

DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE (JAPC)

JAPC Briefing FreeStyle Libre 2/Dexcom ONE

JAPC has classified Freestyle Libre 2/Dexcom ONE as **GREY after diabetes consultant/specialist initiation within a Derbyshire diabetes service***. **The criteria and process below must be strictly adhered to.**

* Permitted for NHS patients started outside of Derbyshire that comply with NHSE criteria and undertaking the national audit or following an APC shared care agreement

Identification

Consultant identifies those with Type 1 diabetes

- Or with any form of diabetes on haemodialysis and on insulin treatment
 - who are clinically indicated as requiring intensive monitoring >8 times daily
 - OR with diabetes associated with cystic fibrosis on insulin treatment
- Pregnant women with Type 1 Diabetes, with 12 months in total inclusive of post-delivery period
- 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.
- People with Type 1 diabetes for whom the specialist diabetes MDT determines have occupational or psychosocial circumstances that warrant a 6-month trial of Libre with appropriate adjunct support.
- For those with Type 1 diabetes who have recently developed recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia (defined for example using Gold score ≥ 4) 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 considers that a Flash Glucose Monitoring system/Dexcom 1 would be more appropriate for the individual's specific situation, then this can be considered.
- 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.

Baseline clinical data

- **Complete baseline FreeStyle Libre 2/Dexcom ONE Audit form** (<https://abcd.care/launch-abcd-nationwide-freestyle-libre-audit>), documenting reason for initiation.
- Ensure recent HbA1c available
- *Consultant* referral for Freestyle Libre 2/Dexcom ONE initiation

Education session

- Contract for Freestyle Libre 2/Dexcom ONE use completed
- Person with diabetes **attends FreeStyle Libre 2/Dexcom ONE education session** or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally)
- Provided with FreeStyle Libre 2 starter kit of reader and 1 sensor (a sensor lasts 14 days) or Dexcom ONE 10-day starter pack (consists of one 10-day sensor and a 3-month transmitter)
- Ensure baseline data collected and HbA1C available from within past 2 months
- Agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time

GP prescription request

- FreeStyle Libre 2/Dexcom ONE request to GP, with assurance of patient eligibility criteria. Practices will be provided with individual patient information to confirm eligibility for Freestyle Libre 2/Dexcom ONE from the specialist.

Follow up

- Consultant responsible for the patient must ensure follow up audit data is captured within 6 months of initiation. Agree to regular reviews with the local clinical teams.
- Continuing prescriptions for long-term use of a sensor - post initial 6 months - would be contingent upon evidence of agreeing with the above conditions and that on-going use of the Flash/Dexcom 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.
- **Stop prescription if no benefit or DNA**

Review

- 6 monthly or periodic review

Existing patients

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.

How do you discard the disposable components, for example sensor pack and applicator?

Freestyle Libre 2:

- Used or unused sensor packaging can go in general waste
- Once the sensor has been placed on the arm, the used applicator (which contains a needle) and the lid can be screwed back together and can be placed in a yellow biohazard bag or sharps box
- The used sensor should be placed in a clinical waste sharps box

Dexcom ONE:

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 local authority.

Suitable sharp boxes include 'Sharpsafe disposal unit 4 litre yellow' and 'Sharpsafe disposal unit 7 litre yellow'

NB – alcohol wipes are no longer supplied with Freestyle Libre – please advise patients that these can be purchased at minimal cost from pharmacies and other retailers. See

<https://freestylediabetes.co.uk/freestyle-libre/faqs>

Dexcom ONE consists of:

1. Sensors with an auto applicator - last 10 days
2. Transmitter - fixed on top of the sensor. 3-month battery life
3. App accessed on a compatible smartphone.

The transmitter should be prescribed every 3 months.

