

Guidance for the implementation of flash glucose monitoring prescribing across the NHS in London

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Summary

This guidance, developed by the London Diabetes Clinical Network and NHS London Procurement Partnership, provides advice on the implementation of flash glucose monitoring prescribing across the NHS in London.

The first release of this guidance was published in May 2018, for the implementation of FreeStyle Libre, one of the first flash glucose monitoring devices available. In March 2019, NHS England published criteria for flash glucose monitoring reimbursement. This funding is not specific to Freestyle Libre and could be used for other flash glucose monitoring devices which enter use within England. This document has been updated to reflect these guidelines.

The London Diabetes Clinical Network asks that this implementation guidance will be universally adopted across the region to ensure equity of access for patients in London.

1. Background

1.1 What is flash glucose monitoring?

The flash glucose monitoring system is a device for the self-monitoring of glucose levels. Unlike traditional finger-prick devices (that measure the glucose level in the blood), flash measures the glucose level in the interstitial fluid, via a sensor that sits just under the skin.

It can provide a near-continuous record, which is produced by the patient scanning the sensor with their reader-device, as and when required.

Additional education and training is necessary for any healthcare professionals or patients who wish to use this system.

FreeStyle Libre was listed in the Drug Tariff on 1 November 2017 and is currently the only available flash glucose monitoring device in England.

1.2 Quality assurance

Abbott, the manufacturer of FreeStyle Libre, were asked for relevant certification regarding quality assurance for the device and LPP are happy to forward these on to individual organisations, if required. EC certification (93/42/EEC Medical Device Directive) and Abbott's declaration of conformity to the following was also sent:

- 92/42/EEC Medical Device Directive
- 2014/53/EU Radio Equipment Directive
- 2011/65/EU Restriction of Hazardous Substances Directive

1.3 How accurate is it?

Assessment of available evidence in the NICE Medtech Innovation Briefing 110 (July 2017) deemed the FreeStyle Libre device to be clinically acceptable in terms of accuracy when compared to self-monitoring blood glucose measurement devices.

1.4 Is this a replacement for fingerprick blood glucose testing?

As flash glucose monitoring measures glucose levels in the interstitial fluid, it is not a complete substitute for blood glucose testing. Self-monitoring blood glucose (SMBG) measurements are required in certain circumstances, including:

- during times of rapidly changing glucose levels when interstitial fluid glucose levels, may not accurately reflect blood glucose levels,
- when scanned glucose results do not correspond with the user's symptoms,
- where the reader indicates a low glucose reading,
- to meet Driving and Vehicle Licensing Agency requirements for "Group 2" drivers,
- to use bolus calculators.

The average daily number of SMBG strips required for the individual should be discussed and sufficient test strips should be provided in addition to flash glucose monitoring, if prescribed.

1.5 Notes on the use of SMBG testing alongside flash glucose monitoring

The FreeStyle Libre device has the option to use the handset as a SMBG and ketone meter, in conjunction with FreeStyle Optium blood glucose and ketone strips. Organisations are advised that it is not essential to use this functionality (and these strips) and patients can continue to use their current SMBG meter alongside the Libre device. It is important to ensure that patients have enough SMBG testing strips as per their requirements, but the brand chosen should continue to reflect local formularies, the functionality required and patient choice.

1.6 Do these devices have alarms?

Caution should be noted for those with impaired awareness of hypoglycaemia and/or frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities, as flash will not provide warnings or alarms about low or high glucose levels.

1.7 How should the device be used?

In order to gain maximum benefit from the device, sensors should be worn continuously and ideally scans should be undertaken to provide 24/7 readings. At a minimum the sensor must be scanned at least eight times per day to provide continuous glucose levels covering 20-24 hours per day, every day.

1.8 Who will be prescribing this?

Initiation should only be carried out by the local specialist diabetes team. Specialist centres available will vary locally and may comprise either secondary or both secondary and intermediate care services. Prescribing is expected to be transferred to primary care at 2 months (see later information on processes). Transfer of prescribing must be accompanied by clear monitoring responsibilities and information on ongoing review and it is suggested that the transfer of care documents (supplied separately) are used.

1.9 How was this guidance formulated?

In September 2017, NHS London Procurement Partnership (LPP) were asked to facilitate the production of a pan-London clinical consensus for the use of the FreeStyle Libre flash glucose monitoring system in the NHS.

Expert opinion on local implementation was sought from the NHS England London Diabetes Clinical Network, its Clinical Leadership Group and Type 1 Diabetes Network. Additional advice was sought from members of the South East Coast and London Children and Young Peoples Diabetes Network for paediatric patients.

These groups contain a variety of clinician, commissioner and patient representatives and ongoing review regarding the practicalities and implementation of this document was facilitated by the input of external commissioner, formulary and primary care pharmacists via the NHS LPP Responsible Diabetes Prescribing Group.

