

Use of Continuous Glucose Monitors (CGMs) within NHS Grampian Position Statement April 2023

This document outlines the NHS Grampian position on use of continuous glucose monitors (CGMs) which are available on prescription in Primary Care and supersedes previous information relating to FreeStyle Libre® prescribing.

This document does <u>not</u> refer to CGMs only available through central procurement (typically used with insulin pump therapy to allow automatic or semi-automatic adjustment of insulin delivery).

Summary of Position Statement:

- Primary Care prescribing of CGMs must only be undertaken on the recommendation from the appropriate diabetes specialist service (adults or paediatrics).
- NHS Grampian diabetes specialist service support the prescribing of FreeStyle Libre[®] 2
 and Dexcom ONE[®] CGMs for patients with diabetes mellitus when specified criteria and
 prerequisites are met (see <u>Appendix 1</u>).
- Other CGM's are available however at present prescribing is not recommended by the diabetes specialist service.

Background Information:

Update to guidance:

FreeStyle Libre® CGM has been available in NHS Grampian since September 2018. Due to the availability of alternative CGM devices the Grampian Diabetes Devices Subgroup have reviewed their CGM implementation plan.

Continuous Glucose Monitors:

A CGM consists of three parts:

- A glucose sensor which measures glucose levels. These are factory-calibrated and measure interstitial fluid glucose levels (thin layer of fluid which surrounds the body's cells just under the skin), rather than blood glucose levels. Sensors are inserted just under the skin with the use of an applicator.
- A recorder/transmitter which collects data from the sensor.
- A receiver that displays the glucose information. This may be a dedicated receiving device, a mobile phone application or an insulin pump.

CGM systems can either be real-time or intermittently sensed:

- Real-time systems (e.g. Dexcom ONE®) automatically transmit glucose data to the user with glucose data (trend and numerical) in real time along with alerts to a receiver, smart watch, or smartphone.
- Intermittently sensed CGM systems (e.g. FreeStyle Libre® 2) require the user to purposely scan the sensor to obtain information.
- Regardless of which type of sensor, all provide either threshold or predictive alerts and alarms based on preprogramed alert settings.

CGM vs capillary (fingertip) bloody glucose testing:

- Whilst the accuracy of glucose measurement from CGMs is no better than capillary (fingertip) blood glucose testing systems, CGMs allows glucose levels to be measured over time and without finger pricking.
- CGMs can therefore provide information regarding trends in glucose levels that blood glucose testing does not. This allows people with diabetes on insulin therapy to make timely decisions to improve their care.

Costs:

- CGMs comes at a significant cost and therefore the Grampian Diabetes Devices Subgroup have developed clear criteria for eligibility, continuation and discontinuation of CGMs (within this document) which will be under the supervision of the diabetes specialist service.
- Whilst the use (and therefore cost) of blood glucose test strips is expected to fall substantially for patients using and stabilised on a CGM, ongoing attention to prescribing the most suitable and cost effective glucose test strips is encouraged.

CGM Guidance:

- In 2018, guidance was issued by the <u>Scottish Health Technology Assessment Group</u> outlined criteria for the FreeStyle Libre[®] CGM to be offered to people with diabetes mellitus treated with intensive insulin therapy.
- In 2022 the National Institute of Clinical Excellence (NICE) updated their Type 1 diabetes in adults guidance to state that a CGM should be offered to all adults with Type 1 diabetes (<u>section 1.6.10</u>). NICE also updated their Type 2 diabetes in adults guidance to state that a CGM should be offered to selected people where certain criteria are met (<u>Section 1.6.17</u>).
- Access to technology was a key theme identified in a recent <u>Scottish survey of patients and healthcare professionals</u>.
- NHS Grampian has specific criteria for the prescribing of CGM's. All prescribing should be undertaken following recommendation from an appropriate diabetes specialist service (adults or paediatrics).

Benefits of CGMs:

- A <u>New England Journal of Medicine study</u> reported that use of FSL2 in people with an HbA1c of 58-97mmol/mol resulted in a reduced HbA1c as well as a reduction in time spent in a hypoglycaemic range and an increase in time spent within glycaemic range.
- A recent <u>Scottish observational study</u> also reported a reduction in HBA1c when using this technology.

