Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Flash Glucose Monitoring
Position Statement

This statement covers the use of Flash Glucose Monitoring devices for use in adults, young people and children, current examples include both the Freestyle Libre and Freestyle Libre 2 sensors.

NTAG recommends Flash Glucose Monitoring as a diabetes specialist initiated option for glucose monitoring in the North East and North Cumbria for patients as follows:

NTAG Approved Criteria Flash Glucose Monitoring (23rd February 2021)

NTAG only recommends the use of Flash Glucose Monitoring for:

1. For those with Type 1 diabetes and recurrent severe hypoglycemia or impaired awareness of hypoglycemia, 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.

   NTAG recommend consideration of use in the following circumstances::
   - 2 or more admissions with diabetic ketoacidosis or 2 or more episodes of hypoglycaemia requiring third party assistance (per year) as per the previous Regional Medicines Optimisation Committee (RMOC) criteria.
   - Those who meet the current NICE criteria for insulin pump therapy (HbA1c 69.4mmol/mol (>8.5%) or disabling hypoglycaemia as described in NICE TA151) where a successful trial of Flash Glucose Monitoring may avoid the need for pump therapy as per the previous Regional Medicines Optimisation Committee (RMOC) criteria.

2. OR with any form of diabetes on hemodialysis and on insulin treatment

Who, in either of the above, require intensive monitoring with recurrent hypoglycaemia , as demonstrated on a meter download/review over the past 3 months

3. OR with diabetes associated with cystic fibrosis on insulin treatment

4. Those with pre-existing diabetes (type 1 & type 2) on insulin who are actively trying to conceive or are currently pregnant.

   Total duration of Flash Glucose monitoring under these criteria will be for 12 months in total: inclusive of pregnancy and the immediate post-partum period. Thereafter; patients will be expected to return to their previous method of blood glucose testing

   (Patients developing gestational diabetes are excluded from this recommendation)

5. 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.

6. 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 Flash Glucose Monitoring with appropriate adjunct support.

7. 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.

8. People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.

Use of Flash Glucose Monitoring devices in Type 2 diabetes (other than within criteria 2, 4 and 8 in this document) is not recommended.

Existing patients started on Flash Glucose Monitoring under previous RMOC or NHS England criteria remain eligible provided they continue to meet the agreed criteria for continuation.

Other requirements:
1. Education on Flash Glucose Monitoring has been provided (online or in person)

2. Agree to scan glucose levels no less than 3 times per day and use the sensor >70% of the time. 'The frequency of scans should be guided by outcome measures such as a reduction in hypoglycaemia (time below range) or improvement in time in range based on individual targets set jointly with the patients diabetes specialist team. A minimum of 3 scans per day is required (every 8 hours) in order to capture all glucose data. Sensor use of more than 70% is required to facilitate good diabetes management'

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)

Note:
Continuing prescription for long-term use of Flash Glucose Monitoring-post initial 6 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 events such as DKA or hypoglycaemia; or improvement in psycho-social wellbeing.

The decision to start Flash Glucose Monitoring for an initial 6 month trial period can only be made by the diabetes specialist. The specialists are responsible for providing 2 sensors with the reader (reader not available on prescription) and the necessary education, then communicating via the standard letter to the GP for ongoing prescriptions. The provision of two sensors is to allow the relevant communications to go out to practices and to stop patients chasing practices immediately for their next supply. The specialist will write to patent's GP practice requesting that they continue to prescribe and confirm which criteria the patient meets for initiation along with 6-month review date.

At 6 months the patient will be reviewed by the diabetes specialist and will only continue to receive flash glucose monitoring if they meet criteria listed in the NTAG statement, the specialist will communicate the outcome of this 6-month review to the patient's GP.

Patients to be informed that if they do not continue to meet criteria then prescribing will be stopped.
Continuing prescription for long-term use of Flash Glucose Monitoring-post initial 6 months-would be contingent upon evidence of:

- **The frequency of scans should be guided by outcome measures such as a reduction in hypoglycaemia (time below range) or improvement in time in range based on individual targets set jointly with the patients diabetes specialist team. A minimum of 3 scans per day is required (every 8 hours) in order to capture all glucose data. Sensor use of more than 70% is required to facilitate good diabetes management.**
- **Attend regular reviews with the local clinical team.**
- **Previous attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally).**
- **Demonstrably improving an individual's diabetes self-management based on NHSE criteria- for example improvement of HbA1c or Time In Range; improvement in events such as DKA or hypoglycaemia; or improvement in psycho-social wellbeing. Or RMOC criteria:**
    1. Reductions in severe/non-severe hypoglycaemia
    2. Improvement of impaired awareness of hypoglycaemia
    3. Episodes of diabetic ketoacidosis
    4. Admissions to hospital
    5. Improvement in HbA1c
    6. Testing strip usage
    7. Quality of Life changes using validated rating scales.
    8. Commitment to regular scans and their use in self-management

Ongoing use should be assessed annually thereafter.