Document updates	Date updated
Disposal information added	Sept 2019
Clarification of identification section the criteria is for patients with type 1 diabetes	Oct 2019
Sharps box information added	
LD included as criteria for initiation	Nov 2020
Traffic light name change from Brown to Grey	Jan 2021
Note on alcohol wipes	March 2021
Addition of Dexcom1 and amendment to Freestyle Libre 2	September 2022
Update info on Dexcome ONE transmitter	Feb 2023
Review date extended to December 2023	March 2023

Useful Links

NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients
<https://www.england.nhs.uk/publication/flash-glucose-monitoring-national-arrangements-for-funding-of-relevant-diabetes-patients/>

Association of Children's Diabetes Clinicians (ACDC) Information to help a formulary case for Freestyle Libre system for use in children, young people and adults with diabetes <http://www.a-c-d-c.org/position-statements/>

Online education platform for the Freestyle Libre <https://abcd.care/node/778>

[Dexcom ONE Glucose Monitor for Type 1 - Type 2 Diabetes | Dexcom UK](#)

The ABCD Nationwide FreeStyle Libre audit is an independent audit supported by an unrestricted grant from Abbott

ABCD Nationwide FreeStyle Libre Audit Pre-FreeStyle Libre Information Collection Form



Hospital Name Centre ID

<p>Date <input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/></p> <p>Name of Clinician <input style="width: 100%;" type="text"/></p> <p>Email <input style="width: 100%;" type="text"/></p> <p style="color: blue; font-size: small;">AFFIX PATIENT LABEL HERE</p> <p>NHS Number <input style="width: 100%;" type="text"/></p> <p>Forename <input style="width: 100%;" type="text"/></p> <p>Surname <input style="width: 100%;" type="text"/></p> <p>Date of Birth <input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/></p> <p>Gender <input type="checkbox"/> Male <input type="checkbox"/> Female</p>	<p>Ethnicity</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">White</td> <td> <input type="checkbox"/> British <input type="checkbox"/> Irish <input type="checkbox"/> Any other white background </td> </tr> <tr> <td>Asian or Asian British</td> <td> <input type="checkbox"/> Indian <input type="checkbox"/> Pakistani <input type="checkbox"/> Bangladeshi <input type="checkbox"/> Any other Asian background </td> </tr> <tr> <td>Black or Black British</td> <td> <input type="checkbox"/> Caribbean <input type="checkbox"/> African <input type="checkbox"/> Any other </td> </tr> <tr> <td>Mixed</td> <td> <input type="checkbox"/> White and black Caribbean <input type="checkbox"/> White Asian <input type="checkbox"/> Any other mixed background group </td> </tr> <tr> <td>Other ethnic group</td> <td> <input type="checkbox"/> Chinese <input type="checkbox"/> Any other group <input type="checkbox"/> Not stated </td> </tr> </table> <p>Driving status</p> <input type="checkbox"/> Does not drive <input type="checkbox"/> Standard licence <input type="checkbox"/> Taxi licence <input type="checkbox"/> HGV licence	White	<input type="checkbox"/> British <input type="checkbox"/> Irish <input type="checkbox"/> Any other white background	Asian or Asian British	<input type="checkbox"/> Indian <input type="checkbox"/> Pakistani <input type="checkbox"/> Bangladeshi <input type="checkbox"/> Any other Asian background	Black or Black British	<input type="checkbox"/> Caribbean <input type="checkbox"/> African <input type="checkbox"/> Any other	Mixed	<input type="checkbox"/> White and black Caribbean <input type="checkbox"/> White Asian <input type="checkbox"/> Any other mixed background group	Other ethnic group	<input type="checkbox"/> Chinese <input type="checkbox"/> Any other group <input type="checkbox"/> Not stated
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Height (metres)	Weight (kg)	Body Mass Index	Duration of diabetes
<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text"/> years
			<input style="width: 100%;" type="text"/> months

Type of diabetes			
<input type="checkbox"/> Type 1	<input type="checkbox"/> Type 2	<input type="checkbox"/> MODY	
During pregnancy:			
<input type="checkbox"/> Gestational diabetes	<input type="checkbox"/> Type 1 diabetes during pregnancy	<input type="checkbox"/> Type 2 diabetes during pregnancy	
<input type="checkbox"/> Other (please specify)	<input style="width: 100%;" type="text"/>		