The London Diabetes Clinical Network acknowledged the similarities between the North RMOC position statement and the formulary case from ABCD¹. This was therefore reviewed to gain an insight to the background of the RMOC recommendations, in addition to existing evidence where available:

- NICE MIB 110², including trials referenced in this document
- Diabetes UK consensus guideline for Flash Glucose Monitoring³ and
- Abbott Formulary Pack (available on request from Abbott and can be forwarded via email from NHS LPP/network if needed).

The first FreeStyle Libre Implementation Guidance for London was developed in response to the RMOC position statement for FreeStyle Libre and was published in May 2018. In March 2019 NHS England published criteria for flash glucose monitoring with a reimbursement model. This document has been updated to reflect the new NHS England criteria.

1.10 Purpose of this document and consideration points for local committees

The network recognises that flash glucose monitoring is a novel and innovative device and encourage local organisations to consider the recommendations in this document for the benefit of the groups of patients as specified.

The network and LPP present the following advice to the London health economy on the implementation of the NHS England recommendations into treatment pathways (with clarification, where required).

We ask that this implementation guidance will be universally adopted across the region to ensure equity of access for patients in London. The process of approval will vary depending on local pathways but organisations are encouraged to include their local clinicians in discussions to facilitate local implementation. This document is a comprehensive guide, designed so that sections can be removed and used in practice, as and when appropriate. Further supplementary documentation is provided as detailed at the end of the document.

If these recommendations are accepted, local committees should confirm within their networks the process for initiation and prescribing and are recommended to liaise with the clinical network in regard to organising training.

2. NHS England criteria for reimbursement

The previous RMOC criteria and London implementation have now been superseded by the NHS England criteria in Annex A of the 'Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients' publication (7 March 2019. <https://www.england.nhs.uk/wp-content/uploads/2019/03/flash-glucose-monitoring-national-arrangements-funding-v1.1.pdf>). From 1 April 2019, for patients who satisfy

these criteria, NHS England will reimburse CCGs for the ongoing costs of flash glucose sensors. These criteria, developed with key stakeholders, are estimated to represent up to 20% of England's type 1 diabetes population. The national funding arrangements are time limited to include 2019/20 and 2020/21, which will allow time for CCGs and prescribers to implement NICE guidelines and recoup the financial benefits of flash glucose monitoring usage.

This reimbursement is available to all CCGs regardless of the current level of usage of flash glucose monitoring, and no adjustment has been made to the level of maximum reimbursement to take account of existing CCG expenditure on flash glucose monitoring. In 2019/20 CCGs will be reimbursed £26.03 for each sensor prescribed. This takes into account a proportion of the cost savings to CCGs from a reduced requirement to fund testing strips for finger-prick blood glucose monitoring. Maximum CCG reimbursement levels for 2019/20 are provided in Annex B of 'Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients' publication (7 March 2019. <https://www.england.nhs.uk/wp-content/uploads/2019/03/flash-glucose-monitoring-national-arrangements-funding-v1.1.pdf>).

Reimbursement of sensors will be allocated to CCGs on the basis of FP10 prescribing data. It may therefore be necessary for local arrangements to be considered for reimbursement of the initial sensors provided to new users by specialist providers. Mechanisms may include:

1. Provision of sensors by FP10 from specialist providers
2. Prescription of sensors by FP10 from primary care prior to initiation of flash monitoring
3. Local negotiation of a tariff
4. Consolidated reimbursement from CCG to specialist provider at regular intervals.

Criteria for NHS England Flash Glucose Monitoring Reimbursement

1. People with type 1 diabetes

OR with any form of diabetes on haemodialysis and on insulin treatment

who, in either of the above, are clinically indicated as requiring intensive monitoring >8 times daily, as demonstrated on a meter download/review over the past 3 months

OR with diabetes associated with cystic fibrosis on insulin treatment

2. Pregnant women with type 1 diabetes - 12 months in total inclusive of postdelivery period.
3. People with type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management.

4. People with type 1 diabetes for whom the specialist diabetes MDT determines have occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6-month trial of Libre with appropriate adjunct support.
5. Previous self-funders of Flash Glucose Monitors with type 1 diabetes where those with clinical responsibility for their diabetes care are satisfied that their clinical history suggests that they would have satisfied one or more of these criteria prior to them commencing use of Flash Glucose Monitoring had these criteria been in place prior to April 2019 AND has shown improvement in HbA1c since self-funding.
6. For those with type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes and their clinician consider that a Flash Glucose Monitoring system would be more appropriate for the individual's specific situation, then this can be considered.

