

Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus		
	Version No.	Changes Made
Version of 05.10.2018	V1	Policy ratified by Healthier Lancashire and South Cumbria's Joint Committee of Clinical Commissioning Groups
Version of 28.03.2019	V1.1	<p>The following changes have been made to align the policy with NHS England's guidance on Freestyle Libre devices:</p> <ul style="list-style-type: none"> - Policy criteria 1-7 at section 1.3.2 aligned with the NHS England guidance - The definition of clinicians who are able to prescribe the devices and sensors in section 1.1.1 has been updated to reflect a move from a red RAG status to an amber RAG status. - The continuation criteria at section 1.3.3 have been amended to allow the frequency to be determined by a clinical determination of patient need rather than 6 monthly - Section 1.5 has been updated to reflect the updated position regarding haemodialysis - The references have been updated to include the NHSE guidance. - Appendix 3&4 have been removed as they are no longer relevant.
Version of 18.03.2021	V1.2	<p>The following changes have been made to align the policy with updated NICE NG3 and NHS England guidance:</p> <ul style="list-style-type: none"> - Section 1.2.2 updated with NG3 recommendation for provision of continuous glucose monitoring devices in pregnant women with type 1 diabetes. - Policy criteria 3 and 9 at section 1.3.2 updated to reflect NG3 recommendation relating to flash glucose monitoring, and NHS England guidance for patients with learning disabilities. - References and appendix 2 updated to include NICE NG3 and NHS England updated guidance.

Lancashire and South Cumbria Clinical Commissioning Groups (CCGs)

Policies for the Commissioning of Healthcare

Policy for the Provision of Continuous Glucose Monitoring and Flash Glucose Monitoring to patients with Diabetes Mellitus.

	This document is part of a suite of policies that the CCG uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
1	Policy Criteria
1.1	<p>To be eligible for funding for a device under the provisions of this policy patients (or their parent(s) / guardian(s)) with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production must meet the device specific requirements set out at section 1.2 or 1.3 and:</p> <ul style="list-style-type: none"> a) have been informed of the advantages and disadvantages of continuous/flash glucose monitoring and expressed a continued wish to initiate continuous/flash glucose monitoring. <p>AND</p> <ul style="list-style-type: none"> b) have demonstrated appropriate levels of competence to perform carbohydrate counting (e.g. level 3 carbohydrate counting such as DAFNE regimen; or have been judged by their specialist supervising clinician to have demonstrated an equivalent level of competence through the prior management of the patient's glycaemic control), blood glucose monitoring and to interpret this data to competently adjust insulin doses. <p>AND</p> <ul style="list-style-type: none"> c) demonstrate a willingness to engage in all necessary training regarding the optimal use of continuous/flash glucose monitoring and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered). <p>AND EITHER</p> <ul style="list-style-type: none"> d) in the case of flash glucose monitoring devices, agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time. <p>OR</p> <ul style="list-style-type: none"> e) in the case of continuous glucose monitoring devices, be willing to commit to using it at least 70% of the time or a minimum of 5 days per week and to calibrate it as needed.
1.2	Continuous Glucose Monitoring
1.2.1	Continuous glucose monitoring must be initiated and continually supplied / prescribed by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, GPs with a special interest in Diabetes, Diabetes Specialist Nurses) in limited and controlled settings where patients are attending specialist diabetes mellitus care, as part of strategies to optimise a patient's HbA1c levels and reduce the frequency of hypoglycaemic episodes.

