

CONTINUOUS GLUCOSE MONITORING REALTIME (rtCGM) NON PRESCRIBABLE CRITERIA BASED ACCESS (CBA) POLICY

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Application Form	EBI Generic application form if appropriate to apply

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VERSION CONTROL

Document Status:	Current policy
Version:	2324.V6

DOCUMENT CHANGE HISTORY

Version	Date	Comments
1718.v1	October 2017	Inclusion of information
1920.v2	November 2019	Inclusion of NICE recommendations, template update
2021.v2.1	November 2020	Updated following national allocation to extend CGM to all Type 1 pregnant women
2021.v2.1	June 2021	Inclusion of 2 additional cohorts of patients
2021.v3	May 2022	Policy title amended to include rtCGM non-prescribable & inclusion of updated NICE guidance
2223.v4	July 2022	Amendment from SCCG to NHS Somerset ICB. New PALS address
2223.v4a	March 2023	Wording change 3.5
2223.v4b	July 2023	3-year review. Inclusion of cohort as per NICE ng18
2324.v5	January 2024	3-year review. Criteria wording change 2.2 updated NICE TAG943 inclusion + 5 year implementation plan

Equality Impact Assessment (EIA)	N/A
Quality Impact Assessment QIA	July 2021
Sponsoring Director:	Dr Bernie Marden
Document Reference:	2324.V6

1 GENERAL PRINCIPLES (CBA)

- 1.1 Treatment should only be given in line with these general principles. Where patients are unable to meet these principles, in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB's Evidence Based Interventions Service (EBI) by submission of an EBI application form
- 1.2 Clinicians should assess their patients against the criteria within this policy prior to a referral and/or treatment
- 1.3 Treatment should only be undertaken where the criteria have been met and there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment
- 1.4 Referring patients to secondary / community care without them meeting the criteria or funding approval not secured not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment
- 1.5 On limited occasions, the ICB may approve funding for an assessment only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meet the criteria to access treatment in this policy
- 1.6 Patients should be advised being referred does not confirm that they will receive treatment or surgery for a condition as a consent discussion will need to be undertaken with a clinician prior to treatment
- 1.7 The policy does not apply to patients with suspected malignancy who should continue to be referred under 2 week wait pathway rules for assessment and testing as appropriate
- 1.8 Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be

encouraged to lose weight further prior to seeking surgery.
<https://www.sciencedirect.com/science/article/pii/S1198743X15007193>
(Thelwall, 2015)

- 1.9 Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing

2 POLICY CRITERIA – CRITERIA BASED ACCESS (CBA)

2.1 Existing paediatric patients

Existing paediatric patients receiving Continuous Glucose Monitoring (rtCGM) prior to the transfer of commissioning to the ICB may continue with the treatment on the recommendation of a consultant and the activity to be included within the contract arrangements in place with providers

- 2.2 Hybrid closed loops are routinely commissioned only for patients fulfilling the criteria as set out in NICE TA943

<https://www.nice.org.uk/guidance/ta943/resources/hybrid-closed-loop-systems-for-managing-blood-glucose-levels-in-type-1-diabetes-pdf-82615666856389>

Subject to Somerset ICS 5-year implementation plan

<https://www.england.nhs.uk/long-read/hybrid-closed-loop-technologies-5-year-implementation-strategy/>

- 2.3 **THE ICB DOES NOT ROUTINELY COMMISSION** Non prescribable real time Continuous Glucose Monitoring (rtCGM) for any other group of patients other than those detailed under section 2.5

Patients who are not eligible for treatment under this policy, please refer to section 3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS on how to apply for funding with evidence of clinical exceptionality

- 2.4 For recommendations on prescribable real time CGM (rtCGM) and intermittent scanning CGM (rtCGM) refer to the Somerset Formulary Guidance

- 2.5 The ICB will routinely commission the choice of non-prescribable rtCGM (Providing the CGM device does not exceed £2000* per patient for 12 months) for new patients who fulfil one of the criteria below:

- a) Are pregnant with Type 1 diabetes and deemed not suitable after a shared decision-making review for prescribable rtCGM **OR**
- b) Have type 1 diabetes and a Learning Disability (patient on their GP LD register) or Autism and are deemed unsuitable after a shared decision-making review for prescribable rtCGM **OR**