Good practice for diabetes services to audit their use of flash glucose monitoring to ensure compliance with NTAG guidance and provide ongoing evidence of outcomes within their service.

In those patients with pre-existing type 1 diabetes who previously self-funded their own Flash Glucose Monitors review of the individuals' clinical history by those practitioners with active clinical responsibility will be required. If following this review the available evidence suggests that they would have satisfied one or more of the NHSE 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 will be entitled to NHS prescriptions

Adjunct blood glucose testing strips should continue to be prescribed based upon individual patient needs and according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced.

Used sensors should be disposed of in a sharps bin. 4L and 7L Sharpsafe disposal bins need to be available for the safe disposal of diabetes devices as per device company advice. This can be prescribed on an FP10 prescription by the GP. The collection and disposal of the full bins should be as per local arrangements applicable to that CCG/local authority.

It is recommended that the regionally agreed letter template be used when by specialists when asking the GP to prescribe following initiation.

Flash Glucose Monitoring System, has been available to prescribe since 1st November 2017 following the inclusion of the FreeStyle Libre® device in the Drug Tariff. Freestyle Libre was the first available Flash Glucose Monitoring System.

FreeStyle Libre is an innovative blood glucose monitoring device which removes the need for frequent finger-prick testing by utilising an in-situ sensor worn on the patient's arm and a handheld "flash" monitoring device which, if regularly used to scan the sensor, can track blood glucose trends as well as give the current reading. Further information is available from NICE's Medtech Innovation Briefing.

The Regional Medicines Optimisation Committee (North) has made a recommendation on the cost-effective use of FreeStyle Libre, published on 1st November 2017. This position was endorsed by the Northern Treatment Advisory Group (NTAG) meeting on the 21st of November 2017 for patients in the North East and Cumbria.

NHS England published national criteria for Flash Glucose Monitoring Reimbursement from 1st April 2019 on the 7th March 2019, and amended on 3rd November 2020. This position was endorsed by the Northern Treatment Advisory Group (NTAG) for patients in the North East and Cumbria.

On the 23rd February 2021 use in type 1 women trying to conceive, type 2 pregnant women, and further information around use in patients with high HbA1C at was approved by NTAG. Also changed to refer to Flash Glucose Monitoring throughout rather than Freestyle Libre

Currently available and NTAG approved Flash Glucose Monitoring Device as of February 2021:

Device	Cost (Drug tariff Feb 2021)	Comments
Freestyle Libre	£35 per sensor*	
Freestyle Libre 2	£35 per sensor*	• Has optional glucose alarms to let patients know when glucose levels are too or too low. • Bluetooth connectivity. • FreeStyle Libre 2 Sensors are not interchangeable with FreeStyle Libre Sensors and require a different reader. • Available from January 2021.

*each sensor lasts 14 days.

From 1st January 2021, all new users will be provided the FreeStyle Libre 2 system. There is no change to the tariff price or cost impact of making this change.

What is the process for existing Freestyle Libre users switching to FreeStyle Libre 2?
The specialist diabetes team will be informing patients at their next routine appointment and they will receive information on any updated functionality. The patient will also be informed to use any existing **sensors they have** prior to starting the updated product. The specialist diabetes team will contact the GP practice to request a prescription change to the Freestyle Libre 2 sensor.

The FreeStyle Libre 2 sensor can be scanned with either the free, FreeStyle LibreLink app4 or with a FreeStyle Libre 2 reader. However, patients choose which device they want to receive alarms: FreeStyle Libre 2 reader or FreeStyle LibreLink app. They must start their FreeStyle Libre 2 sensor with that selected device. Once the patient scans their FreeStyle Libre 2 sensor with that device, they can receive alarms only on that device.
Existing patients using FreeStyle Libre that do not have a compatible phone to download the FreeStyle LibreLink app will need to request a new Reader. Users can request a new FreeStyle Libre 2 reader free of charge from Abbott.
The preferred option locally is for patient to use the FreeStyle LibreLink app.

Criteria for NHS England Flash Glucose Monitoring Reimbursement Until 31st March 2021

1. People with Type 1 diabetes

   OR with any form of diabetes on hemodialysis 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 post-delivery 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 hypoglycemia or impaired awareness of hypoglycemia, 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.

7. People with Type 1 diabetes or insulin treated Type 2 diabetes who are living with a learning disability and recorded on their GP Learning Disability register.

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)

Note:

Continuing prescription for long-term use of Flash Glucose Monitoring-post initial 6 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.