<p>1.2.2</p>	<p>The CCG will only commission continuous glucose monitoring devices with alarms in patients with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production who fulfil the requirements of section 1.1 and who MEET ONE OR MORE OF THE FOLLOWING CRITERIA despite optimised use of insulin therapy and conventional blood glucose monitoring:</p> <ol style="list-style-type: none"> 1. complete loss of awareness of hypoglycaemia (as indicated by a maximal score on the Gold or Clarke scales). OR 2. loss of awareness of hypoglycaemia (indicated by a score of more than 4 on the Gold or Clarke scales) accompanied by: <ol style="list-style-type: none"> i. adverse consequences (seizures or anxiety) or ii. frequent (more than 2 episodes per week) asymptomatic hypoglycaemia. OR 3. have an inability to recognise, or communicate about, symptoms of hypoglycaemia (for example because of cognitive or neurological disabilities). OR 4. have experienced more than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause. OR 5. have an extreme fear of hypoglycaemia (only in patients eligible for a flash glucose monitoring device who intensively monitor due to extreme fear of hypoglycaemia and who prefer to use continuous glucose monitoring). OR 6. have hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. <p><i>NB for children and young people, consent; commitment to use the device; and demonstration of competence may be the responsibility of the parent or guardian depending on the child or young person's level of understanding.</i></p> <p>From March 2021, continuous glucose monitoring devices with alarms will be offered to all pregnant patients with type 1 diabetes for a duration of 12 months. Flash glucose monitoring may be offered as an alternative to continuous glucose monitoring for pregnant women with type 1 diabetes who are unable to use continuous glucose monitoring or express a clear preference for flash (see 1.3.2)</p> <p>Arrangements for the Provision of CGM beyond the initial 12 months period and for pregnant women with non-type 1 diabetes will be reviewed and details included in an updated version of this policy (expected September 2021).</p>
<p>1.2.3</p>	<p>To secure continued funding of continuous glucose monitoring with alarms patients must show:</p> <ol style="list-style-type: none"> 1. appropriate device use and compliance (as demonstrated by a minimum of 70% use or 5 days wear per week) at 1 month and at any subsequent review. 2. A clearly documented achievement of targets for glycaemic control measures at 3 months and at any subsequent review including:

	<p>a) rate and severity of hypoglycaemia. OR</p> <p>b) quality of life measures (e.g. NICE referenced EQ-5D assessment and / or DQoL questionnaire), hypoglycaemia unawareness (Clarke or Gold score) or fear of hypoglycaemia. OR</p> <p>c) HbA1c (an improvement of 5mmol/mol [0.5%] from baseline HbA1c is required if HbA1c was more than 59 mmol/mol [7.5%] at initiation of continuous glucose monitoring). *</p> <p>* For adult patients with a HbA1c of 75 mmol/mol (9%) or higher at the initiation of continuous glucose monitoring, continued funding will be secured if at the 6-month review and at any subsequent review:</p> <ul style="list-style-type: none"> - HbA1c has been reduced to 53 mmol/mol (7%) or below and/or - there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more from their baseline HbA1c <p>All targets must be agreed by a responsible specialist clinician.</p>
<p>1.2.4</p>	<p>The CCG will not commission continuation of continuous glucose monitoring commenced in the private sector (self-funded) either in the UK or abroad. However, exceptions are permissible when NHS funded treatment would normally be made available to NHS patients within the terms detailed in this policy. The following statement(s) must apply:</p> <ul style="list-style-type: none"> • the patient must have demonstrably satisfied the initiation criteria detailed in this policy at the time of commencing the self-funded continuous glucose monitoring or flash glucose monitoring device, as confirmed and documented by the specialist clinician through a review of the patient’s medical history. • At the point of device renewal, the patient must satisfy the continuation eligibility criteria above and have previously satisfied the initiation criteria at the time of commencing the continuous glucose monitoring or flash glucose monitoring device.
<p>1.3</p>	<p>Flash Glucose Monitoring</p>
<p>1.3.1</p>	<p>Flash glucose monitoring must be initiated by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, GPs with a special interest in Diabetes, Diabetes Specialist Nurses). For patients who do not routinely attend appointments with specialist clinicians flash glucose monitoring devices may be supplied by a clinician responsible for the wider care and management of the patient’s diabetes.</p> <p>The initiating clinician must have received appropriate training on the initiation and use of flash glucose monitoring products and will supply the patient with a scanning device and sensors to cover the initial 2 weeks of use of flash glucose monitoring.</p> <p>Following initiation, ongoing supply of sensors will be via primary care prescribing on an FP10 prescription.</p>