Further information:

Further information can be found in the following appendices:

- Appendix 1: Continuous Glucose Monitors (CGM) Frequently asked questions for healthcare professionals
- Appendix 2: Continuous Glucose Monitors (CGM) Frequently asked questions for patients / carers

Appendix 1: Continuous Glucose Monitors (CGM) - Frequently asked questions for Healthcare Professionals

1. Which adults with diabetes will be eligible for a CGM in NHS Grampian?

A CGM can be recommended for adult patients by the diabetes specialist service to be prescribed by a Primary Care clinician where one of the following primary eligibility criteria is met:

- Type 1 diabetes,
- Secondary diabetes which is treated with insulin (e.g. monogenic diabetes, cystic fibrosis related diabetes, post pancreatic resection)
- Type 2 diabetes on basal bolus insulin regimen (defined a basal insulin injection(s) plus quick acting insulin for meals)
- Type 2 diabetes on multiple daily injections (defined as two or more insulin injections per day) plus any of the following additional criteria:
 - o Recurrent hypoglycaemia or severe hypoglycaemia, or
 - o Impaired hypoglycaemia awareness, or
 - A condition or disability which means the patient cannot self-monitor their blood glucose by capillary blood glucose but can use a CGM device (or have it scanned for them).

Where an adult patient meets one of the above primary eligibility criteria they must then also meet all of the following criteria prior to the diabetes specialist service making a recommendation to Primary Care to prescribe a CGM:

- Be attending specialist diabetes clinic for their diabetes care (in NHS Grampian this can mean attending clinics in Dr Gray's, Aberdeen Royal Infirmary, Aberdeen Health Village, Kincardine Community Hospital or Fraserburgh Hospital), and
- Have completed appropriate training as directed by the appropriate diabetes specialist service to use insulin therapy and the CGM system safely and effectively, and
- Agrees to share their CGM data with the diabetes specialist service.

Where primary eligibility criteria is not met, or the patient cannot commit to the subsequent prerequisites a CGM will not be recommended and therefore should not be prescribed in Primary Care.

2. Which children with diabetes will be eligible for a CGM in NHS Grampian?

All children with diabetes are encouraged, when appropriate, to move to CGM on completion of their new patient education pathway. Children with diabetes should not be initiated on a CGM without prior recommendation from the diabetes specialist service.

- FreeStyle Libre® 2 is currently licensed for children aged 4 years or above
- Dexcom ONE® is licensed for children aged 2 years or above.

Where a child has been deemed suitable for a CGM, the child and/or carer must also meet all of the following criteria prior to the diabetes specialist service making a recommendation to Primary Care to prescribe:

- Be attending diabetes specialist service clinics for diabetes care (in NHS Grampian this can mean attending clinics at Royal Aberdeen Children's Hospital or Dr Gray's Hospital), and
 - Have completed appropriate training as directed by the diabetes specialist service relating to how to use insulin therapy and the CGM system safely and effectively, and
- Agrees to share CGM data with the diabetes specialist service.

3. What are the expectations and ongoing responsibilities of patients/ carers who have been approved for a CGM?

Patients/carers should:

- Ensure all CGM data is available for each 24-hour period and use the information to optimise glucose levels.
- Share CGM data with the diabetes specialist service.
- Accept that continued availability of a CGM on prescription will depend on the ongoing
 effective use of the technology to improve self-management as assessed by the diabetes
 specialist service.
- Agree to switch capillary (fingertip) blood glucose and ketone monitoring products to the most cost effective choices (noting that the NHS Grampian preferred products may change over time).
- Agree to the discontinuation of CGM if the criteria for continuation are no longer met.
- 4. What are the expectations and ongoing responsibilities of Primary Care in relation to the prescribing of CGM's?

Primary Care should:

- Prescribe CGM in accordance with diabetes specialist service recommendations.
- Report any concerns regarding CGM use to the appropriate diabetes specialist service.
- Support the rollout of any updates in the approved devices recommended by manufacturers or the regulators.

5. Are CGMs accepted by the DVLA?

This is dependent on the type of driver's license held:

Group 1 (e.g. "normal" car licence)

- CGM may be used for monitoring glucose at times relevant to driving Group 1 vehicles.
- Users of these systems must carry finger prick capillary glucose testing equipment for driving purposes as there are times when a confirmatory finger prick blood glucose level is required.
- If using CGM, blood glucose levels must be confirmed with a finger prick blood glucose reading in the following circumstances:
 - o when the glucose level is 4.0 mmol/L or below,
 - o when symptoms of hypoglycaemia are being experienced, or
 - when the CGM gives a reading that is not consistent with the symptoms being experienced (for example, symptoms of hypoglycaemia and the system reading does not indicate this)

Group 2 (e.g. bus or lorry licences)

- There is a legal requirement for Group 2 drivers to monitor their blood glucose for the purpose of Group 2 driving.
- CGM is not permitted for the purposes of Group 2 driving and licensing.
- Group 2 drivers who use CGMs must continue to monitor finger prick capillary blood glucose levels

For further information, patients should be referred to the <u>gov.uk</u> website which contains the most up to date guidance.