PATIENT USE OF FREESTYLE LIBRE

Is this assessment:

<input type="checkbox"/> Recorded prior to commencing FreeStyle Libre?	<input type="checkbox"/> Recorded retrospectively – i.e. after FreeStyle Libre started?
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What is the date of FreeStyle Libre start? (best estimate if uncertain) **If not, intended date of initiation of FreeStyle Libre**

<input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/>	<input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/> / <input style="width: 100px;" type="text"/>
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Use of a CGM within the last 6 month before starting FreeStyle Libre? **Funding of FreeStyle Libre**

<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> NHS funded <input type="checkbox"/> Non-NHS funded
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If non-NHS funded please give details

<input type="checkbox"/> Professional recommendation	<input type="checkbox"/> Other (please specify)
<input type="checkbox"/> Patient initiated	<input style="width: 100%;" type="text"/>

Reason for starting FreeStyle Libre (please tick as many boxes as apply)

<input type="checkbox"/> High HbA1c	<input type="checkbox"/> Recurrent hospital admissions (>2 DKA or hypo per year)	Replacement of SMBG <input type="checkbox"/> ≥ 8 tests per day <input type="checkbox"/> < 8 tests per day
<input type="checkbox"/> Frequent hypoglycaemia	<input type="checkbox"/> Recently developed hypoglycaemic unawareness	<input type="checkbox"/> NICE criteria for insulin pump fulfilled, where successful trial might avoid insulin pump
<input type="checkbox"/> Fear of hypoglycaemia	<input type="checkbox"/> High glucose variability	<input type="checkbox"/> Unable to self monitor, need third party assistance
<input type="checkbox"/> Gastroparesis	<input type="checkbox"/> Patient choice	<input type="checkbox"/> Hemodialysis
<input type="checkbox"/> Cystic fibrosis	<input type="checkbox"/> Pregnant (estimated date of delivery) / /	
<input type="checkbox"/> Psychosocial circumstance	<input type="checkbox"/> Previous self funder with HbA1c improvement	<input type="checkbox"/> Occupational circumstance
<input type="checkbox"/> Other diabetes complications (please specify)	<input type="text"/>	
<input type="checkbox"/> Other reasons (please specify)	<input type="text"/>	

HAS THE PATIENT HAD STRUCTURED EDUCATION?

Yes Not as far as I am aware Don't know

If yes, please specify

DAFNE DESMOND/X-PERT Other (please specify)

Date of last training (best estimate if uncertain) / /

USE OF NHS RESOURCES BEFORE STARTING FREESTYLE LIBRE

Answer for 12 MONTH period before starting Freestyle Libre.
If filling in retrospectively please fill in follow up form at the same visit.
 For all questions extract data from records otherwise use best estimate where possible.

Average number of SMBG tests in the last 2 weeks Average number per day Don't know

In the year before starting FreeStyle Libre	Hyperglycaemia/DKA	Hypoglycaemia	Unclassifiable diabetes related	Other
Number of admissions	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date(s)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of paramedic call outs not resulting in admission	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date(s)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of hypoglycaemic episodes requiring third party assistance not resulting in paramedic call outs or admission	Number <input type="text"/>	Date(s) <input type="text"/>	Don't know <input type="checkbox"/>	

HYPOLYCAEMIC AWARENESS BEFORE STARTING FREESTYLE LIBRE

PLEASE DON'T ENTER RECOLLECTED INFORMATION. Only enter if information obtained prospectively or contemporaneous data present in patient records.

Assessment of awareness of hypoglycaemia (Gold Score). Does the patient know when hypos are commencing?

1 2 3 4 5 6 7

1 = Always aware, 7 = Never aware.

CAPILLARY BLOOD GLUCOSE MONITOR METER DOWNLOAD DATA BEFORE STARTING FREESTYLE LIBRE (IF AVAILABLE)

Number of days downloaded	Average tests per day	% of tests showing capillary blood glucose equal or < 3.9	% of tests showing capillary blood glucose equal or > 10.1 mmol/L	Tests <2.5mmol within past 14 days
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Please add all available data even if you do not have it all.