<p>1.3.2</p>	<p>The CCG will only commission flash glucose monitoring devices in patients aged 4 years and above with type 1 diabetes mellitus or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production, or with any form of diabetes on haemodialysis, who use insulin treatment, have been assessed by the clinician responsible for their wider diabetes care and treatment, fulfil the requirements of section 1.1 and MEET ONE OR MORE OF THE FOLLOWING CRITERIA:</p> <ol style="list-style-type: none"> 1. people who, in any 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 2. people with diabetes associated with cystic fibrosis on insulin treatment. OR 3. pregnant women with Type 1 Diabetes who are unable to use continuous glucose monitoring or express a clear preference for flash glucose monitoring - 12 months in total inclusive of the postdelivery period. OR 4. 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. OR 5. 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. OR 6. 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. OR 7. 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 OR 8. children who require third parties to carry out monitoring and where conventional blood testing is not possible. This includes children who are unable to test as frequently as clinically appropriate, once all other clinical options have been evaluated. OR 9. 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.
<p>1.3.3</p>	<p>To secure continued funding of the flash glucose device sensors patients must:</p>

	<ol style="list-style-type: none"> 1. agree to scan glucose levels no less than 8 times per day and use the sensor >70% of the time. 2. demonstrate a clearly documented achievement of targets for glycaemic control measures or improvements in fear / anxieties related to finger prick testing at 6 months and at any subsequent review (frequency of review will be determined by the clinician responsible for the patients wider diabetes treatment and care based on the patient's clinical circumstances) defined by an improvement in Quality of Life measures (e.g. NICE referenced EQ-5D assessment and / or DQoL questionnaire) and one or more of the following: <ol style="list-style-type: none"> a. reduction in the rate of severe hypoglycaemia or hyperglycaemic episodes (including diabetic ketoacidosis) b. reduction in frequency of non-severe hypoglycaemia by more than 1 episode per week c. HbA1c reduction of 5mmol/mol [0.5%] from the baseline HbA1c within 6 months d. significant reduction in testing strip usage e. improvement in anxiety / fear using validated rating scales e.g. Hypoglycaemia Fear Survey-II (HSF-II) or an improvement in social occupational function. <p>Where the above criteria are not met, flash glucose monitoring should be discontinued, and an alternative method of monitoring used.</p>
1.4	<p>For insulin pump patients unable to achieve targets for glycaemic control measures as defined by the current local insulin pump policy, the decision to discontinue the insulin pump; or trial an insulin pump with integrated continuous glucose monitoring (where insulin pump patients are not already using continuous glucose monitoring); or trial a combination of insulin pump and flash glucose monitoring device; should be made by the responsible specialist clinician in conjunction with the patient.</p> <p>Combination continuous glucose monitoring and flash glucose monitoring will not be routinely commissioned by the CCG.</p> <p>Continuous glucose monitoring or flash glucose monitoring should only be continued in patients if they demonstrate the additional benefits defined in policy sections 1.2.3 and 1.3.3 respectively.</p>
1.5	<p>Neither the NICE clinical guidelines or the RMOC position statement provide guidance recommending continuous glucose monitoring or flash glucose monitoring for patients with type 2 diabetes as a cost-effective use of NHS resource. On this basis, the CCG will only commission flash glucose monitoring in patients with type 2 diabetes mellitus on haemodialysis in accordance with the guidance of NHS England.</p>
2	<p>Scope and definitions</p>
2.1	<p>This policy is based on the CCGs' Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).</p>