6. Under what circumstances might the diabetes specialist service recommend cessation of CGM prescribing?

The diabetes specialist service may consider discontinuation if any one of the following occurs. This would normally be discussed with the patient/carer prior to action being taken:

- Failure to attend follow up appointments,
- Failure to share CGM data with their diabetes specialist service team,
- Failure to engage with the diabetes specialist service team to optimise issues with glycaemic control,
- Evidence of greater harm than benefit on clinical and psychological health (e.g. increased frequency of hypos, increased psychological morbidity).

7. Once a CGM has been recommended how will Primary Care be made aware of the ongoing prescribing requirements?

- GP practices should only provide prescriptions for a CGM on the recommendation of the diabetes specialist service.
- Once a patient has been assessed by the diabetes specialist service as meeting the criteria for initiation, a letter recommending CGM prescribing will be sent to their GP practice.
- Quantities of sensors ordered by patients should not exceed what is required, this is monitored centrally within NHS Grampian and where excessive quantities are identified GP practices will be alerted. The table below provides details of annual quantities of CGM's.
- It is recommended that the prescribing of CGM's is done monthly or bi-monthly.

CGM	Duration of use	Annual quantities
FreeStyle Libre® 2	14 days	26 sensors
Dexcom ONE® sensor*	10 days	37 sensors
Dexcom ONE® transmitter*	90 days	4 sensors

^{*}Both Dexcom ONE® sensors and transmitters are required for the Dexcom ONE® CGM system to work.

8. Can a CGM be prescribed for a patient who has previously received via private prescription or self-funded purchase?

It is recognised that a number of people with diabetes will have initiated a CGM privately (i.e. paid the cost of the CGM via private prescription or self-funding). No patient can be transferred to NHS prescribing of CGMs unless they have been assessed by the appropriate diabetes specialist team and meet all of the NHS Grampian criteria for initiation (see question 1 and 2).

9. If a patient believes the meet the criteria for CGM prescribing, how do they obtain a recommendation for prescribing?

Primary Care should not prescribe a CGM without prior recommendation by the diabetes specialist service and confirmation of prerequisites having being met (see details above).

For patients who are attending hospital based diabetes clinic:

- Requests should be discussed at their next appointment with the diabetes specialist service
- If patients have not attended clinical for a period of time they can check with the reception team of the clinic they attend (details below) to ascertain when their next appointment is likely to be.

Clinic Address	Contact details
JJR Macleod Diabetes Clinic, David	Reception – 01224 555700
Anderson Building, Aberdeen Royal	
Infirmary, Foresterhill Rd, Cornhill Rd,	
Aberdeen, AB25 2ZN	
Diabetes Clinic, Dr Gray's Hospital, Elgin.	Reception – 01343 567882
IV30 1SN	
1	Reception – 01346 513151
Fraserburgh. AB43 9NF.	
Kincardine Hospital, Stonehaven. AB39	Reception – 01569 765150
2NJ.	

For patients not currently attending a hospital based diabetes clinic:

 Requests can be discussed with Primary Care clinician and when appropriate referral made to one of the hospital based clinics.

10. Which CGM devices are currently available on prescription in NHS Grampian?

Currently Freestyle Libre® 2 and Dexcom ONE® are the only CGMs supported for prescribing within NHS Grampian. Other CGM's are listed in the <u>Scottish Drug Tariff</u>, but prescribing of these is not supported within NHS Grampian at this time. These recommendations may change in the future as other CGM's become available.

Appendix 2 - Continuous Glucose Monitors (CGM) - Frequently asked questions for Patients/Carers

1. Which adults with diabetes will be eligible for a CGM in NHS Grampian?

A CGM can be recommended for adult patients by the diabetes specialist service to be prescribed by your GP practice where one of the following primary eligibility criteria is met:

- Type 1 diabetes,
- Secondary diabetes which is treated with insulin (e.g. monogenic diabetes, cystic fibrosis related diabetes, post pancreatic resection),
- Type 2 diabetes on basal bolus insulin regimen (defined a basal insulin injection(s) plus quick acting insulin for meals),
- Type 2 diabetes on multiple daily injections (defined as two or more insulin injections per day) plus any of the following additional criteria:
 - o Recurrent hypoglycaemia or severe hypoglycaemia, or
 - o Impaired hypoglycaemia awareness, or
 - A condition or disability which means that they cannot self-monitor their blood glucose by capillary blood glucose but can use a CGM device (or have it scanned for them).

Where one of the above primary eligibility criteria has been met patients must then also meet all of the following criteria prior to the diabetes specialist service making a recommendation to your GP practice to prescribe a CGM:

- Be attending specialist diabetes clinics for diabetes care (in NHS Grampian this can mean attending clinics in Dr Gray's, Aberdeen Royal Infirmary, Aberdeen Health Village, Kincardine Community Hospital or Fraserburgh Hospital), and
- Have completed appropriate training as directed by the diabetes specialist service relating to how to use insulin therapy and the CGM system safely and effectively, and
- Agrees to share CGM data with the diabetes specialist service.