Other requirements:

1. Education on Flash Glucose Monitoring has been provided (online or in person)
2. Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time.
3. Agree to regular reviews with the local clinical team.
4. Previous attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally)

CCGs may wish to agree to make Flash Glucose Monitoring available to additional groups of patients who are not covered within the national criteria. These patients would not be covered by the reimbursement arrangements.

Continuing prescription for long-term use of flash glucose monitoring post the initial six months would be contingent upon evidence of agreeing with the above conditions and that on-going use of the flash glucose monitoring is demonstrably improving an individual's diabetes self-management; for example, improvement of HbA1c or time in range, improvement in symptoms such as DKA or hypoglycaemia, or improvement in psycho-social wellbeing.

2.1 How are the NHS England reimbursement criteria different to initial London implementation guidance?

- Patients with an Hb1AC >69mmol/mol (8.5%) are not covered by NHS England funding, unless they meet one of the other criteria.

- Patients who should intensively monitor, but do not and thus do not have three months evidence of intensive monitoring do not qualify for NHS England funding, except through pathway 2.
- NHS England have not stated the outcomes of interest. London Diabetes Clinical Network recommends the following for consideration:
 - Improvement in HbA1c
 - Improved commitment to regular scans and their use in self-management
 - Reduction in testing strip usage
 - Quality of Life improvement using validated rating scales
 - Reductions in severe/non-severe hypoglycaemia
 - Reduction in episodes of diabetic ketoacidosis
 - Reduction in related admissions to hospital
 - Reversal of impaired awareness of hypoglycaemia

We recommend that if no improvement is demonstrated in one or more of these areas over a 6-month trial then the use of flash monitoring should be discontinued and an alternative method of monitoring used.

Reference 1. Association of British Clinical Diabetologists Information to help a formulary case for Flash glucose monitoring System published 13th October 2017 accessed at <https://abcd.care/getting-freestyle-libre-your-formulary>

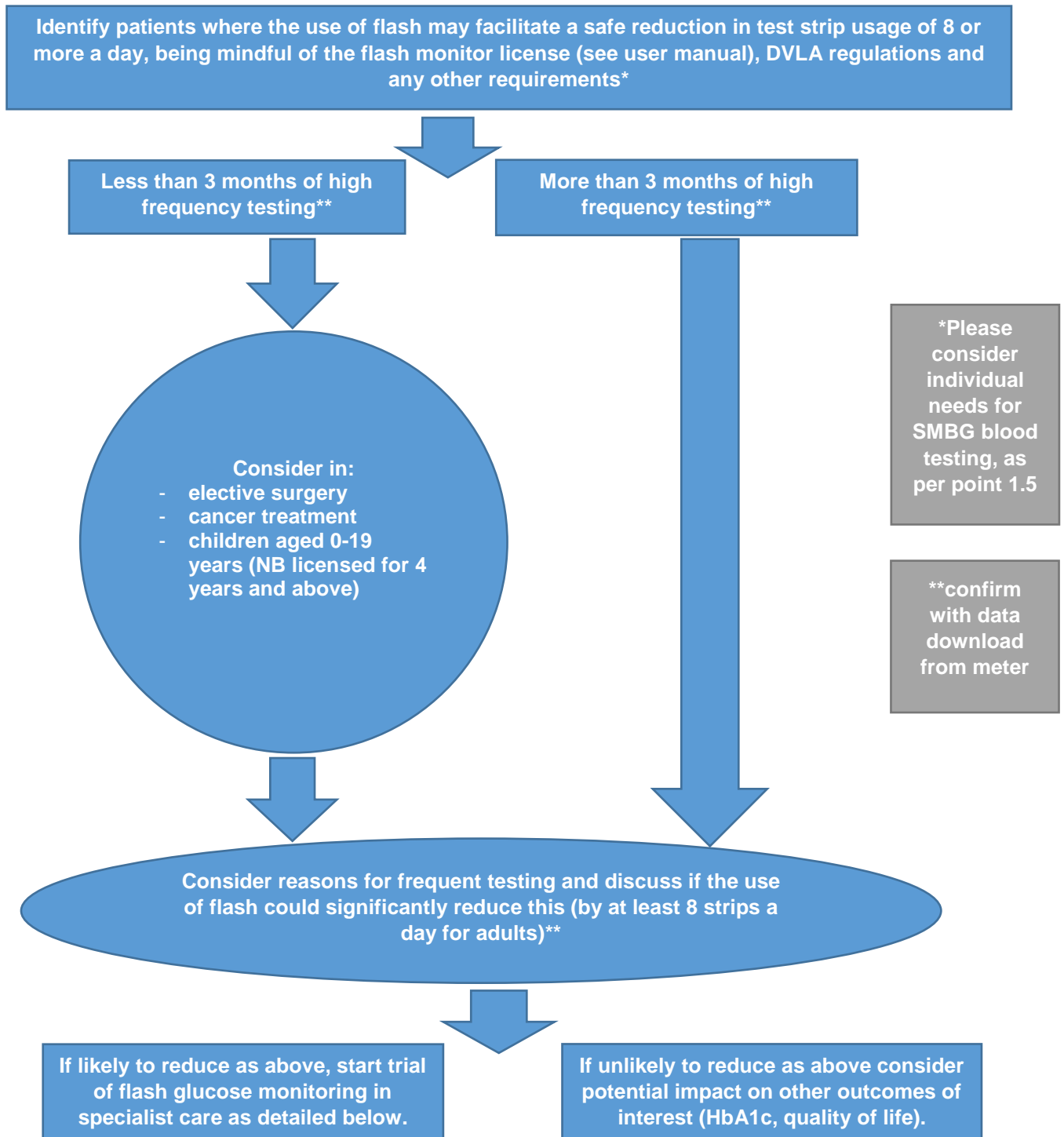
Reference 2. NICE Flash glucose monitoring for glucose monitoring Medtech innovation briefing [MIB110] Published date: July 2017 Last updated: September 2017 accessed at <https://www.nice.org.uk/advice/mib110>

