NHS
Staffordshire and Stoke-on-Trent
Integrated Care Board

Continuous Glucose Monitoring Insulin Pump Commissioning Policy

Policy Folder & Policy Number	Commissioning
Version:	v. 2.1
Ratified by:	Integrated Care Board
Date ratified:	1st July 2022
Name of originator/author:	Sarah Evans – Commissioning Manager
Name of responsible committee/individual:	Strategy & Transformation Committee
Date approved by Committee	See inside cover
Date issued:	Nov 2017
Review date:	Every three years
Date of first issue	Nov 2017
Target audience:	ICB and Partner organisations temporary staff

CONSULTATION SCHEDULE		
Name and Title of Individual	**Groups consulted**	**Date Consulted**
Membership Boards	East Staffs, S.E. Staffs & SaS CCGs	June 2022

APPROVALS & RATIFICATION SCHEDULE	
Name of Committee approving Policy	**Date**
North Staffs & Stoke-on-Trent CCG Gov Body	Oct 2017
Staffordshire & Stoke-on-Trent ICB	1st July 2022

VERSION CONTROL			
V	**Version/Description of amendments**	**Date**	**Author/amended by**
1.	New policy North Staffs & Stoke-on-Trent CCG	Nov 2017	Sarah Evans - CCG
2.	Reviewed and adopted across 6 CCGs	June	Simon Runnett –
2.	Adapted for ICB	July 2022	Simon Runnett –

Impact Assessments – available on request			
	Stage	Complete	Comments
Equality Impact Assessment	1	08.02.2022	
Equality Impact Assessment	2	10.03.2022	
Quality Impact Assessment		27. 07.2021	

1. Treatment	**Continuous Glucose Monitoring (CGM) Device.**
2. For the Treatment of	Type 1 diabetes mellitus.
3. Background	**Definition** Continuous glucose monitoring is a way to measure glucose levels in real-time. The glucose sensor is inserted under the skin, which measures blood glucose levels throughout the day and night, enabling patients with variable and unpredictable glucose levels to achieve safer and more stable overall control.
4. Scope	The scope of this policy is to outline eligibility criteria for continuous glucose monitoring for patients diagnosed with type 1 diabetes mellitus.
5. Commissioning Position	**<u>Commissioned Services</u>** Providers of CGM are required to seek prior approval from the commissioner for new patients that they consider suitable for a CGM device. **Requests should be made by a consultant Diabetologist.** CGM 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. Requests should be made for **funding following a trial of short term (6 months) continuous glucose monitoring** (at the Supplier / Providers expense); patients should show a positive response as well as compliance. Requests for long term funding should be made to Commissioners based on the results of this trial and should clearly outline the patient outcome. A referral proforma should be completed by the Consultant Diabetologist and submitted to the commissioner, post assessment, to confirm eligibility for treatment (Appendix 1) **<u>Eligibility Criteria</u>** The commissioner will consider the request against the criteria outlined below: **1. Disabling hypoglycaemia despite optimal self-management supported by a secondary care specialist team** CGM should only be considered following structured education, optimised insulin analogue basal-bolus insulin therapy, frequent conventional finger-prick self-monitoring of blood glucose and insulin pump therapy. 'Disabling hypoglycaemia' comprises of:

	i. *More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause.* **and** ii. *Complete loss of awareness of hypoglycaemia* – Loss of early warning symptoms is associated with 6-fold increased risk of severe hypoglycaemia, but some individuals are able to avoid severe events by reliance on the presence of a 'carer'; obsessional conventional glucose monitoring; or avoidance of normal activities which may induce hypoglycaemia / mask symptoms / or lead to personal danger if hypoglycaemia ensues eg exercise. CGM can substitute 'technological awareness' for 'physiological awareness'. ***and*** iii. Extreme f*ear of hypoglycaemia* – Disability, glucose levels chronically above target and reduced quality of life due to phobic worry and behaviours leading to hypoglycaemia avoidance. **and** iv. Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities **2. Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times daily** **3. For pregnant women with labile blood glucose or dangerous hypoglycaemia** CGM only to be considered following structured education, optimised insulin analogue basal-bolus insulin therapy, frequent conventional finger-prick self-monitoring of blood glucose and insulin pump therapy. The incidence of pregnant women requiring CGM is expected to be low and by exception. Funding for this patient cohort will only be up to the time the expectant mother has given birth and is no longer breastfeeding. Further funding will be subject to the eligibility criteria being met in full. **4. Transition from paediatric care** Already using CGM and having demonstrated significant clinical benefit justifying ongoing provision. **Real-time glucose monitoring should not be routinely offered to adults with type 1 diabetes.**
6. Indicative numbers	It is expected that CGM will largely be used as an 'add on' therapy for those already using insulin pumps and may often be provided through a sub-specialty insulin pump service. The lack of available evidence makes it difficult to gauge the true numbers who would benefit from CGM however the Acute Trust has indicated c5-7% of insulin pump patients.
7. Effective from	July 2022

8. Summary of evidence/rationale	NICE Type 1 diabetes in adults: diagnosis and management –July 16 [NG17] NICE Diabetes (type 1 and type 2) in children and young people: diagnosis and management –November 2016 [NG18] NICE Diabetes in pregnancy: management from preconception to the postnatal period – August 2015 [NG3] NICE Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus [TA151]
9. Review Date	July 2025

Appendix 1:

Staffordshire and Stoke on Trent ICB Referral Form **Continuous Glucose Monitoring (CGM)** *(to be read in conjunction with Stafffordshire and Stoke on Trent ICB's CGM Commissioning Policy)*	This form must be fully completed during the patients' assessment and returned to ifrteam@nhs.net for pre-approval to ensure that the patient meets the ICB's eligibility criteria prior to commencing any treatment. Incomplete forms will be returned to the referring clinician for further information before any further treatment can be undertaken.
PATIENTS NAME, NHS No & POSTCODE:	GP'S NAME: ICB:
DATE OF DIAGNOSIS:	DATE CGM TRIAL COMMENCED:

		YES	**NO**
1	Patient has undergone 6mths trial of CGM and shown compliance:		

AND

2A	Prior to the trial a patient had hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times daily		

OR

2B	Patient has disabling hypoglycaemia despite optimal self-management meeting **ALL** the criteria defined below:		
	i. More than one episode per year of severe hypoglycaemia with no obvious preventable precipitating cause.		
	ii. Complete loss of awareness of hypoglycaemia		
	iii. Extreme fear of hypoglycaemia		
	iv. Frequent (more than 2 episodes per week) asymptomatic hypoglycaemia that is causing problems with daily activities.		
	Transition from paediatric care		

For pregnant women with labile blood glucose or dangerous hypoglycaemias please refer to the Commissioning Policy (Section 5).

Any other relevant information:

Consultant Making Request
Print **Signature** **Date**
Approved by
Print **Signature** **Date**
PID NUMBER