Where primary eligibility criteria is not met, or the patient cannot commit to the subsequent prerequisites a CGM will not be recommended and therefore should not be prescribed.

2. Which children with diabetes will be eligible for a CGM in NHS Grampian?

All children with diabetes are encouraged, when appropriate, to move to CGM on completion of their new patient education pathway. Children with diabetes should not be initiated on a CGM without prior recommendation from the diabetes specialist service.

- FreeStyle Libre® 2 is currently licensed for children aged 4 years or above
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Where a child has been deemed suitable for a CGM, the child and/or carer must also meet all of the following criteria prior to the diabetes specialist service making a recommendation to their GP practice to prescribe:

- Be attending diabetes specialist service clinics for diabetes care (Royal Aberdeen Children's hospital or Dr Gray's hospital), and
- Have completed training as directed by the diabetes specialist service relating to how to use insulin therapy and the CGM system safely and effectively, and
- Agrees to share CGM data with the diabetes specialist service.

3. What are the expectations and ongoing responsibilities of patients/ carers who have been approved for a CGM?

Patients/carers should:

- Ensure all CGM data is available for each 24-hour period and use the information to optimise glucose levels.
- Share CGM data with the diabetes specialist service.
- Accept that continued availability of a CGM on prescription will depend on the ongoing
 effective use of the technology to improve self-management as assessed by the diabetes
 specialist service.
- Agree to switch capillary (fingertip) blood glucose and ketone monitoring products to the most cost effective choices (noting that the NHS Grampian preferred products may change over time).
- Agree to the discontinuation of CGM if the criteria for continuation are no longer met.

4. Are CGMs accepted by the DVLA?

This is dependent on the type of driver's license:

Group 1 (e.g. "normal" car licence)

- CGM may be used for monitoring glucose at times relevant to driving Group 1 vehicles.
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 - o when the glucose level is 4.0 mmol/L or below,
 - o when symptoms of hypoglycaemia are being experienced, or
 - when the CGM gives a reading that is not consistent with the symptoms being experienced (for example, symptoms of hypoglycaemia and the system reading does not indicate this)

Group 2 (e.g. bus or lorry licences)

- There is a legal requirement for Group 2 drivers to monitor their blood glucose for the purpose of Group 2 driving.
- CGM is <u>not</u> permitted for the purposes of Group 2 driving and licensing.
- Group 2 drivers who use CGMs must continue to monitor finger prick capillary blood glucose levels

For further information please refer to the <u>gov.uk</u> website which contains the most up to date guidance.

5. Under what circumstances might CGM prescribing be stopped once started?

The diabetes specialist service may consider discontinuation if any one of the following occurs. This would normally be discussed with the patient/carer <u>prior</u> to action being taken:

- Failure to attend follow up appointments,
- Failure to share CGM data with their diabetes specialist service team,
- Failure to engage with the diabetes specialist service team to optimise issues with glycaemic control,
- Evidence of greater harm than benefit on clinical and psychological health (e.g. increased frequency of hypos, increased psychological morbidity).

6. How do I get CGM on prescription?

- GP practices will only provide prescriptions for a CGM on the recommendation of the diabetes specialist service.
- Once a patient has been assessed (by the diabetes specialist service) as meeting the criteria for initiation, a letter recommending CGM prescription will be sent to their GP practice.
- Quantities of sensors ordered should not exceed what is required, this is monitored centrally within NHS Grampian and where excessive quantities are identified GP practices will be alerted. The table below provides details of annual quantities of CGM's, the frequency of prescribing will be determined by individual GP practices e.g. monthly or bi-monthly prescriptions.

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7. Can a CGM be prescribed by my GP practice if I have previously accessed via private prescription or self-funded purchase?

It is recognised that a number of people with diabetes will have initiated a CGM privately (i.e. paid the cost of the CGM via private prescription or self-funding). No patient can be transferred to NHS prescribing of CGMs unless they have been assessed by the appropriate diabetes specialist team and meet all of the NHS Grampian criteria for initiation (see question 1 and 2).

8. I believe I meet the criteria and am eligible for a CGM. How do I obtain a device?

Your GP practice will not prescribe a CGM without prior recommendation by the diabetes specialist service and confirmation of prerequisites having being met (see details above).

9. Which CGM devices are currently available on prescription in NHS Grampian?

- Currently Freestyle Libre® 2 and Dexcom ONE® are the only CGMs recommended for prescribing within NHS Grampian. Other CGM's are not supported within NHS Grampian at this time.
- The diabetes specialist service, in collaboration with the patient/carer are responsible for deciding what CGM is most appropriate for the patient.
- These recommendations may change in the future as other CGM's become available.