physician, in discussion with the person receiving the treatment or their carer, should set appropriate targets for such improvements.
- As a management tool by healthcare professionals to obtain a more detailed picture of the glucose profile for an individual. In particular, for patients having difficulties in achieving their personalised treatment target, someone who is troubled by frequent hypoglycaemia, hyperglycaemia or both. People who have recently developed hypoglycaemia unawareness could use Flash GM, with the support of their healthcare professional team, 'to troubleshoot', which may help stabilise their blood glucose levels and re-establish their hypo awareness. Such usage should be limited to one month's trial, with monthly extensions in exceptional circumstances provided ongoing monthly review by specialist diabetes team. In these circumstances, all prescribing limited to specialist hospital diabetes team.

* As Flash Glucose testing is not currently accepted for purposes of DVLA, it would not be an appropriate choice for those with high frequency testing as a result of their driving requirements.”

About Health Technology Wales (HTW)

Health Technology Wales has been established to provide a strategic, streamlined and nationally coordinated approach to the appraisal and adoption of health technologies into practice across NHS Wales, working with, but independently of, NHS Wales. Its remit covers all health technologies that are not medicines, including medical devices, surgical procedures, telemonitoring, psychological therapies, rehabilitation or other healthcare interventions. Further details can be found at: www.healthtechnology.wales.

Purpose of statement

The purpose of this statement is to provide a brief summary of evidence-based guidance on the FreeStyle Libre glucose monitoring system, as applies to NHS Wales. It may provide helpful background information when making healthcare decisions, but **does not make any recommendations** about the technology. The statement is publicly available. The main intended audience includes healthcare services decision-makers, healthcare professionals, and policy-makers; it may also be of interest to patients and other stakeholders.

References

FreeStyle Libre. 2017. https://www.freestylelibre.co.uk/libre/?gclid=CjwKCAjw-NXPBRB4EiwAVNRLKuaDXgyL4s74da1rfDkXlpdwxVVxg-ilmUrYJs_uNi3gcfh6oyKLmxoClEQAvD_BwE Accessed 28 October 2017.

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