

**Information to help a formulary case for Freestyle Libre System**

(intended for use alongside DUK’s consensus guideline for Flash Glucose Monitoring & Abbott’s Formulary Pack (via this [link](https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/request-a-callback)) & NICE MIB 110-see appendices)

**What is Freestyle Libre (FSL)?**

FreeStyle Libre flash glucose monitoring system is a sensor-based, factory-calibrated system that measures glucose levels in interstitial fluid (not blood) in people (aged 4 and above) with diabetes mellitus, including pregnant women. As described in the Diabetes UK position statement, this device can revolutionise the lives of people with diabetes as it reduces the need for painful finger stick blood tests.

**What does the evidence show? (**For further details see Abbott formulary pack – to obtain pack please contact via <https://freestylediabetes.co.uk/health-care-professionals/freestyle-libre/request-a-callback>)

The evidence for this device is summarised in the NICE MIB. In randomised controlled trials, it significantly reduced hypoglycaemia in patients with both Type 1 and Type 2 diabetes. Five observational studies have reported improvements in HbA1c but to date there are no randomised controlled trials reporting improvements in HbA1c.

**What do UK clinicians think?**

NICE recommends blood glucose monitoring 4-10+ times per day in those with Type 1 diabetes. We now have a safe, affordable alternative which reduces the need for painful fingerprick tests and allows unlimited frequent testing at no extra cost to the payer. FSL has been made available to patients in many countries across the world.

Diabetologists in the UK have witnessed the impact this device has on quality of life, with many patients opting to self-fund at a cost of £96 per month. This had led to inequitable access to a device (1) which many describe as ‘life changing’. We would support access for all who may benefit, as outlined in the Diabetes UK position statement (See appendix).

However, we also appreciate the challenging financial climate the NHS is currently facing and as such a team of expert diabetes clinicians have reached the following consensus for recommending funding. It is also recommended that real world evidence is collected in the absence of significant RCT data to evidence the impact of FSL in clinical use.

**Recommendations for NHS funding**

People with Type 1 diabetes, attending specialist Type 1 care, using multiple daily injections or insulin pump therapy who meet the following criteria:

Potential to be cost equivalent or demonstrate short term cost savings

* Those already performing ≥ 8 SMBG (self-monitoring of blood glucose) per day; FSL is cost equivalent at 8 blood tests per day.
* Those who meet current NICE criteria for insulin pump therapy (HbA1c ≥8.5% or disabling hypoglycaemia as described in NICE TA151) where a successful trial of FSL may avoid the need for pump therapy, therefore demonstrating a cost saving.
* Those who have recently developed impaired awareness of hypoglycaemia. A trial of FSL can reduce hypoglycaemia (2,3) and may prevent future need for Continuous Glucose Monitoring (CGM), demonstrating cost saving. It is noted that for *persistent* hypoglycaemia unawareness, NICE recommend GCM with alarms, not FSL.
* Women who are currently pregnant or trying to conceive (frequent glucose monitoring is recommended in pregnancy).
* Frequent admissions (> 2 per year) with DKA or hypoglycaemia, on assumption FSL trial could prevent future admissions.

Potential to demonstrate long term costs savings (Invest to save – see model below)

FSL should be provided as **a 6-month trial** to see whether individuals can demonstrate improvements in HbA1c, reducing risk of future complications:

* Young adults 18-25 who have not reached personalised HbA1c target despite SBGM
* Those that have not reached HbA1c target as a result of infrequent testing. FSL has demonstrated effectiveness in this scenario (4)

Other groups who should have FSL made available:

* Those who require third parties to carry out monitoring (e.g. mentally or physically unable to undertake blood glucose testing)
* Those with professions that make SMBG at work difficult
* Those who have been using Freestyle Libre (i.e. self-funded or as part of research project) that meet criteria below

Continuation criteria for FSL (any of the following, depending on the indication)

* Reduction in severe/non- severe hypoglycaemia frequency by >1 episode per week
* Reversal of impaired awareness of hypoglycaemia
* Reduction in DKA events
* HbA1c reduction of 0.5% within 6 months
* PWD performs >4 scans per day, demonstrating evidence of FSL use in self-management

Discontinuation criteria

* Failure to achieve any of the above criteria (dependant on the indication)
* Failure to attend 2 consecutive specialist Type 1 diabetes follow-up appointments

**Financial Considerations**

FreeStyle Libre will be available on the NHS at £35 per sensor, £910 annual acquisition costs.