Reference 3. Diabetes UK Consensus Guideline for Flash Glucose Monitoring Date published September 2017 accessed at 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

3. Implementation guidance pathways

3.1 Patients with type 1 diabetes on MDI or insulin pump therapy who test frequently

Pathway 1: Recommended implementation of flash glucose monitoring prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently (>8 times per day) – pathway for specialist initiation



3.1.1 Recommended implementation of flash glucose monitoring prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently (>8 times per day) – further information, including transfer into primary care

- a) **Outcome for review** – If flash glucose monitoring is initiated for the above indication, the key intention should be to reduce test strips by at least 8 strips a day (7 in children aged 0-19 years). If this is not achieved by 6 months prescribing should be discontinued unless flash glucose monitoring is demonstrably improving an individual's diabetes self-management (as per section 2). This should be discussed and agreed with the patient at initiation (see patient contract).
- b) **Suggested timeframe** – It is suggested that the reduction in the use of SMBG test strips is gradual and takes place over the initial 6 weeks, as familiarity with the system increases. Details of this will be agreed between the specialist and patient at initiation and detailed in the letter from the specialist team. The specialist will continue to review this item and the average reduction in SMBG test strip usage at future clinic appointments, but it is suggested that primary care practitioners also discuss self-monitoring requirements with the patient at around 6 weeks and take this opportunity to consider if the product will be placed on repeat prescription from 2 months. Please see further details of this process under “review and prescribing timelines”.
- c) **Key consideration** – If it is likely that a significant reduction (as detailed above) will not be achieved and a high number of SMBG tests will still be required (e.g. for ‘Group 2’ drivers) then this product is not suitable for prescribing under this recommendation (duplication of therapies). The primary outcome for review is the average reduction in SMBG test strips when considering cost-effectiveness, and this should be discussed as opposed to a “target” daily amount. It is important to make sure that sufficient SMBG test strips are prescribed for the individual's needs as per the points detailed in point 1.5 (estimate average monthly usage); the recommended amount for retention on prescription will be detailed in the initiation letter, but may change depending on additional outcomes observed with the flash glucose monitoring.
- d) **Information for self-funders who identify as coming under this recommendation** – Prior to review in specialist services, it is recommended that primary care prescribing data for SMBG test strips from the patient's primary care clinical record is reviewed for the previous year (as well as recent meter download information, which can be reviewed in clinic) and that these are provided as evidence for continuation of flash glucose monitoring on an NHS prescription (i.e. evidence of reduced usage of SMBG test strips as detailed above, following initiation of flash glucose monitoring). Data for number of strips required prior to initiation (at least 6 months), date of initiation, information on SMBG testing 6 months post initiation and concurrent changes in HbA1c should be considered, wherever possible. If patients fulfil criteria for NHS prescribing they will then continue to be reviewed as per the terms of this document.

3.1.2 Additional notes on those who can be considered for continuous glucose monitoring (CGM) as per NG17 and NG18

The Diabetes Clinical Network also note that real-time CGM can be used as a strategy for the optimisation of HbA1c and/or reduction in hypoglycaemic episodes, as per NG17¹ (type 1 diabetes in adults) and NG18² (type 1 and type 2 diabetes in children and young people). For adults meeting the criteria in NG17 CGM should be made available in line with London Guidance: Recommended Commissioning Arrangements for Continuous Glucose Monitoring (CGM) in Adults with Type 1 Diabetes available here: <http://www.londonscn.nhs.uk/publication/london-guidance-recommended-commissioning-arrangements-for-continuous-glucose-monitoring-cgm-in-adults-with-type-1-diabetes>

NG17¹ states: “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.”