- c) Have Type 1 diabetes and during the 6-month trial have a been identified with a clinical (e.g., Sensitivities to the device, for example local skin reactions) or technological incompatibility with licensed prescribable rtCGM **OR**
 - d) Have Type1 diabetes and are ineligible for a licensed prescribable rtCGM due to age
- 2.6 Offer real-time continuous glucose monitoring (rtCGM) to children and young people with type 2 diabetes if any of the following apply. They:
- have a need, condition or disability (including a mental health need, learning disability or cognitive impairment) that means they cannot engage in monitoring their glucose levels by capillary blood glucose monitoring
 - would otherwise be advised to self-monitor at least 8 times a day
 - have recurrent or severe hypoglycaemia. [2023]
- 2.6.1 Consider rtCGM for children and young people with type 2 diabetes who are on insulin therapy. [2023]
- 2.6.2 Consider intermittently scanned continuous glucose monitoring (rtCGM, commonly referred to as 'flash') for children and young people with type 2 diabetes aged 4 years and over who are on insulin therapy if:
- rtCGM is contraindicated for them or
 - they express a clear preference for rtCGM

*Subject to contractual position re procurement limit

<https://www.supplychain.nhs.uk/product-information/contract-launch-brief/insulin-pumps-and-associated-products/>

3 EVIDENCE BASED INTERVENTIONS APPLICATION PROCESS

- 3.1 Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or Consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy
- 3.2 Completion of a **Generic EBI Application Form** by a patient's GP or Consultant is required
- 3.3 Applications cannot be considered from patients personally
- 3.4 Only electronically completed EBI applications will be accepted to the EBI Service

3.5 It is expected that clinicians will have ensured that the patient, on behalf of who they are forwarding the application for, is appropriately informed about the existing policies prior to an application to the EBI service. This will reassure the service that the patient has a reasonable expectation of the outcome of the application and its context

3.6 EBI funding application are considered against clinical exceptionality. To eliminate discrimination for patients, **social, environmental, workplace, and non-clinical personal factors cannot be taken into consideration.**

For further information on 'clinical exceptionality' please refer to the NHS Somerset ICB EBI webpage [Evidence Based Interventions - NHS Somerset ICB](#) and click on the section titled Generic EBI Pathway.

3.7 Where appropriate photographic supporting evidence can be forwarded with the application form

3.8 An application put forward for consideration must demonstrated some unusual or unique clinical factor about the patient that suggests they are exceptional as defined below:

- Significantly different to the general population of patients with the condition in question
- Likely to gain significantly more benefit from the intervention than might be expected from the average patient with the condition

4 ACCESS TO POLICY

4.1 If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Patient Advice and Liaison Service on Telephone number: 08000 851067

4.2 **Or write to us:** NHS Somerset ICB, Freepost RRKL-XKSC-ACSG, Yeovil, Somerset, BA22 8HR or **Email** us: somicb.pals@nhs.net

5 REFERENCES

The following sources have been considered when drafting this policy:

- 5.1 <https://www.nice.org.uk/guidance/ng28>
<https://www.nice.org.uk/guidance/ng28/chapter/Recommendations#continuous-glucose-monitoring>
- 5.2 <https://www.nice.org.uk/guidance/ng17>
<https://www.nice.org.uk/guidance/ng17/chapter/Recommendations#continuous-glucose-monitoring>
- 5.3 <https://www.nice.org.uk/guidance/ng18>
<https://www.nice.org.uk/guidance/ng18/chapter/Recommendations#continuous-glucose-monitoring>
- 5.4 <https://www.nice.org.uk/guidance/ta151/resources/continuous-subcutaneous-insulin-infusion-for-the-treatment-of-diabetes-mellitus-pdf-82598309704645>

- 5.5 <https://www.diabetes.co.uk/news/2018/jul/nice-announces-guidelines-review-for-cgm-use-in-pregnant-women-with-type-1-diabetes-98166414.html>
- 5.6 [NHS England » Type 2 Diabetes Prevention Programme and Type 1 diabetes glucose monitoring: Letter from Professor Jonathan Valabhji, Professor Partha Kar and Tom Newbound](#)
- 5.7 Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. Published December 2023 TA943 <https://www.nice.org.uk/guidance/ta943/resources/hybrid-closed-loop-systems-for-managing-blood-glucose-levels-in-type-1-diabetes-pdf-82615666856389>