References:
NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients. 3rd November 2020. Available at: https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/

Appendix 1 – Suggested Letter Template to GP re Switch to FreeStyle Libre 2

[INSERT LOGO]

[INSERT NHS TRUST CONTACT DETAILS]

Dear Doctor,

Re: FreeStyle Libre 2 system *Repeat prescription amendment required*

Your patient is currently prescribed the *FreeStyle Libre flash glucose monitoring system* in line with the local prescribing policy.

We would like to bring to your attention that the '*FreeStyle Libre 2 flash glucose monitoring system*' is now available on the NHS BSA Drug Tariff. From 1st January 2021, all new users will be provided the FreeStyle Libre 2 system. There is no change to the tariff price or cost impact of making this change.

All existing users will also be upgraded over the coming months. The specialist team will be informing patients at their next routine appointment and they will receive information on any updated functionality. The patient will also be informed to use any existing sensors they have prior to starting the updated product.

Please can we request that the repeat prescription record is updated as follows:

Please ensure that the previous prescription of FreeStyle Libre sensors [PIP: 405-9028] is removed from the patient's repeat record.

FREESTYLE LIBRE 2

QUANTITY: 2 SENSORS / 28 DAYS (1 SENSOR LASTS 14 DAYS)

PIP CODE: 416-3416

[BLOOD GLUCOSE TEST STRIP BRAND]

[TEST STRIP QUANTITY + FREQUENCY]

[TEST STRIP PIP CODE]

[BLOOD KETONE TEST STRIP BRAND]

[TEST STRIP QUANTITY + FREQUENCY]

[TEST STRIP PIP CODE]

Thank you for your help,

Specialist Diabetes Team

Frequently Asked Questions

Indications for Use

The FreeStyle Libre 2 Flash Glucose Monitoring System is indicated for measuring interstitial fluid glucose levels in people (aged 4 and older) with diabetes mellitus, including pregnant women. The Reader and Sensor are designed to replace blood glucose testing in the self-management of diabetes, including dosing of insulin. The indication for children (aged 4-12) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the Reader and Sensor and also for interpreting or assisting the child to interpret Sensor glucose readings.

What are the differences between the FreeStyle Libre system and the FreeStyle Libre 2 system?

Just like the FreeStyle Libre system, the FreeStyle Libre 2 system is discreet, convenient and easy to use[1]. Because of its excellent accuracy[2,3], there's no need to prick your finger when using the FreeStyle Libre 2 system - even when glucose is low, falling or rapidly changing. However, finger pricks are required if glucose readings and alarms do not match symptoms or expectations.

The FreeStyle Libre 2 system also offers peace of mind when you need it most with three optional real-time alarms for those who need them. There is a Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm.

More information about the FreeStyle Libre 2 system: www.freestylediabetes.co.uk/update

Does the patient require a new reader to scan the FreeStyle Libre 2 sensor?

The FreeStyle Libre 2 sensor can be scanned with either the free, FreeStyle LibreLink app[4] or with a FreeStyle Libre 2 reader. However, patients choose which device they want to receive alarms: FreeStyle Libre 2 reader or FreeStyle LibreLink app. They must start their FreeStyle Libre 2 sensor with that selected device. Once the patient scans their FreeStyle Libre 2 sensor with that device, they can receive alarms only on that device.

Many patients choose to use the free, FreeStyle LibreLink app[4] to scan their sensor. These patients can continue to use their app to scan FreeStyle Libre 2 sensors, they do not need to download a new app. The patient must ensure that they have updated their app to the latest version (2.5) to enable additional functionality of the FreeStyle Libre 2 system.

Existing patients using FreeStyle Libre that do not have a compatible phone to download the FreeStyle LibreLink app will need to request a new Reader. Users can request a new FreeStyle Libre 2 reader free of charge from Abbott. They will need to provide the serial number of their current FreeStyle Libre reader; however, they will not be required to return this to Abbott.

From 5th January 2021, Reader replacements will be provided by Abbott free of charge, direct to patient. Healthcare professionals should direct their patients who need a FreeStyle Libre 2 reader to the online request portal:

www.freestylelibre.co.uk/replacement (Note: this page will not be live until 5th January 2021).

The Customer Careline is also available to support those patients unable to access the online portal: 0800 170 1177 (Mon-Fri 08:00 – 20:00, Sat 09:00 – 17:00 excl. bank holidays)

From 1st January 2021, Readers provided to new patients will be FreeStyle Libre 2 readers.

Where can I direct patients for further information?