NG18² states: “Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have:

- frequent severe hypoglycaemia or
- impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or
- inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).

Consider ongoing real-time continuous glucose monitoring for:

- neonates, infants and pre-school children
- 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 comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult.

Consider intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.”

Flash glucose monitoring may be considered as an option if traditional CGM devices are deemed not to be suitable or practical (including for patients already

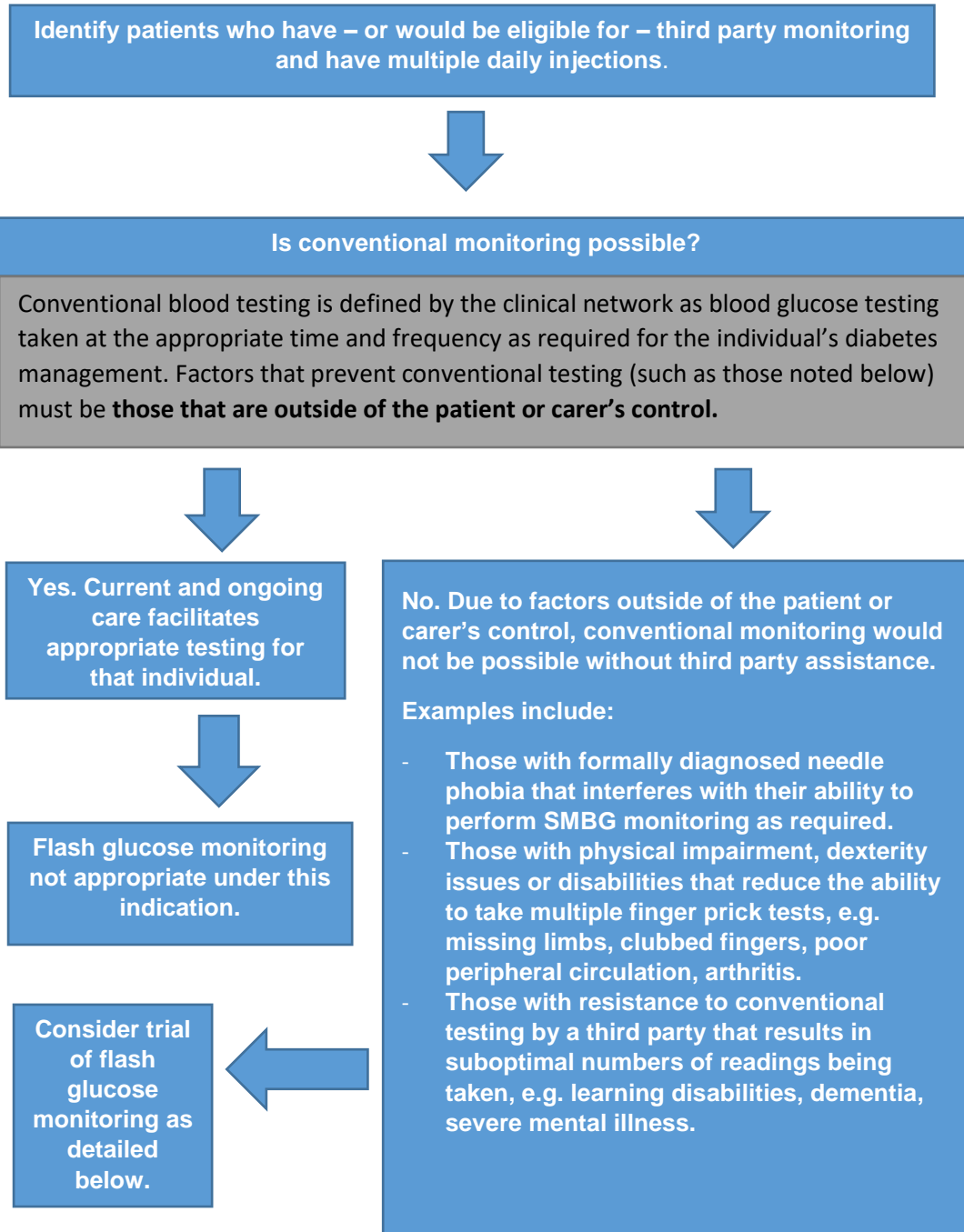
on an insulin pump). Particular caution is advised for prescribing where there is impaired awareness of hypoglycaemia, a history of severe hypoglycaemia (defined as requiring the assistance of another person, as per NICE guidelines such as NG17, TA151), or frequent asymptomatic episodes as the use of a device with warnings or alarms is strongly advised.

Reference 1. Type 1 diabetes in adults: diagnosis and management NICE guideline [NG17] Published date: August 2015 Last updated: July 2016

Reference 2. Diabetes (type 1 and type 2) in children and young people: diagnosis and management NICE guideline [NG18] Published date: August 2015 Last updated: November 2016

3.2 Patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing

Pathway 2: Recommended implementation of flash glucose monitoring prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing (due to disability, occupational or psychosocial reasons) – pathway for specialist initiation



It is not envisaged that those under community nursing services will be automatically eligible for flash glucose monitoring under this indication. The London Diabetes Clinical Network discussed how it was unlikely that monitoring would be a sole reason for any nursing visits and therefore the use of flash would not have a significant effect on reducing workload or enhancing monitoring, without the provision of additional training.

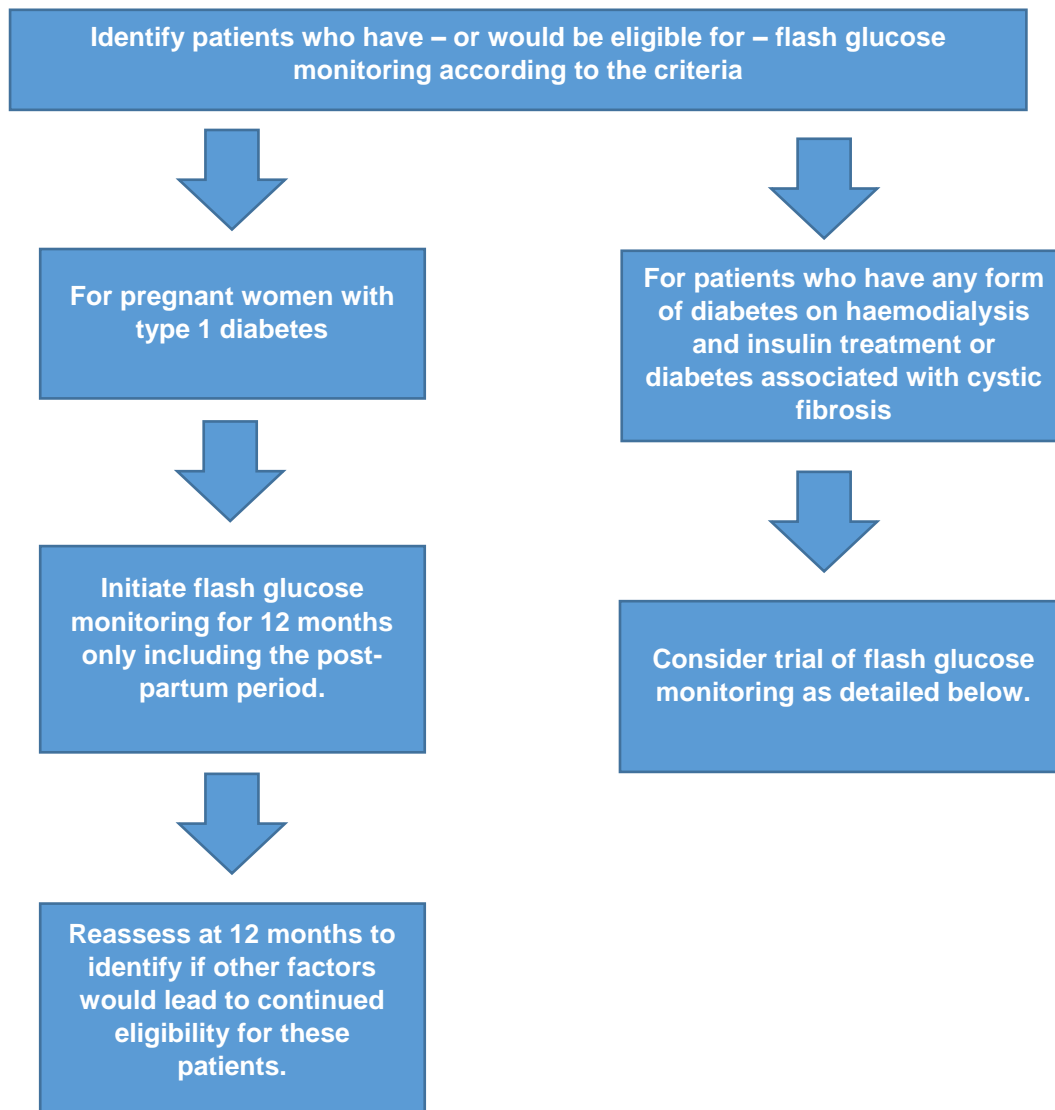
3.2.1 Recommended implementation of flash glucose monitoring prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing (due to disability, occupational or psychosocial reasons) – further information, including transfer into primary care

- a) **Outcome for review** - If flash glucose monitoring is initiated for the above indication, the intention should be to ensure appropriate monitoring of glucose levels is possible for the patient. The definition of appropriate monitoring is dependent on the individual and should be defined and noted following discussion between the specialist and patient at the initial consultation.
- b) **Suggested timeframe** – It is hoped that appropriate monitoring will be achieved relatively quickly after introducing the use of flash glucose monitoring. The level of monitoring agreed at initiation will be detailed in the initiation letter and reviews may take place in primary care or at the specialist clinic, to determine continuation of prescribing in primary care at 6-8 weeks. Please note that if a primary care or clinic appointment is not organised before the end of 2 months some acute prescribing in primary care may be needed. A decision regarding continuation should be made as per the terms defined at initiation by 3 months.
- c) **Key consideration** – the flash glucose monitoring would not be appropriate under this indication for those where adequate monitoring is already in place, even if via a third party. It is also not appropriate where adherence or compliance issues are the sole barrier to conventional monitoring (engagement with therapy should be addressed first-line).
- d) **Information for self-funders who identify as coming under this recommendation** – Prior to review in specialist services, it is recommended that primary care prescribing data for SMBG test strips from the patient's primary care clinical record is reviewed for the previous year (as well as recent meter download information, which can be reviewed in clinic) with consideration of monitoring prior (recommended 6 months) and post (recommended 6 months) initiation of flash glucose monitoring and concurrent changes in HbA1c. This data should inform discussions alongside considerations regarding the improvements seen in monitoring from the patient and/or carer's perspective.

3.3 Patients who have any form of diabetes on haemodialysis and insulin treatment, are pregnant and have type 1 diabetes, or have diabetes associated with cystic fibrosis and are on insulin treatment

Pathway 3: Recommended implementation of flash glucose monitoring prescribing for patients who:

Have any form of diabetes on haemodialysis **OR**
Are pregnant and have type 1 diabetes **OR**
Have diabetes associated with cystic fibrosis
AND are on insulin treatment – pathway for specialist initiation



4. Recommended review and prescribing timeline for all recommendations

Month	Activity	Paperwork required
Month -1	Initial discussion regarding flash glucose monitoring and agreement between prescriber and specialist clinician.	Patient-prescriber agreement to be read through and discussed. Referral to in-house training session.
Month 0	Group training session at specialist site. If patient wishes to continue, completion of training will result in supply of flash glucose monitoring handset and sensor starter pack, plus one additional sensor. Complete and sign patient-prescriber agreement.	Notify GP of initiation of flash glucose monitoring, by sending completed patient-prescriber agreement. Clinic to complete initiation data collection form (see later section on data and monitoring).
Month 1	Patient to attend specialist centre for initial usage review (recommended in original training group) to discuss any potential issues with the technology. If continuation agreed, one further month of sensors (2 sensors) to be supplied from specialist care. Request short-term prescribing from primary care using appropriate form.	Prescription for 2 sensors from specialist centre. Send short-term prescribing request (indication 2) or request for prescribing review (1/3). Patient to book primary care appointment for 6 weeks post initiation, if applicable.*
Month 2	If locally agreed - GP to inform clinic of progress of outcomes for recommendations 1 and 3 following primary care appointment at 6 weeks. Primary care is asked to supply acute prescriptions for up to a further 3 months. The clinic will confirm continuation and need for repeat prescribing after next scheduled clinic appointment (at 3-4 months).	Primary care prescriptions – acute – for up to 3 months if GP practice has agreed.
Month 3-4	Specialist review of outcome achievement (may be facilitated by information from GP for 1 and 3) and formal request for long-term prescribing.	If continuation confirmed send long-term prescribing agreement to primary care. Continuation data collection form by specialist care. Set up of repeat prescription in primary care, if applicable.
1 year	Review here and annually thereafter	Continuation data collection form by specialist care.

*Potential for GP practices to conduct an initial primary care review of outcomes at 6-8 weeks (recommendations 1 and 3) should be confirmed at a local level.

Please note detailed supplementary documentation is available at <http://www.lpp.nhs.uk/categories/medicines-optimisation-pharmacy-procurement/task-and-finish-groups/responsible-diabetes-prescribing-group/implementation-of-freestyle-libre%C2%AE-prescribing-guidance-in-london/> (login available for LPP members).

5. Ordering information

FreeStyle Libre monitoring readers (with one sensor) will be supplied to clinics free of charge by Abbott. Subsequent sensors should be supplied on prescription and the Diabetes Clinical Network and LPP recommend that this is a further three from specialist care and then long-term continuation in primary care.

FreeStyle Libre sensors are not available by standard wholesalers and pharmacies must set up a direct account with Abbott. Delivery is next day (if ordered before 5pm) via UPS.

6. Data collection

The Diabetes Clinical Network appreciates the need for real-life data to be collected on this and are grateful for the production of the ABCD audit material. These forms can be found here: <https://abcd.care/launch-abcd-nationwide-freestyle-libre-audit>.

7. Exclusions for prescribing of flash glucose monitoring

Flash glucose monitoring may NOT be suitable in some circumstances, even if the patient meets the requirements of the listed indications. Consider alternatives to monitoring with flash for the following patients:

- Those who will not realistically reduce their test strip usage by the amount specified above (if initiated under recommendation 1), leading to a significant cost pressure.
- Those with no hypoglycaemia awareness (including where CGM had been deemed not suitable or practical).
- Those with an allergy to medical grade adhesive.
- Children and young people on CSII who need to test their blood glucose frequently to make insulin dosing decisions, including with pump algorithms. A reasonable number of SMBG strips will be required for this as many require blood glucose measurements. Some pump devices (e.g. Medtronic 640G) can use glucose levels from interstitial fluid for these calculations but blood glucose is deemed to be more appropriate. If interstitial glucose levels are to be measured and used with pumps where the algorithm supports this, ideally this should be from a CGM device.
- Patients (or carers, where appropriate) who have not had appropriate basic diabetes education to date, covering at the very least: principles of insulin dose

adjustment, appropriate management of hypoglycaemia and hyperglycaemia, and general self-management. These must be completed first, including follow-up, before considering introducing flash glucose monitoring.

- Those not under the care of a specialist team with skills to support the initiation of flash for the first 6 months.

The use of flash must be associated with sufficient training and engagement in order to ensure that its use is safe and effective for ongoing measurement of glucose levels. Please see training recommendations below.

8. Training recommendations

There are currently 27,145 people with type 1 diabetes in London (NDA 2016/17). NHSBSA prescribing data suggests around 1400 of these test 8 or more times a day, but the number eligible under recommendations 2 and 3 is uncertain. Regardless of total numbers, the need for a controlled and supported rollout is recognised.

One of the most important parts of implementation is adequate training for clinicians (who will then provide this to patients). The network has liaised with Abbott to ensure this is provided in a fair and timely manner for FreeStyle Libre (as well as reviewing content). This device must only be initiated in specialist care and therefore clinic resources will stagger uptake across the region. It is recommended that services attempt to offer at least one session per month (approximately 1 hour) for 12-16 patients at a time; this must take place before the device is provided. The network and NHS LPP will liaise with primary care in order to ensure that primary care practitioners receive adequate information about this device and feel supported in prescribing the sensors when care is continued. Detailed transfer of prescribing documentation and patient contracts are also provided to support care across the treatment pathway.

We will learn from current and successful training programmes and recommended training competencies have been published as supplementary documents. As an overview:

- The London Diabetes Clinical Network has discussed and agreed key topics for inclusion in training sessions at each level.
- The content for specialist training by Abbott for Freestyle Libre have been agreed between Abbott and clinical network leads and details of this will be available in supplementary documentation.
- This will be rolled out over localities as guidance is approved.
- Once members of the specialist centres have been trained for initiation and patient training, it is advised each centre holds 1-3 sessions for 12-16 patients at a time (1 hour) each month (depending on capacity of clinic).
- Minimum content of patient training and additional resources have been advised in supplementary documentation.
- Basic information for primary care prescribers (how to use device is covered in a supplementary sheet, with links to instructional videos that are publicly available from Abbott for Freestyle Libre). Additional online material is available via Abbott's website.

Supplementary documentation on training recommendations includes:

- Initiating clinicians must be able to:
- Continuing prescribers must be able to:
- Patients must be able to:

All documents highlighted above can be found here: <http://www.londonscn.nhs.uk/networks/cardiovascular/diabetes/freestyle-libre/>

9. Future reviews and recommendations

The London Diabetes Clinical Network recognises that flash glucose monitoring is a novel and innovative device and encourage local organisations to consider the recommendations above for the benefit of groups of patients, as specified previously.

The network is also aware that there are other potential groups of patients who may benefit that are not included in these recommendations. The network would emphasise that this guidance is suitable for the initial roll-out of flash prescribing, and later reviews may include additional groups, as and when more data becomes available.

The network also recognises that if the price falls, or other similar devices come to market, then the place of flash in the pathways above should be reviewed in line with any new information.

10. Supplementary documents

Additional supplementary documents available:

- Estimated numbers for the region and associated costings for each recommendation
- Shared care/transfer of care documentation and patient-prescriber agreement (as per section 3)
- Recommended additional information for patients (beyond user training) including sensor adhesion guide, what to do if a sensor falls off, disposal guidance, etc.
- Detailed training recommendations