North Central London
Joint Formulary Committee

FreeStyle Libre® for glucose monitoring: Position Statement

GPs should not initiate FreeStyle Libre sensors on the NHS.

NHS diabetes specialist teams will assess both new and existing patients for the NHS provision of Freestyle Libre at their next routine follow-up appointment.

New patients will undergo a trial period with Freestyle Libre. Patients will receive their first 6 months' supply from their NHS diabetes specialist team with prescribing responsibility transferred to GPs if the NHS diabetes specialist team feel this is appropriate and the GP is in agreement. The assessment of effectiveness of Freestyle Libre is the responsibility of the NHS diabetes specialist team.

GPs should only prescribe FreeStyle Libre sensors if the patient's NHS diabetes specialist team has confirmed they meet the approved eligibility and continuation criteria (this includes new patients and established patients who were previously self-funding).

Only patients with type 1 diabetes who are not under the care of an NHS diabetes specialist service need to be referred if requesting or could benefit from FreeStyle Libre.

FreeStyle Libre is not recommended for patients with type 2 diabetes.

FreeStyle Libre measures glucose levels via a sensor as an alternative to routine finger-prick blood glucose testing. Finger-prick testing remains necessary for driving and monitoring during acute illness or hypoglycaemic episodes.

Background

- FreeStyle Libre measures glucose levels from a sensor applied to the skin as an alternative to routine finger-prick blood glucose testing, and can produce a near-continuous record of measurements which can be accessed on demand. FreeStyle Libre does not provide real-time continuous glucose monitoring or a hypoglycaemia alarm.[1]
- FreeStyle Libre is not a complete substitute for blood glucose testing as finger-prick testing is still required for patients using a bolus calculator, during times of rapidly changing glucose levels (i.e. acute illness), if hypoglycaemia is reported, if impending hypoglycaemia is reported, or if symptoms do not match the system reading. Finger-prick testing is also required prior to and during driving to meet current DVLA requirements.[2]
- NICE has not issued guidance on the use of FreeStyle Libre; it issued a 'Medtech innovation briefing' which summarised the costs, evidence base and perceived benefits, however, it did not include a recommendation.
- The NHS England 'Regional Medicines Optimisation Committee' (RMOC) produced a national position statement on the use of Freestyle Libre.[3]

- NHS London Procurement Partnership (LPP) and the London Diabetes Clinical Network (LDCN) have worked in collaboration to safely and effectively implement the RMOC national position statement. This work has subsequently been adapted for use in North Central London; and the full NCL implementation guide is available on the NCL website.

Eligibility criteria for NHS funding of Freestyle Libre

Assessment and initiation of patients on FreeStyle Libre will be done by **NHS diabetes specialist teams ONLY** for the following patients:

1) Patients with type 1 diabetes 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, being mindful of circumstances where patients still need to use finger-prick testing (see 'Background' section above).
2) Patients with type 1 diabetes with HbA1c ≥8.5% (69.4 mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy.
3) Patients with type 1 diabetes on multiple daily injections or on insulin pump therapy where conventional monitoring with finger-prick blood glucose testing devices is not possible due to factors outside the patient or carer's control.

The NHS diabetes specialist teams will be responsible for monitoring and recording the effectiveness of FreeStyle Libre; a data collection form has been built into the Blueteq forms to support this. If a GP has concerns about effectiveness of Freestyle Libre for an individual patient they should contact the NHS specialist diabetes team.

Responsibilities for GPs

- Referrals:
  - Do not refer patients with type 1 diabetes who are already under an NHS diabetes specialist service for the sole purpose of initiation of Freestyle Libre, they will be seen in time at their next routine appointment.
  - Refer patients with type 1 diabetes who are not under the care of an NHS diabetes specialist service who request Freestyle Libre, or who may benefit from the device, provided you feel the patient fulfils the NHS eligibility criteria.
  - Do not refer patients with type 2 diabetes for initiation of Freestyle Libre.
- Prescribing:
  - Do not initiate Freestyle Libre for any patient, initiation should be carried out by the NHS specialist diabetes team. Patients will obtain their first 6 months supply of Freestyle Libre from the NHS specialist diabetes clinic.
  - Only prescribe Freestyle Libre sensors if the patient's diabetes specialist team has confirmed the patient meets the approved eligibility and continuation criteria (this includes new patients and patients who were already self-funding).
  - Sensors that fall off/malfunction **should not** be replaced on prescription – Abbott should be contacted directly by the patient and they will send out a replacement.
  - Prescribe sufficient quantities of SMBG test strips, where relevant, as advised by the NHS diabetes specialist team
- Expected communication from NHS specialist diabetes team to GP:
  - At initiation: Notification via clinic letter of patient eligibility, trial initiation and expected patient outcomes. Include a copy of the patient-prescriber agreement.
  - At assessment for long term continuation (typically 6 months):
    - If trial successful: requests for GP to continue prescribing Freestyle Libre with clinical information confirming that the continuation criteria has been met (typically a copy of the 'continuation' audit [Blueteq] form)