<p>2.2</p>	<p>Type 1 diabetes mellitus is a chronic metabolic disorder caused by the destruction of insulin-producing cells in the pancreas that leads to an absolute lack of the hormone and subsequent loss of blood glucose control. Treatment of type 1 diabetes mellitus is by insulin therapy to achieve blood glucose control.</p> <p>Type 2 diabetes mellitus is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia). Patients with type 2 diabetes mellitus may initially be managed with lifestyle and dietary changes alone, although due to the progressive nature of the disease many patients will require interventions with medicines including insulin as glycaemic control deteriorates.</p> <p>To help maintain control of blood glucose levels, NICE guidelines recommends that type 1 patients self-monitor their blood glucose levels between 4 and 10 times a day. NICE guidelines do not recommend routine self-blood glucose monitoring in type 2 patients, except in patients using medicines which may cause hypoglycaemia (e.g. sulphonylureas and insulins).</p> <p>Currently most patients self-monitor blood glucose by applying a drop of blood to a testing strip. This strip is then inserted into a meter to display a blood glucose level. For those patients who are not satisfactorily managed with self-monitored finger prick blood-glucose testing, continuous glucose monitoring and flash glucose monitoring are alternative glucose monitoring methods.</p> <p>Continuous glucose monitoring systems use a sensor to continuously measure interstitial fluid glucose levels and automatically transmit readings to a receiver every 5 minutes. Continuous glucose monitoring devices may be fitted with alarms to alert patients when blood glucose levels are too high or low and can be integrated into continuous subcutaneous insulin infusion devices (insulin pumps) to allow real time adjustment of insulin doses or suspend insulin delivery following a low-glucose warning.</p> <p>Flash glucose monitoring systems use a sensor to measure interstitial fluid glucose levels every minute and stores glucose levels at 15-minute intervals for 8 hours. Glucose levels can be seen at any time by scanning a reader over the sensor. The sensor must be scanned at least every 8 hours to provide a full 24 hours of data. The device does not provide a hypoglycaemia alarm; the sensor must be scanned to detect when the glucose level is too high or too low.</p>
<p>2.3</p>	<p>The scope of this policy includes requests for continuous glucose monitoring and flash glucose monitoring devices for adults and children of any age with a confirmed diagnosis of type 1, type 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production (e.g. cystic fibrosis-related diabetes, post-pancreatic destruction, post-pancreatectomy diabetes) where these patients fulfil NICE TA151 criteria in every regard other than having type 1 diabetes.</p>
<p>2.4</p>	<p>The scope of this policy does not include the provision of continuous glucose monitoring and flash glucose monitoring devices for adults and children who do not</p>

	have a confirmed diagnosis of diabetes mellitus or any other aspects of the management of type 1 or type 2 diabetes mellitus or cystic fibrosis-related diabetes.
2.5	<p>The CCG recognises that a patient may have certain features, such as:</p> <ul style="list-style-type: none"> • having type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production; • wishing to have a service provided for type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production; • being advised that they are clinically suitable for a continuous glucose monitoring or flash glucose monitoring device; and • being distressed by having type 1 or 2 diabetes mellitus or non-type 1, non-type 2 diabetes patients caused primarily by (near-) absence of insulin production. <p>This alone is not sufficient to meet the criteria specified in this commissioning policy.</p> <p>Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.</p>
2.6	Terms and abbreviations used in this policy are explained and defined in Appendix 1. Throughout this policy any term is used with the meaning described in that appendix.
2.7	This policy references the advice of NHS England (NHSE) (published March 2019), the Regional Medicines Optimisation Committee (RMOC) (published in October 2017) and The National Institute for Health and Care Excellence (NICE), in particularly NG17 and NG18 (both published in August 2015), which relates to adults and to children & young people respectively. Appendix 2 contains statements from the relevant guidelines to support recommendations within the policy.
3	Appropriate Healthcare
3.1	The purpose of continuous glucose monitoring and flash glucose monitoring devices are to reduce the variability of blood glucose levels. This is achieved by enabling patients to intervene quicker (than would have been possible with finger prick glucose testing) when blood glucose levels deviate from euglycaemia due to more frequent testing and availability of blood glucose data. Improved control of blood glucose levels reduces the likelihood of short-term complications such as episodes of low blood glucose (hypoglycaemia) or life-threatening emergencies such as diabetic ketoacidosis (a consequence of high blood glucose levels).
3.2	The CCG regards the achievement of this purpose of continuous glucose monitoring and flash glucose monitoring as according with the Principle of Appropriateness. Therefore, this policy does not rely on the principle of appropriateness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider the Principle of Appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.
4	Effective Healthcare