Abbott Diabetes Care are willing to provide a free starter pack for those starting FSL. This will include a reader and 1 sensor, effectively supplying the first 2 weeks of usage without cost. The manufacturer will also provide education on the use of FSL to both patients and HCPs free of charge.

Reduction in HbA1c required for cost effectiveness

80% of NHS diabetes spending is spent on treating complications (5). Early intervention to reduce HbA1c has been shown to reduce microvascular complications such as retinopathy and amputation. The IMS Core Diabetes Model is a validated model (6) for projecting these potential cost savings and is used by several regulatory bodies including NICE.

**Using the IMS core diabetes model it is estimated that the annual cost of FSL would offer cost effectiveness if a reduction in Hba1c of 5mmol/mol is delivered for the PWD as a consequence of its use**.

This is a conservative estimate and is currently being confirmed by a statistician. This is a similar reduction in HbA1c that has been proposed for type 2 diabetes medications.

This HbA1c reduction has formed the basis for our suggestion that each suitable individual that uses FSL should be reassessed at 6 months using HbA1c measurement. If the above target is reached then payers can be assured that the initial investment represents value for money and the prescription can be continued. If the targets are not met then the prescription should cease meaning only those with proven benefit should continue to obtain FSL on the NHS.

Reduction in glucose strip use

If a PWD is currently using 8 SBGM strips daily to currently manage their T1 DM, then the use of FSL is approximately cost neutral (depending on local strip costs). In the IMPACT study SMBG strip use reduced to 0.5 per day on average in those using FSL.

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|  | **4 Blood Glucose Tests per Day (£)** | **7 Blood Glucose Tests per Day (£)** | **8 Blood Glucose Tests per Day (£)** | **10 Blood Glucose Tests per Day (£)** |
| 1Annual lancet and strip cost  | 482 | 843 | 964 | 1205 |
| Cost per SMBG patient per year | 482 | 843 | 964 | 1205 |
| 2Acquisition Cost difference FreeStyle Libre vs SMBG, per patient, per year | 488 | 127 | 7 | -234 |

1Assuming test strip cost of £0.29 and lancet cost of £0.04 (Average weighted cost of top 10 suppliers, can be localised)

2Assuming FGM acquisition costs of £970 (£910 for sensors @ £35/sensor and £60 for continued SMBG use

These calculations can be adjusted to local conditions. Abbott representatives can help develop a local case based on strip use.

References

1. [Flash Glucose Monitoring is associated with improved glycaemic control but use is largely limited to more affluent people in a UK diabetes centre.](https://www.ncbi.nlm.nih.gov/pubmed/28103416) McKnight JA, Gibb FW.Diabet Med. 2017; May;34(5):732.

2. Haak T, Hanaire H, Ajjan R, Hermanns N, Riveline JP, Rayman G., Flash Glucose-Sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-Treated Type 2 Diabetes: a Multicenter, Open-Label Randomized Controlled Trial. Diabetes Ther. 2017 Feb; 8(1):55-73. doi: 10.1007/s13300-016-0223-6.

3. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kroger J, Weitgasser R., Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial [published online September 12, 2016]. Lancet. 2016

4. [An alternative sensor-based method for glucose monitoring in children and young people with diabetes.](https://www.ncbi.nlm.nih.gov/pubmed/28137708) Edge J, Acerini C, Campbell F, Hamilton-Shield J, Moudiotis C, Rahman S, Randell T, Smith A, Trevelyan N. Arch Dis Child. 2017 Jun;102(6):543-549. doi: 10.1136/archdischild-2016-311530. Epub 2017 Jan 30

5. Estimating the current and future costs of Type 1 and Type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs.N.Hex et al; Diabetic Medicine Volume 29, Issue 7; July 2012; Pages 855–862

# 6. Validation of the IMS CORE Diabetes Model; McEwan et al; Value in Health 2014  <http://dx.doi.org/10.1016/j.jval.2014.07.007>

[NICE MIB 110](https://www.nice.org.uk/advice/mib110)

[Diabetes UK Consensus Statement on Flash Glucose Monitoring](https://www.diabetes.org.uk/resources-s3/2017-09/1190_Flash%20glucose%20monitoring%20guideline_SB_V9%5B4%5D.pdf?_ga=2.137083376.1339632840.1505301182-2056973880.1505301182)