        - If trial unsuccessful: notification of discontinuation of Freestyle Libre and not to be prescribed in primary care.
    - Annually thereafter: Notification of confirmation of continued benefit following annual review
- Training:
    - Learn about the FreeStyle Libre system; a one page summary is available
    - Recommended competencies for GPs continuing Freestyle Libre prescriptions are available via the LDCN website.
    - Patients unable to effectively use the device should be referred back to the initiating NHS diabetes specialist team

Responsibilities for NHS diabetes specialists

- Initiation:
    - Initiate in accordance with the North Central London FreeStyle Libre prescribing implementation guidance; including patient-prescriber agreement and 'initiation' Blueteq form
    - Send a copy of the patient-prescriber agreement to the patient's GP
    - Provide information to GP on prescribing quantities for SMBG test strips, where relevant
    - Provide patient with training and information, and ensure they are competent to use FreeStyle Libre
    - Provide FreeStyle Libre handset, sensor starter pack and one additional sensor at initiation
- Supplying sensors
    - Supply sensors for the first 6 months of treatment
- Clinic review
    - Monitor and review progress of clinical outcome criteria as described for the individual patient for 6 months after initiation of Freestyle Libre
    - Discontinue Freestyle Libre if the agreed benefits and outcomes not achieved at 6 months or if patient DNA clinic appointments for review.
    - Complete 'continuation' Blueteq form for all patients (including those who should not continue) so this data is captured and can be analysed
- Communication to GP:
    - On initiation: Notify the GP of patient eligibility, trial initiation and expected patient outcomes. Include a copy of the patient-prescriber agreement.
    - At 6 months: Notify the GP with outcome of the patient assessment (supply copy of 'continuation' Blueteq form) and detail whether the patient requires long-term prescribing of Freestyle Libre in primary care
    - At any time point: Notification of confirmation of continued benefit following annual review or prompt communication with the GP if treatment is changed
- For patients who met the approved eligibility criteria, have self-funded Freestyle Libre for ≥6 months and meet the approved continued criteria, it is reasonable to ask their GP to take on long-term prescribing without a hospital supply. In such cases, specialists should complete the 'initiation' and 'continuation' Blueteq forms and send a copy of the continuation form to the GP.

Responsibilities for patients

- Understand their responsibilities as outlined in the patient-prescriber agreement
- Wear the sensor continuously and scan at least four times per day, providing 20-24 hours of continuous glucose readings per day
- Participate in follow up clinic or telephone appointments at month 1, month 3-4, month 6 and at least annual appointments thereafter
- Inform the NHS diabetes specialist clinic if they have any problems in the use of FreeStyle Libre
- Contact Abbott customer care for a replacements sensor if it falls off within 14 days or malfunctions

Disclaimer

This document includes extracts from LPP/LDCN materials produced for Freestyle Libre.

References

1. National Institute for Health and Care Excellence. MIB110: FreeStyle Libre for glucose monitoring. (2017). Available at: https://www.nice.org.uk/advice/mib110/chapter/Summary. (Accessed: 25th September 2017)
2. The East of England Priorities Advisory Committee. Guidance Statement - FreeStyle Libre Glucose Monitoring System. PAC interim recommendations. (2017).
3. NHS England. Regional Medicines Optimisation Committee FreeStyle Libre Position Statement: Flash Glucose monitoring System RMOC Statement final. (2017).

Groups / Individuals who have overseen the development of this guidance:	Haringey CCG, Barnet CCG, Camden CCG, NCL JFC Support
Groups which were consulted and have given approval:	NCL Libre Working Group, NCL CCGs
File name:	NCL Freestyle Libre_Position Statement_V3.0_FINAL.Docx
Version number:	V3.0
Available on:	NCL MON website
Disseminated to:	All Trusts and CCGs in NCL
Equality impact assessment:	Low
NCL Joint Formulary Committee Approval date:	December 2018
Review date:	December 2021