Implementation of Freestyle Libre® prescribing guidance across the NHS in North Central London

Contents

Additional supplementary paperwork:

- Patient Frequently Asked Questions (FAQ)
- NCL Position Statement (inc roles and responsibilities for primary and secondary care)
- Patient-prescriber agreement (complete after training session)
- Training pack for health care professionals and patients delivered by Abbott
- Information sheet for primary care and community pharmacies
- Recommended competencies for initiating clinicians, patients and continuing prescribers

Section 1 – Background to the document

1.1 Background to the North Central London implementation recommendations

NHS London Procurement Partnership (LPP) were asked to facilitate the production of a pan-London clinical consensus for the use of FreeStyle Libre in the NHS at the London Chief Pharmacist and CCG lead meeting on the 28th of September 2017.

An interim advice document was then written and agreed with senior members from the NHSE London diabetes clinical networks and the Children and Young People's South East Coast & London Diabetes Network, as well as stakeholders within LPP's Responsible Diabetes Prescribing Group (RDPG). This was published on the 13th of October 2017. The key recommendation from this was the following: *Prescribers in primary care should not prescribe Freestyle Libre sensors on an NHS prescription until the Freestyle Libre device has been evaluated and approved for use through local governance processes.*

On the 1st of November, a national position statement was issued by the NHSE Regional Medicines Optimisation Committee (RMOC): https://www.sps.nhs.uk/articles/regional-medicines-optimisation-committee-freestyle-libre-position-statement/

The diabetes clinical networks in London had several discussions regarding the use of Freestyle Libre in London both before and after the RMOC statement. Post publication, they met on the 3rd of November and discussed the statement and made a number of suggestions regarding how this could be implemented in London. This was fed back to the London RMOC on the 9th of November by Vicky Chaplin (LPP) and the broad scope of how this could work was agreed.

In the context of clinical priorities and the configuration of services within the London Region, London RMOC members identified that more detailed implementation guidance is essential and recommended that the London Diabetes Clinical Network, working in collaboration with LPP, be approached to develop guidance within the next 3 months to support the implementation of FreeStyle Libre.

The LPP/LDCN guidance was amended for local use by the North Central London (NCL) 'Freestyle Libre Implementation Group' which included consultant and/or diabetes specialist nurse membership from both adult and paediatric diabetes services from each Trusts, an RMOC member, NCL CCGs and NEL CSU.

1.2 What is FreeStyle Libre?

The FreeStyle Libre 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), Freestyle Libre 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 the 1st of November 2017.

1.3 Quality assurance

Abbott 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

1.4 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.

1.5 Is this a replacement for finger prick blood glucose testing?

As FreeStyle Libre 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,
- 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 Freestyle Libre, if Freestyle Libre is prescribed.

1.6 Notes on the use of SMBG testing alongside Freestyle Libre

The Freestyle Libre reader device has the option to be used 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 Freestyle Libre system. 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.

1.7 Does this device have alarms?

Caution should be noted for those with hypoglycaemia unawareness and/or frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily

activities, as Freestyle Libre will not provide warnings or alarms about low or high glucose levels.

1.8 Who will be prescribing this?

Initiation should only be carried out by the local NHS specialist diabetes team. Specialist centres available will vary locally and may comprise either secondary or both secondary and intermediate care services.

Specialist centres can transfer prescribing responsibility to GPs after 6 months on treatment for patients who reach their pre-specified target outcomes.

1.9 Which groups of patients are eligible?

The device is initially indicated for use in people with type 1 diabetes, under specialist care, using multiple daily injections (MDI - 4 or more doses of insulin a day) or insulin pump therapy, as per the RMOC statement released in November 2017. The specific cohorts of patients within this group are detailed in the recommendations below.

1.10 How was this guidance formulated?

Expert opinion on local implementation of the RMOC statement was sought from the NHSE London diabetes clinical networks (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.