4.1	The CCG does not call into question the effectiveness of continuous glucose monitoring or flash glucose monitoring and therefore this policy does not rely on the Principle of Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.
5	Cost Effectiveness
5.1	<p>This policy relies on the Principle of Cost-Effectiveness. The CCG considers that in most patients able to achieve their agreed HbA1c target without disabling hypoglycaemia using alternative methods of self-monitoring of blood glucose, the use of continuous glucose monitoring and flash glucose monitoring to improve blood glucose control would not represent a cost-effective use of NHS resources.</p> <p>In determining the circumstances under which continuous glucose monitoring and flash glucose monitoring are cost-effective, the CCGs have referenced the guidance of NHSE, the RMOG and NICE clinical guidelines NG17, NG18 and NG28 which relate to adults with type 1 diabetes mellitus; children and young people with type 1 and 2 diabetes mellitus; and adults with type 2 diabetes mellitus respectively.</p>
6	Ethics
6.1	The CCG does not call into question the ethics of continuous glucose monitoring or flash glucose monitoring and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.
7	Affordability
7.1	The CCG does not call into question the affordability of continuous glucose monitoring or flash glucose monitoring and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.
8	Exceptions
8.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
8.2	In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidelines in driving decisions of this CCG. A circumstance in which a patient satisfies NICE guidelines but does not satisfy the criteria in this policy does not amount to exceptionality.
9	Force

9.1	This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.
9.2	<p>In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:</p> <ul style="list-style-type: none"> • If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory. • If the new NICE guidance does not have mandatory status, then the CCG will aspire to review and update this policy accordingly. However, until the CCG adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this CCG are concerned.

10	References
	<ol style="list-style-type: none"> 1. NHS England Flash Glucose Monitoring: National Arrangements for Funding of Relevant Diabetes Patients. Available at https://www.england.nhs.uk/wp-content/uploads/2019/03/National-arrangements-for-funding-of-relevant-diabetes-patients-June-2020-Updated-final.pdf 2. National Institute for Health and Clinical Excellence (2008) Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Technology appraisal guideline 151 (TA151). Available at https://www.nice.org.uk/guidance/ta151 3. National Institute for Health and Care Excellence (2016) Type 1 diabetes in adults: diagnosis and management. NICE guideline (NG17). Available at https://www.nice.org.uk/guidance/ng17 4. National Institute for Health and Care Excellence (2016) Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline (NG18). Available at https://www.nice.org.uk/guidance/ng18 5. National Institute for Health and Care Excellence (2015) Type 2 diabetes in adults: management. NICE guideline (NG28). Available at https://www.nice.org.uk/guidance/ng28 6. Regional Medicines Optimisation Committee (2017) Flash Glucose Monitoring Systems Position Statement. Available at https://www.sps.nhs.uk/wp-content/uploads/2017/11/Flash-Glucose-monitoring-System-RMOC-Statement-final-2.pdf 7. NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110 8. ABCD Type 1 Diabetes Clinical Collaborative: Information to help a formulary case for Freestyle Libre System October 2017. Available at https://abcd.care/getting-freestyle-libre-your-formulary 9. ACDC (2017) A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 Years. Available at https://www.bsped.org.uk/clinical/docs/CGM-FGS-ACDC-Guideline.pdf 10. Diabetes UK (2017) Diabetes UK Consensus Guideline for Flash Glucose Monitoring. Available at https://www.diabetes.org.uk/resources-s3/2017-09/1190_Flash%20glucose%20monitoring%20guideline_SB_V9%5B4%5D.pdf