HbA1c TESTS DONE IN THE LAST 12 MONTHS BEFORE STARTING FREESTYLE LIBRE
HbA1c tests after starting FreeStyle Libre to be captured on follow up form

Date of test:	<input type="text"/> / <input type="text"/> / <input type="text"/>	HbA1c	<input type="text"/>	mmol/mol
Date of test:	<input type="text"/> / <input type="text"/> / <input type="text"/>	HbA1c	<input type="text"/>	mmol/mol
Date of test:	<input type="text"/> / <input type="text"/> / <input type="text"/>	HbA1c	<input type="text"/>	mmol/mol
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Date of test:	<input type="text"/> / <input type="text"/> / <input type="text"/>	HbA1c	<input type="text"/>	mmol/mol

MEDICATIONS

Metformin
 Sulphonylureas
 TZDs
 GLP-1 agonists
 DPP4 inhibitors
 SGLT-inhibitors

Quick acting insulin
 Basal insulin
 Insulin mixtures
 Basal bolus
 Insulin pump

Total insulin dose units per day

Other medications which could affect glycaemic control

DIABETES DISTRESS SCREENING SCALE

DO NOT ENTER RECOLLECTED INFORMATION. Only enter if information obtained prospectively or contemporaneous data present in patient records.

	Not A Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1 Feeling overwhelmed by the demands of living with diabetes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 Feeling that I am often failing with my diabetes routine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

OTHER PATIENT COMMENTS?**OTHER HEALTHCARE PROFESSIONAL COMMENTS?**

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ABCD Nationwide FreeStyle Libre Audit Follow Up Visit Data Collection Form



Clinician Centre ID

GENERAL INFORMATION

PATIENT INFORMATION

Visit date	<input type="text"/> / <input type="text"/> / <input type="text"/>	Please record patient name and date of birth below OR	
If this is the first follow up visit please confirm the date patient started FreeStyle Libre	<input type="text"/> / <input type="text"/> / <input type="text"/>	Affix patient label here	
Patient still using FreeStyle Libre?	<input type="checkbox"/> Yes <input type="checkbox"/> No	Has the patient had training and education on FreeStyle Libre? <input type="checkbox"/> Yes <input type="checkbox"/> No	
If no, when was FreeStyle Libre stopped?	<input type="text"/> / <input type="text"/> / <input type="text"/>	If yes, which:	
Why was FreeStyle Libre stopped?	<input type="checkbox"/> Lack of funding <input type="checkbox"/> Patient choice <input type="checkbox"/> Lack of benefit <input type="checkbox"/> FreeStyle Libre site problem <input type="checkbox"/> Other (please specify) <input type="text"/>	<input type="checkbox"/> Online <input type="checkbox"/> Group education <input type="checkbox"/> One to one education <input type="checkbox"/> Yes <input type="checkbox"/> No	
FreeStyle Libre site problems?	<input type="checkbox"/> Yes <input type="checkbox"/> No	If FreeStyle Libre utilised during pregnancy has patient now delivered <input type="checkbox"/> Yes <input type="checkbox"/> No	
If yes, please describe	<input type="text"/>	If yes: actual date of delivery <input type="text"/> / <input type="text"/> / <input type="text"/>	
		Any other problems with using FreeStyle Libre (please specify)	
		<input type="text"/>	

USE OF NHS RESOURCES SINCE STARTING FREESTYLE LIBRE

For all questions extract data from records otherwise use best estimate where possible.

Since last visit

	Hyperglycaemia/DKA	Hypoglycaemia	Unclassifiable diabetes related	Other
Number of admissions	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date(s)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of paramedic call outs not resulting in admission	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Date(s)	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Number of hypoglycaemic episodes requiring third party assistance not resulting in paramedic call outs or admission

Number Date(s) Don't know

HYPOGLYCAEMIC AWARENESS

PLEASE DON'T ENTER RECOLLECTED INFORMATION. Only enter if information obtained prospectively or contemporaneous data present in patient records.

Assessment of awareness of hypoglycaemia (Gold Score). Does the patient know when hypos are commencing?

1 2 3 4 5 6 7

1 = Always aware, 7 = Never aware.

HYPOGLYCAEMIA IN GENERAL

With initial use of FreeStyle Libre did the user detect a greater proportion of time in hypoglycaemia than when using blood glucose monitoring?

No	<input type="text"/>	Yes	<input type="text"/>	Unchanged	<input type="text"/>
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With ongoing use of FreeStyle Libre has the user been able to reduce the proportion of time in hypoglycaemia?

No	<input type="text"/>	Yes	<input type="text"/>	Unchanged	<input type="text"/>
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As a result of FreeStyle Libre has the patient been able to reduce the rate of hypoglycaemia?

No	<input type="text"/>	Yes - a little less	<input type="text"/>	Yes - a lot less	<input type="text"/>
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As a result of FreeStyle Libre has the patient been able to reduce the rate of nocturnal hypoglycaemia?

No	<input type="text"/>	Yes - a little less	<input type="text"/>	Yes - a lot less	<input type="text"/>
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FREESTYLE LIBRE DOWNLOAD DATA – MINIMUM ONE SENSOR/14 DAYS WEAR REQUIRED

Patient target range 3.9-10
(if data from reader check target range is 3.9-10)

Time in target	Average glucose	Standard deviation if using Diasend	Above	In target	Below
14 days	<input type="text"/> mmol/l	<input type="text"/> mmol/l	<input type="text"/> %	<input type="text"/> %	<input type="text"/> %
Average number of daily SMBG tests in the last two weeks of Freestyle Libre use	Average number per day	<input type="text"/>	Don't know	<input type="text"/>	<input type="text"/> %

Sensor usage (data can be retrieved
from the FreeStyle Libre reader)

Scans per day	Captured sensor data
14 days	<input type="text"/>
FreeStyle Libre sensor use:	Continuous <input type="text"/> % Not continuous <input type="text"/>
FreeStyle Libre used	>70% of the time <input type="text"/> % < 70% of the time <input type="text"/>

HbA1c SINCE STARTING FREESTYLE LIBRE, OR SINCE LAST FREESTYLE LIBRE AUDIT FOLLOW UP FORM COMPLETED

Please enter either	<input type="text"/> %	OR	<input type="text"/> mmol/mol	Date of Test	<input type="text"/>
Please enter either	<input type="text"/> %	OR	<input type="text"/> mmol/mol	Date of Test	<input type="text"/>
Please enter either	<input type="text"/> %	OR	<input type="text"/> mmol/mol	Date of Test	<input type="text"/>
Please enter either	<input type="text"/> %	OR	<input type="text"/> mmol/mol	Date of Test	<input type="text"/>
Please enter either	<input type="text"/> %	OR	<input type="text"/> mmol/mol	Date of Test	<input type="text"/>
Please enter either	<input type="text"/> %	OR	<input type="text"/> mmol/mol	Date of Test	<input type="text"/>
Current weight	<input type="text"/> Kg	Body Mass Index	<input type="text"/>		

DIABETES DISTRESS SCREENING SCALE

PLEASE DON'T ENTER RECOLLECTED INFORMATION. Only enter if information obtained prospectively or contemporaneous data present in patient records whilst using FreeStyle Libre.

	Not A Problem	A Slight Problem	A Moderate Problem	Somewhat Serious Problem	A Serious Problem	A Very Serious Problem
1 Feeling overwhelmed by the demands of living with diabetes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 Feeling that I am often failing with my diabetes routine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PATIENTS OVERALL RATING OF FREESTYLE LIBRE – PLEASE COMMENT

Patient opinion of FreeStyle Libre monitoring overall

0 0.5 1 1.5 2 2.5 3 3.5 4 4.5 5 5.5 6

0 = No value, 6 = Excellent.