- Educational material for patients and healthcare professionals can be accessed at: https://progress.freestylediabetes.co.uk/
- Product Information can be found at: www.freestylediabetes.co.uk
- User manuals: https://www.diabetescare.abbott/support/manuals/uk.html
- For additional support and troubleshooting, patients should contact the Customer Careline via:

  Email, Live Chat, Request a Call Back:

  https://www.freestylelibre.co.uk/libre/help/contact-us.html

  Phone:

  0800 170 1177 (08:00 – 20:00 Mon – Fri, 09:00 – 17:00 Sat – excl. bank holidays)

References

1. Data on file, Abbott Diabetes Care, Inc.
2. Alva S, et al. Accuracy of a 14-Day Factory-Calibrated Continuous Glucose Monitoring System With Advanced Algorithm in Pediatric and Adult Population With Diabetes. Journal of Diabetes Science and Technology. September 2020. doi:10.1177/1932296820958754.
3. Data on file, Abbott Diabetes Care, Inc.
4. Patients choose which device they want to receive alarms: FreeStyle Libre 2 reader or FreeStyle LibreLink app. They must start their FreeStyle Libre 2 sensor with that selected device. Once the patient scans their FreeStyle Libre 2 sensor with that device, they can receive alarms only on that device. The FreeStyle LibreLink app is only compatible with certain mobile devices and operating systems. Please check the website for more information about device compatibility before using the app. Use of FreeStyle LibreLink requires registration with LibreView

Appendix 2 - Suggested Letter Template - HCP to Patient re FreeStyle Libre 2

INSERT LOGO]

[INSERT NHS TRUST CONTACT DETAILS]

Dear Patient,

Re: Moving from FreeStyle Libre system to FreeStyle Libre 2 system

You are currently prescribed the FreeStyle Libre flash glucose monitoring system in line with the local prescribing policy. We would like to bring to your attention that the 'FreeStyle Libre 2 flash glucose monitoring system' is now available and you will be automatically moved over to it.

What is the difference between the FreeStyle Libre system and the FreeStyle Libre 2 system?

- **No finger pricks:** There's no need to prick your finger when using the FreeStyle Libre 2 system - even when glucose is low, falling or rapidly changing. However, finger pricks are required if glucose readings and alarms do not match symptoms or expectations and the current DVLA recommendations remains unchanged.
- **Excellent accuracy[1,2]:** Outstanding accuracy in the low glucose range when it matters most
- **Optional alarms:** Peace of mind when it's needed most, with three optimal real-time alarms for those who need them. There is a Low Glucose Alarm, High Glucose Alarm and Signal Loss Alarm.

What you need to do

STEP 1: Choose which device you want to receive alarms on:

IMPORTANT: You are not able to receive alarms on multiple devices. You need to choose which device you want to receive alarms, either the FreeStyle Libre 2 reader or a compatible phone with FreeStyle LibreLink. You must start your FreeStyle Libre 2 sensor with the device you want to receive alarms.

Using your mobile phone

Already have the app? No action required: You can continue to use your current app to scan FreeStyle Libre 2 sensors, you do not need to download a new app. Ensure you have updated your app to the latest version (2.5).

If you don't currently use the FreeStyle LibreLink app but would like to start: Download the app for free* on the App Store or Google Play store. Further details, including device compatibility can be found at: www.FreeStyleLibre.co.uk

*Internet connection is required to download the app. Data charges may apply.

Using a FreeStyle Libre 2 reader

Action:
Order a free of charge, FreeStyle Libre 2 reader from Abbott directly.
Order online: www.freestylelibre.co.uk/replacement
Or call Abbott customer service: 0800 170 1177
(Mon-Fri 08:00 – 20:00, Sat 09:00 – 17:00 excl. bank holidays)

STEP 2: Connect with your Diabetes Specialist Team on LibreView

If you are not already sharing your glucose data with your team via **LibreView**[ñ], it is important you do this so we can help you remotely.

Your Practice (*hospital*) ID is [XXXXXX]

App/phone users: Enter this Practice ID via the **FreeStyle LibreLink** app

Open FreeStyle LibreLink App > Menu > Connected Apps > LibreView (Manage) > Connect to a Practice > Enter Practice ID

FreeStyle Libre 2 reader users - Visit www.LibreView.com to sign up and follow the instructions on screen.

For more information & training on alarm functionality and the FreeStyle Libre 2 system visit: www.FreeStyleDiabetes.co.uk/progress

Yours,

Specialist Diabetes Team

1. Alva S, et al. Accuracy of a 14-Day Factory-Calibrated Continuous Glucose Monitoring System With Advanced Algorithm in Pediatric and Adult Population With Diabetes. Journal of Diabetes Science and Technology. September 2020. doi:10.1177/1932296820958754.
2. Data on file, Abbott Diabetes Care, Inc.
ñ The LibreView website is only compatible with certain operating systems and browsers. Please check www.libreview.com for additional information.