	11. National Institute for Health and Care Excellence (2020) Diabetes in pregnancy: management from preconception to the postnatal period. NICE guideline (NG3). Available at https://www.nice.org.uk/guidance/ng3
11	Appendix 1 – Terms and abbreviations
	<p>CCG – Clinical Commissioning Group.</p> <p>NICE – National Institute for Health and Care Excellence</p> <p>RMOC – Regional Medicines Optimisation Committee</p> <p>NHSE – NHS England</p> <p>Diabetes mellitus – As defined by the World Health Organisation 2006 plasma glucose criteria (fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).)</p> <p>Euglycaemia – Normal concentration of glucose in the blood within an optimal range of 90–130 mg/dl</p> <p>HbA1c - Glycated haemoglobin measured using methods that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation.</p> <p>MDI – Multiple daily injections. In this policy this refers to four or more daily injections of insulin.</p> <p>NG17 – NICE guideline 17 (Type 1 diabetes in adults: diagnosis and management).</p> <p>NG18 – NICE guideline 18 (Diabetes [type 1 and type 2] in children and young people: diagnosis and management).</p> <p>NG28 – NICE guideline 28 (Type 2 diabetes in adults: management).</p> <p>TA151 – NICE technology appraisal guideline 151 (Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus).</p> <p>Adult – A person over the age of 18 years.</p> <p>Children and young people – Covers people under the age of 18 years as defined by NG18. Children may be defined as people under the age of 12 years and young people defined as people between the ages of 12 and 18 years. (However, the separate definitions for children and young people are not stated in NG18 or TA151).</p> <p>DAFNE – Dose Adjustment For Normal Eating (regimen for patient self-management).</p> <p>Gold Score – A method used to assess impairment of awareness of hypoglycaemia. This comprises a single question “do you know when your hypos are commencing” and a 7-point Likert scale for responses ranging from 1 (always aware) to 7 (never aware). A score of ≥ 4 implies impaired awareness of hypoglycaemia.</p>

	<p>Clarke Score – A method used to assess impairment of awareness of hypoglycaemia. This comprises a set of 8 questions relating to hypoglycaemia where patient can score “1” or “0” for each question depending on response. A score of ≥ 4 implies impaired awareness of hypoglycaemia.</p> <p>Disabling hypoglycaemia – defined by TA 151 as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.</p> <p>Severe hypoglycaemia – an episode of low blood glucose levels that requires assistance from another person to treat (i.e. a person unable to swallow, convulsing or unconscious).</p> <p>GPwSI in Diabetes – GP with Special interest in Diabetes</p> <p>DKA – Diabetic Ketoacidosis.</p> <p>EQ-5D – Validated Quality of Life measure developed by EuroQol and referenced by NICE.</p> <p>DQoL – Diabetes Quality of Life measure. A validated tool designed by the Diabetes Control and Complications Research Group.</p> <p>Intensive monitoring – For the purposes of the policy, patients who perform 8 or more additional blood glucose monitoring tests above the minimum frequency of daily testing outlined by NICE clinical guidance (i.e. 12 or more tests daily).</p>

12	Appendix 2 – Applying NICE, RMOG and NHSE guidance to the policy	
	Policy Section	Guidance
1.2.1		<p>NG17 1.6.24 - “Real-time continuous glucose monitoring should be provided by a centre with expertise in its use, as part of strategies to optimise a person's HbA1c levels and reduce the frequency of hypoglycaemic episodes”.</p>
1.2.2		<p>NICE Quality statement [QS125], quality statement 4 “Children and young people with type 1 diabetes who have frequent severe hypoglycaemia are offered ongoing real-time continuous glucose monitoring with alarms.”</p> <p>NG17 1.6.22 “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:</p> <ul style="list-style-type: none"> • 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.” <p>NG18 1.2.62 – “Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have:</p> <ul style="list-style-type: none"> • 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).” <p>NG18 1.2.63 – “Consider ongoing real-time continuous glucose monitoring for:</p> <ul style="list-style-type: none"> • 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)