1.11 Summary of recommendations

The consensus from clinical colleagues regarding the safe and effective implementation of the RMOC national position statement, was that recommendations should be reviewed and presented in relation to their potential position in existing treatment pathways. This approach has resulted in displaying the five RMOC recommendations as three distinct groups/treatment areas:

1. **Recommended implementation of Freestyle Libre prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently and where the use of Freestyle Libre may facilitate a safe reduction in test strip usage of 8 (adults) or 7 (children and young adults aged 4-19 years) strips per day.**
2. **Recommended implementation of Freestyle Libre prescribing for patients with type 1 diabetes with HbA1c ≥8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per TA151 (plus additional notes on those who can be considered for continuous glucose monitoring as per NG17 and NG18).**
3. **Recommended implementation of Freestyle Libre prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing.**

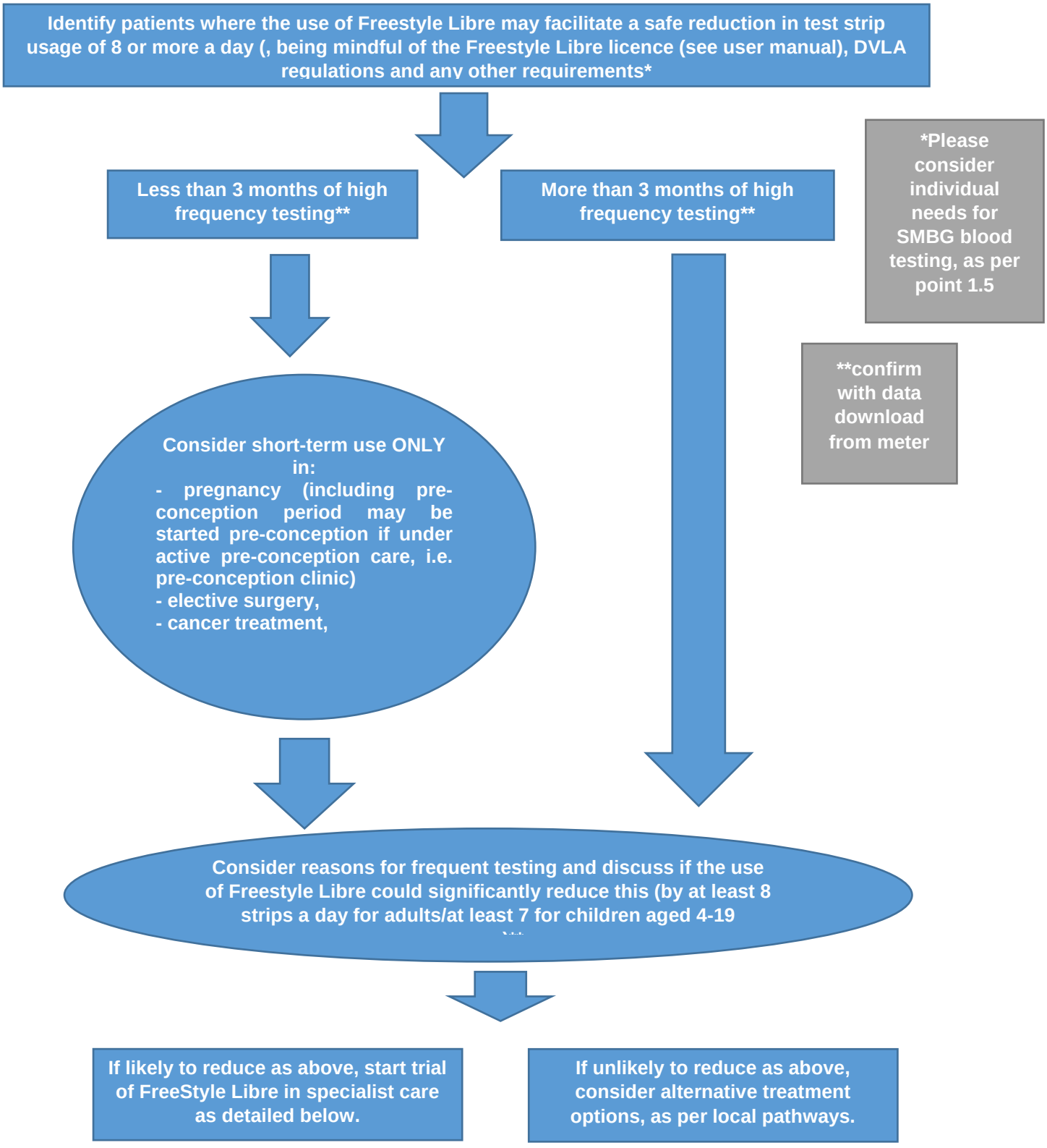
Reference 1. Association of British Clinical Diabetologists Information to help a formulary case for Freestyle Libre System published 13th October 2017 accessed at https://abcd.care/getting-freestyle-libre-your-formulary

Reference 2. NICE FreeStyle Libre 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

Section 2 – Implementation guidance pathways

Criteria 1: **Recommended implementation of Freestyle Libre prescribing for patients with type 1 diabetes on MDI or insulin pump therapy who test frequently and where the use of Freestyle Libre may facilitate a safe reduction in test strip usage of 8 (adults) or 7 (children and young adults aged 4-19 years) strips per day**



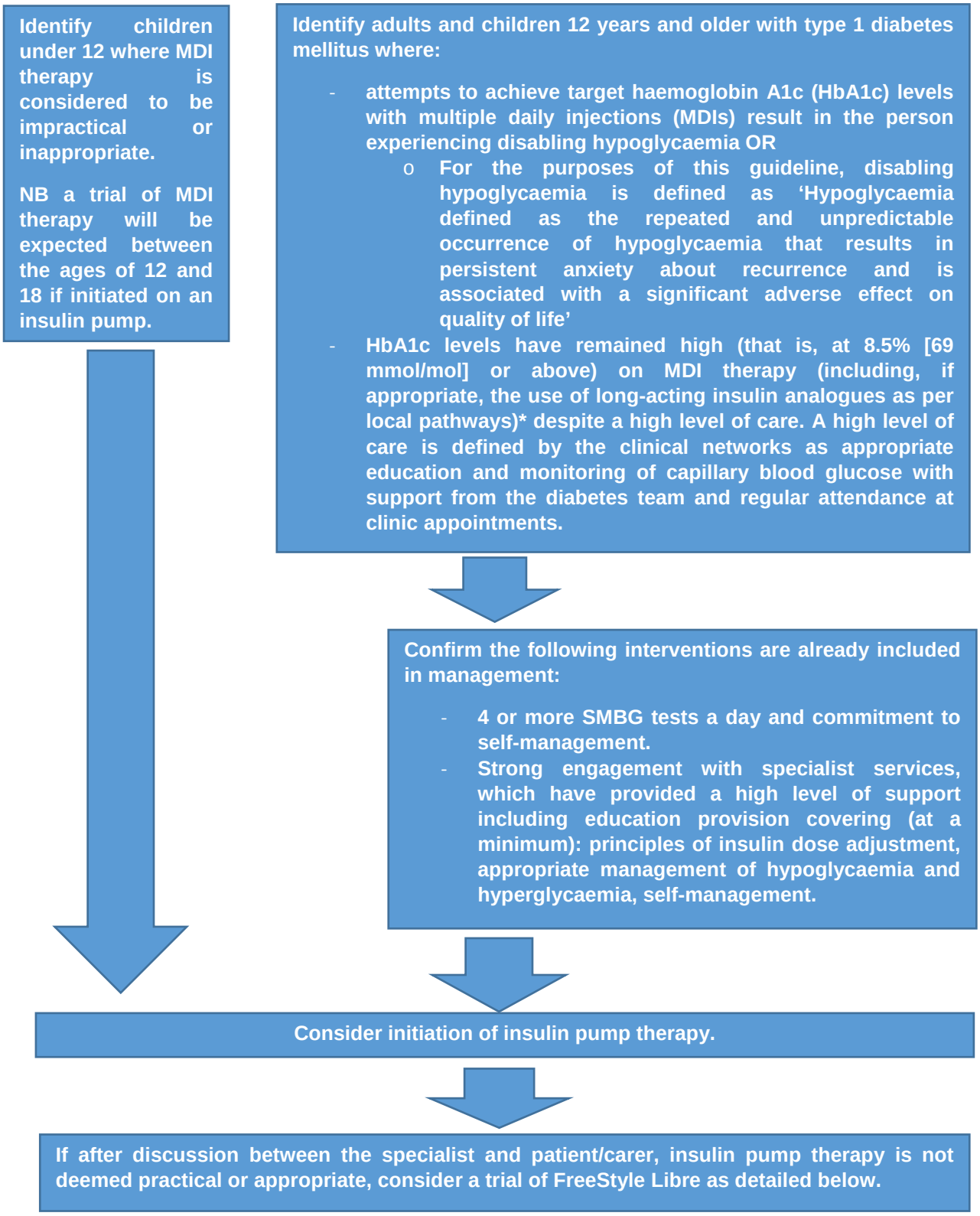
a) **Outcome for review** - If Freestyle Libre is initiated for the above indication, the intention should be to reduce test strips by at least 8 strips a day (7 in children aged 4-19 years). If this is not achieved by 6 months prescribing may be discontinued and this should be discussed and agreed with the patient at initiation (see patient-prescriber agreement).

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 clinic letter from the specialist team. The specialist will continue to review the use of Freestyle Libre the average reduction in SMBG test strip usage at future clinic appointments. 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 frequent drivers) then Freestyle Libre is not suitable for prescribing under this recommendation (due to duplication of therapies as NCL recommends against substituting SMBG testing with Freestyle Libre before and during driving, as to do so would be in breach of DVLA requirements). 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 clinic letter, but may change depending on additional outcomes observed with the Freestyle Libre. Patients eligible for Freestyle Libre due to short-term high intensity testing (e.g. antenatal period) should have the time limited nature of Freestyle Libre provision explained at the point of initiation. It was agreed Freestyle Libre would be funded for 6 months postpartum, which is consistent with the approach in Hertfordshire and West Essex.

d) **Information for self-funders who identify as coming under this recommendation** – Prior to review in NHS specialist diabetes 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 Freestyle Libre on an NHS prescription (i.e. evidence of reduced usage of SMBG test strips as detailed above, following initiation of Freestyle Libre). Data (at least 6 months) for number of strips required prior to initiation, date of initiation and information on SMBG testing 6 months post initiation should be considered, wherever possible. If 6 months of prescribing data is not available (e.g. overseas patients), considerations should be given to delaying Freestyle Libre until there is evidence of long-term high use of SMBG testing. If patients fulfil criteria for NHS prescribing they will then continue to be reviewed as per the terms of this document.

Criteria 2: **Recommended implementation of Freestyle Libre prescribing for patients with type 1 diabetes with HbA1c ≥8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per TA151[1] – pathway for specialist initiation**



Reference 1. Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus Technology appraisal guidance [TA151] Published date: 23 July 2008.

a) **Outcome for review** - If Freestyle Libre is initiated for the above indication, the intention should be to reduce HbA1c by 0.6% (6.6mmol/mol) and/or sustained improvements in hypoglycaemia, as set by the responsible physician in discussion with the person receiving the treatment or their carer. The networks feel that if these outcomes are not achieved with Freestyle Libre, then consideration of other locally available and appropriate technologies should be revisited. Expected outcomes should be discussed by the specialist and patient at initiation and noted in the clinical records and patient-prescriber agreement.

b) **Suggested timeframe** – It is suggested that a review of outcomes should take place with the specialist team around 3-6 months after initiation.

c) **Key considerations** - The clinical networks discussed the place of Freestyle Libre in treatment pathways involving insulin pumps and CGM and considered where Freestyle Libre should feature. Whilst explicit commissioning policies are not in place across all of London, the need to comply with TA151 and provide the option to all eligible patients is clearly understood. They noted that the Freestyle Libre device is not a like-for-like alternative to pump therapy and patients eligible under TA151 should always be considered for an insulin pump if this is the most appropriate choice for the individual patient. There may be some circumstances where the patient and clinician feel that Freestyle Libre should be trialled prior to pump therapy.

   The networks would also like to emphasise that if a patient is suitable for CGM as per NICE guidance this should be considered and eligibility reviewed in line with local commissioning policies. Libre® is not a like-for-like alternative in regards to all features of currently available CGM devices (e.g. Freestyle Libre device does not have alarms) and should not be automatically substituted where CGM was previously considered. This is especially the case for patients with impaired awareness of hypoglycaemia, a history of severe hypoglycaemia, or frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities.

d) **Information for self-funders who identify as coming under this recommendation** – Patients who have used Freestyle Libre with the intention to reduce HbA1c (from at least 8.5% (69.4mmol/mol)) or to reduce disabling hypoglycaemia, are expected to have these documented in historical clinical records (ideally within the last year) and should be able to demonstrate sustained improvements (as per the outcomes detailed above) post initiation of Freestyle Libre over a period of 6 months or more. The specialist team will review these with the patient and confirm if prescribing can be continued on the NHS.

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

The clinical networks 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 NG17[1] (type 1 diabetes in adults) and NG18[2] (type 1 and type 2 diabetes in children and young people):

NG17[1] 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."*

NG18[2] 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.*

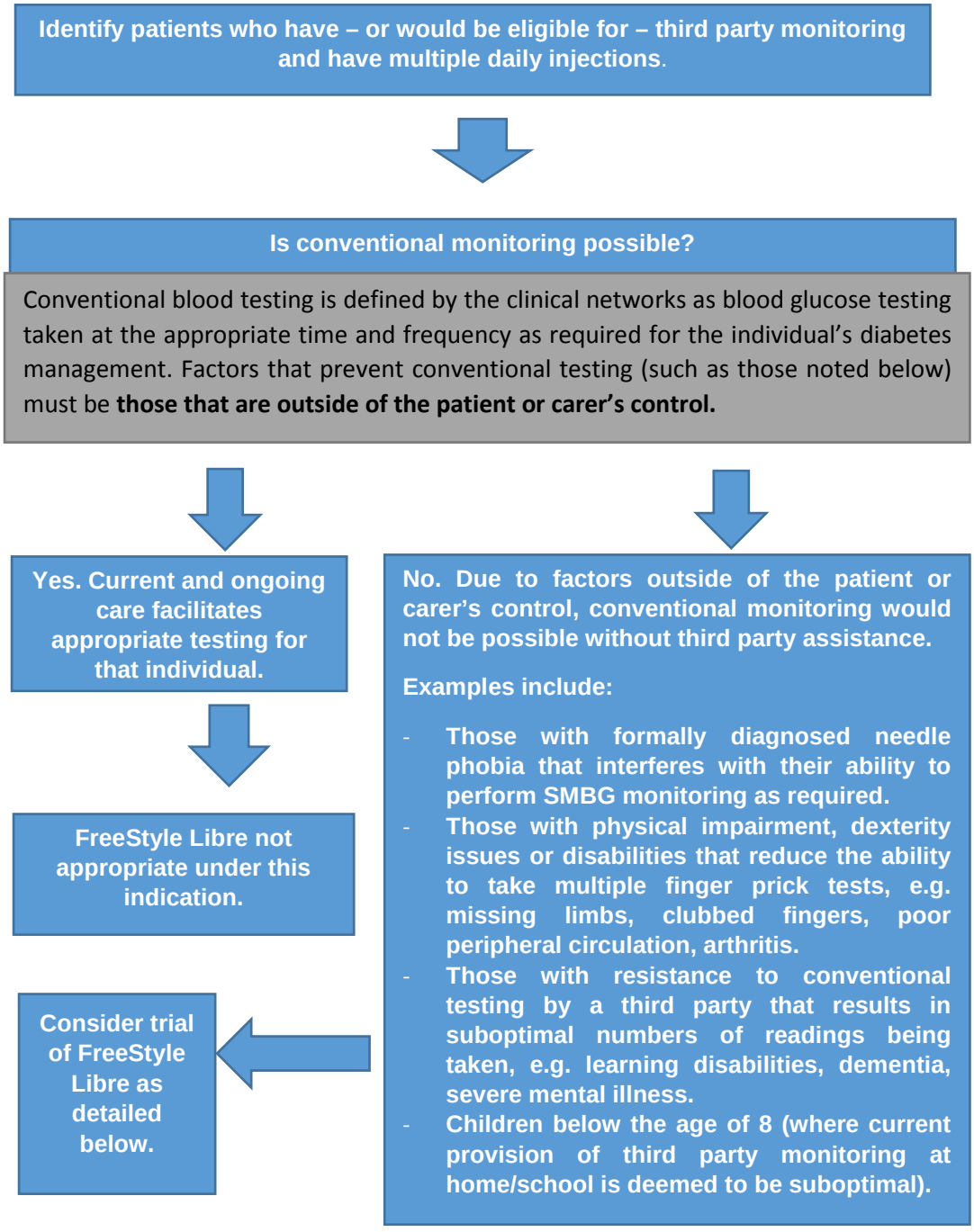
Consider intermittent (real‑time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support."

Freestyle Libre 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

Criteria 3: **Recommended implementation of Freestyle Libre prescribing for patients with type 1 diabetes on MDI or insulin pump therapy where conventional monitoring is not possible with SMBG testing – pathway for specialist initiation**



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

a) **Outcome for review** - If Freestyle Libre 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 Freestyle Libre. The level of monitoring agreed at initiation will be detailed in the initiation letter and reviews will take place in at the specialist clinic, to determine continuation of prescribing. A decision regarding continuation should be by 3 months however all prescribing must remain within the Trust for the first 6 months.

c) **Key consideration** – Freestyle Libre 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).
In regards to use in children, a defined age range is given of those below the age of 8, where current provision of third party monitoring at home/school is deemed to be suboptimal. The reasoning for this is that in many school situations there is full time support for children up to the end of Year 2 (infants). Glucose monitoring is undertaken for the child by the one to one carer, but provision of this will vary locally. After Year 2 (approximately the age of 8) care is gradually reduced so that by Year 6 the child is expected to be almost self-managing. In regards to continuation beyond 8 years, the specialist is expected to review progress regularly and communicate this with the GP practice. If Freestyle Libre is to be continued for reasons other than assisting monitoring beyond the age of 8 years (e.g. significant improvement in HbA1c) this may be considered for primary care prescribing, dependent on local agreement.

d) **Information for self-funders who identify as coming under this recommendation** – Prior to review in NHS specialist diabetes 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 Freestyle Libre. This data should inform discussions alongside considerations regarding the improvements seen in monitoring from the patient and/or carer's perspective.

Section 3 – Recommended review and prescribing timeline for all recommendations

Month	Activity	Paperwork required
Month -1	Initial discussion regarding Freestyle Libre and agreement between prescriber and specialist clinician.	Patient-prescriber agreement to be read through and discussed. Referral to in-house training session. Specialist care to complete Blueteq initiation form (see later section on data and monitoring).
Month 0	Group training session at specialist site. If patient wishes to continue, completion of training will result in supply of Freestyle Libre handset and sensor starter pack, plus 1 additional sensor. Complete and sign patient-prescriber agreement.	Notify GP of initiation of Freestyle Libre, by sending a paper copy of the completed patient-prescriber agreement.
Month 1	Patient to attend specialist centre for initial usage review (recommended in original training group), OR via telephone consultation, to discuss any potential issues with the technology. If continuation agreed, three further months of sensors (6 sensors) to be supplied from specialist care.	Prescription for 6 sensors from specialist centre delivered to pharmacy.
Month 3-4	Patient to confirm ongoing need for Freestyle Libre via telephone consultation, email, or at specialist centre if attending for routine DSN review. If continuation agreed, two further months of sensors (4 sensors) to be supplied from specialist care.	Prescription for 4 sensors from specialist centre delivered to pharmacy.
Month 6	Patient to attend specialist centre for review of outcome achievement and formal request for long-term prescribing.	Specialist care to complete Blueteq continuation form irrespective of outcome. If continuation confirmed, specialist care to request GP to commence long-term prescribing of Freestyle Libre and send a paper copy of the completed Blueteq continuation. Set up of repeat prescription in primary care, if applicable.
Month 18	Review annually thereafter	Specialist care to complete follow-up Blueteq form and send a paper copy to the GP.

Section 4 – Ordering information

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

The 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. The prices are as follows:

Community pharmacies £35.00 - using pharmacy portal
: https://www.freestylelibrepharmacyportal.co.uk/

Outsourced outpatient pharmacies £35.00 - using pharmacy portal: https://www.freestylelibrepharmacyportal.co.uk/

NHS Hospital Trust pharmacies £35.00 plus VAT - using pharmacy portal: https://www.freestylelibrepharmacyportal.co.uk/

NHS LPP and the network have enquired regarding procurement of stock and have been informed that procurement teams can order at £48.29 plus VAT, via a Purchase Order should be sent to abbott.freestylelibre@nhs.net Abbott have confirmed they are not currently exploring discount schemes, either nationally or regionally.

Section 5 – Data collection

The London diabetes clinical networks are keen to review real-life data at a regional level and have therefore provided short forms to be completed for regional review. These forms have been digitised and incorporated in to the Blueteq system. NEL CSU will extract data from Blueteq every quarter and submit to LDCN for analysis.

All data collection will take place in specialist care. The time and resource pressure was noted but deemed to be unavoidable in order to contribute to increased data on this device to facilitate regional review. It was decided that the initiation form must be completed at the initial training session and then follow-up form completion is recommended at the next clinic appointment (3-6 months), at 12 months and then annually thereafter.

Section 6 - Expected outcomes

In order to gain maximum benefit from the device, sensors should be worn continuously (one sensor for each consecutive 14 day period) and ideally, scans should be undertaken to provide 24/7 readings (each scan provides 8 hours of data). At a minimum the sensor must be scanned at least four times per day for contemporaneous readings and it is anticipated that the scans taken will be at appropriate intervals to provide continuous glucose levels covering 20-24 hours per day, every day.

Following review, continuation of therapy is only indicated if predetermined outcomes have been observed (depending on initial indication and agreement between the patient and clinician at initiation), which are summarised below. This will ensure that treatment is appropriate and tailored to individual patients:

- A substantial reduction in test strip usage must be seen if the device has been initiated under recommendation 1.
- An improvement in clinical outcomes (as defined for individual) must be seen if initiated under recommendation 2.
- Appropriate monitoring of glucose levels for the individual patient must be observed if initiated under recommendation 3.

Other benefits or outcomes that may be observed include:

- improved quality of life,
- better glycaemic control during acute periods (e.g. pregnancy, surgery)
- improved monitoring for parents (e.g. during school, sleep)

The use of Freestyle Libre may result in improved management, which can theoretically lead to a reduced HbA1c, a reduction in hypoglycaemic episodes, reduction in admissions, etc. Initiating specialist centres must ensure data collection forms are completed as appropriate to ensure that these can be reviewed at a later date to facilitate a review of this implementation guidance. NB Please note, a reduction in the use of test strips does not automatically result in improved clinical outcomes.

If the agreed benefits and outcomes have not been achieved by 3-6 months, the initiating team and patient should have a discussion as to why this may not be. If it is agreed that it is unlikely any further improvements will be seen, then the use of Freestyle Libre should be discontinued, as per the terms in the patient-prescriber agreement.

As more data is collected, this guidance may be reviewed at a later date to include further information on expected clinical outcomes.

Section 7 - Exclusions for prescribing of Freestyle Libre

Freestyle Libre may NOT be suitable in some circumstances, even if the patient meets the requirements of the listed indications. Consider alternatives to monitoring with Freestyle Libre 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 Freestyle Libre.

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

NB the use of Freestyle Libre 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.

Section 8 – Training recommendations

There are currently 27,145 people with type 1 diabetes in London (NDA 16/17). 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 clinical networks have liaised with Abbott to ensure this is provided in a fair and timely manner (as well as reviewing content).

This device must only be initiated in specialist care and therefore clinic resources will stagger uptake across the region. LPP/LDCN recommend 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. Trust delegates from the NCL Freestyle Libre Implementation Group have agreed to introduce Libre at a rate described below:

04 Speed of uptake, Libre costs & data provided by

	Adults					Paediatrics				
	NMUH	RFL - Hamp	RFL - BCF	UCLH	WH	NMUH	RFL - Hamp	RFL - BCF	UCLH	WH
Planned number of patients trained per month	10	6	6	12	10	10	10	8	10	10
Planned number of **NCL** patients trained per month	10	4	4	8	9	10	9	6	4	10

The networks 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. A patient contract and position statement 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 clinical networks have discussed and agreed key topics for inclusion in training sessions at each level.
- The content for specialist training by Abbott 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 the information sheet and position statement. Additional online material is available via Abbott's website.

Supplementary documentation on training recommendations are available for:

- Initiating clinicians
- Continuing prescribers
- Patients

All documents highlighted above can be found here:

https://www.ncl-mon.nhs.uk/faqs/flash_glucose_monitoring/

Section 9 - Funding of Libre

By completing a Blueteq initiation form for a specific patient, Trusts ensure they will be reimbursed for Freestyle Libre they provide, on the proviso the patient meets the agreed eligibility criteria. Trusts should seek reimbursement from CCGs via their established process for high cost drugs. To enable this process clinicians are required to issue a prescription and the sensors dispensed by pharmacy.

Section 10 - Faulty devices

If a sensor fails before the end of its 14 day life, patients should call the Abbott customer care line (these details are given to patients during training sessions run by specialist teams and are present on product packaging).

The patient should inform the care line that they are receiving the sensors on prescription and the care line will investigate any fault. If the sensor is faulty it will be replaced. If the sensor is not faulty but is inoperable (e.g. it has fallen off), Abbott can still replace the sensor, up to a limit of 3 sensors in a 90 day period.