		<ul style="list-style-type: none"> 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.” <p>NG3 1.3.17 “Offer continuous glucose monitoring (CGM) to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes”.</p> <p>NG3 1.3.18 “Offer intermittently scanned CGM (isCGM, commonly referred to as flash) to pregnant women with type 1 diabetes who are unable to use continuous glucose monitoring or express a clear preference for it”.</p>	
	1.3.1	<p>RMOC guidance – “Until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care.”</p> <p>“It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician.....”</p>	
	1.3.2	<p>RMOC guidance – “It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following:</p> <ol style="list-style-type: none"> 1. Patients who undertake intensive monitoring >8 times daily 2. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy. 3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function. 4. Frequent admissions (>2 per year) with DKA or hypoglycaemia. 5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible. 	

In addition, all patients (or carers) must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered).”

NHS England guidance - Criteria for NHS England Flash Glucose Monitoring Reimbursement

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 postdelivery 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 selffunding.
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.

NG3 1.3.18 “Offer intermittently scanned CGM (isCGM, commonly referred to as flash) to pregnant women with

		<p>type 1 diabetes who are unable to use continuous glucose monitoring or express a clear preference for it”.</p>	
	<p>1.3.3</p>	<p>RMOC guidance – “We suggest information is collected on the following:</p> <ol style="list-style-type: none"> 1. Reductions in severe/non-severe hypoglycaemia 2. Reversal of impaired awareness of hypoglycaemia 3. Episodes of diabetic ketoacidosis 4. Admissions to hospital 5. Changes 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. <p>We recommend that if no improvement is demonstrated in one or more of these areas over a 6 month trial then the use of Freestyle Libre® should be discontinued and an alternative method of monitoring used.”</p> <p>NG18 1.2.58 and 1.2.59 – “Advise children and young people with type 1 diabetes and their family members or carers (as appropriate) to routinely perform at least 5 capillary blood glucose tests per day.”</p> <p>“Advise children and young people with type 1 diabetes and their family members or carers (as appropriate) that more frequent testing is often needed (for example with physical activity and during intercurrent illness), and ensure they have enough test strips for this.”</p> <p>NG17 1.6.11 - Support adults with type 1 diabetes to test at least 4 times a day, and up to 10 times a day if any of the following apply:</p> <ul style="list-style-type: none"> • the desired target for blood glucose control, measured by HbA1c level (see recommendation 1.6.6), is not achieved • the frequency of hypoglycaemic episodes increases • there is a legal requirement to do so (such as before driving, in line with the Driver and Vehicle Licensing Agency [DVLA] At a glance guide to the current medical standards of fitness to drive) • during periods of illness • before, during and after sport • when planning pregnancy, during pregnancy and while breastfeeding (see the NICE guideline on diabetes in pregnancy) • if there is a need to know blood glucose levels more than 4 times a day for other reasons (for example, 	

			impaired awareness of hypoglycaemia, high-risk activities)	
	1.5		<p>NG28 (Full guideline) - “The GDG discussed the conflicting evidence presented for continuous glucose monitoring compared with standard SMBG from 2 small, low-quality trials in people on insulin, where 1 trial showed no difference in HbA1c levels at 3 months while the second trial showed a clinically important reduction in HbA1c levels at 12 months. The GDG agreed that there was still uncertainty regarding the effectiveness of continuous glucose monitoring. The GDG noted the overall lack of evidence on diabetes-related complications.”</p> <p>RMOC guidance – “Until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care.”</p> <p>“It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care.....”</p>	

Date of adoption:
Date for review: