NHS
North Yorkshire
Clinical Commissioning Group

Commissioning Statement: Continuous Glucose Monitoring (CGM) for type 1 diabetes (adults and children)

Condition or Treatment:	Continuous Glucose Monitoring (CGM) for type 1 diabetes (adults and children)
Background	Continuous Glucose Monitoring (CGM) systems are available for use in type 1 diabetes to help patients better manage their blood glucose levels, or as a continuous aid in glycaemic control. They use a glucose sensor placed under the skin that continuously measures glucose levels. The Abbot Freestyle Libre (FSL) system is a flash glucose monitoring system which measures glucose continually but needs to be actively scanned using a digital monitor. The upgraded FSL system (FSL2) has an optional alarm system which alerts the patient to either high or low glucose levels, this is already captured within an existing CCG policy. More complex (and expensive) CGM devices transmit a continuous reading to a display unit and alarm if low or high levels occur. Sensor-augmented devices can communicate directly with an integrated insulin pump to suspend delivery if hypoglycaemia is predicted. Cost is around £3000-£3500 a year. NICE have published clinical guidelines which provides recommendations for when to consider CGM in both children (Diabetes (type 1 and 2) in children and young people: diagnosis and management. NICE guideline NG18) and adults (Type 1 diabetes in adults: diagnosis and management NG 17).
Commissioning position:	NHS North Yorkshire CCG commissions continuous glucose monitoring with alarms only for those patients who meet the criteria outlined in this document. **Children up to 18 years** CGM is commissioned for children where, despite optimised use of insulin therapy and conventional blood glucose monitoring (by themselves or their parents/guardians), they • fulfil the CCG criteria for flash glucose monitoring (FreeStyle Libre) (FSL) • FSL has been tried for at least 6 months (as per FSL guidance* with audit), and not demonstrated any improvement in diabetic control and reduction in finger prick testing **OR** • have total hypoglycaemia unawareness (documented with an appropriate scoring system) **OR** • have frequent severe hypoglycaemia **or** • have impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety) or • have an inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological

disabilities)

OR
Where considered clinically appropriate in:

- neonates, infants and pre-school children,
- children and young people who undertake high levels of physical activity
- children and young people who have comorbidities (eg anorexia nervosa) or who are receiving treatments (eg corticosteroids) that can make blood glucose control difficult. "

Adults
CGM is commissioned for adults where, despite optimised use of insulin therapy and conventional blood glucose monitoring (by themselves or their carers,) they

- fulfil the CCG criteria for flash glucose monitoring (FreeStyle Libre) (FSL)
- FSL has been tried for at least 6 months (as per FSL guidance*, with audit), and not demonstrated any improvement in diabetic control and reduction in finger prick testing

OR

- have total hypoglycaemia unawareness (documented with an appropriate scoring system)

AND
They need to fulfill at least ONE additional criteria of the following:

- Have more than 1 episode a year of documented severe hypoglycaemia with no obviously preventable precipitating cause, requiring assistance of another person (eg family, paramedic)
- Have 2 or more admissions to hospital with DKA or hypoglycaemia
- Have complete loss of awareness of hypoglycaemia (documented with an appropriate scoring system)
- Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities

Children and Adults All patients (and their carers) must fulfil all of the following criteria

- Have, according to their diabetes specialist,
  - A high level of engagement with glucose testing and management
  - A willingness to engage with further education and commit to using it at least 70% of the time, with ability to calibrate it as needed
- The device must 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.
- Treatment outcomes must be audited in all patients at, at least 6 and 12 months. Both patient and specialist are responsible for this audit.

	CGM will be provided initially on a 6 month trial basis and it must be possible to demonstrate (where requested by the CCG) at 6 and 12 months, that using the system results in improved diabetic control, including • Reduction in usage of blood glucose test strips • Reduction in severe/non-severe hypoglycaemia frequency • Reduction in hospital admissions • Reversal of impaired awareness of hypoglycaemia • Reduction in episodes of DKA • Improved QoL using validated rating scales The requirements of the person or their carer are considerable and not every person or family may be able to fulfil them. Assessment should be carried out by the specialist MDT in secondary care at 6 and 12 months, to ensure the monitor can be used effectively by the person or family concerned, and to provide data to the CCG. To note: CGM in pregnancy for T1 diabetics is commissioned directly via HCV ICS and as part of the NHS long term plan all pregnant women with type 1 diabetes will be offered continuous glucose monitoring, helping to improve neonatal outcomes. This is not covered by this policy. **For all other cases, funding will only be considered by the Individual Funding Request Panel (IFR) where exceptional clinical circumstances are demonstrated.**
Effective From:	1 July 2021
Summary of evidence/ rationale:	NICE NG18 also included: "Consider ongoing real-time continuous glucose monitoring for: • neonates, infants and pre-school children, • children and young people who undertake high levels of physical activity • children and young people who have comorbidities (eg anorexia nervosa) or who are receiving treatments (eg corticosteroids) that can make blood glucose control difficult. " It is thought that around 30% of people with type 1 diabetes have problematic hypoglycaemia which can affect many aspects of daily life and result in significant anxiety. This can have a substantial impact on quality of life by leading people to restrict their daily activities. It can also cause significant anxiety for carers, particularly parents who may have to wake several times a night to check on their child. Impaired awareness of hypoglycaemia - Gold score This scoring system is widely used and based on the response to a single question: 'Do you know when your hypos are commencing?' Biochemical hypoglycaemia is defined as less than 3 mmol/litre. Results are expressed by

	a 7-point Likert scale, where 1 = 'always aware' and 7 = 'never aware'. IAH is suggested by a value of more than or equal to 4. This score is based on results from a prospective case-control study with 60 participants and 12 months follow-up (Gold 1994); 29 participants were noted to have impaired awareness and 31 participants had normal awareness of hypoglycaemia. Participants with IAH had an increased frequency of severe hypoglycaemia episodes (more than or equal to 1 severe hypoglycaemia episodes in 66% with impaired awareness versus 26% with normal awareness; higher incidence of severe hypoglycaemia episodes per patient per year: 2.8 with impaired awareness versus 0.5 with normal awareness). https://www.ncbi.nlm.nih.gov/books/NBK343319/ IAH 2015 (part of CG17) gives more detail. NICE DG21 refers to a modified Clark and Gold score from King's College Hospital, London but it has not been possible to trace any more information about this4. **CGM systems** There are many different types of CGM systems, some of which provide alarms, but no clear consensus or NICE guidance about which to use and the NIHR NTA concluded "…Integrated systems are generally unlikely to be cost-effective given that stand-alone systems are cheaper and, possibly, no less effective. However, evidence in this regard is generally lacking, in particular for children. In addition "the overall evidence base to support the best use of (these) systems needs to be improved in order to demonstrate that using the system results in a sustained clinical impact on preventing or improving control of disabling hypoglycaemia." CGM systems need to be used under the supervision of a trained MDT who are experienced in continuous subcutaneous insulin infusion and continuous glucose monitoring for managing type 1 diabetes. The requirements of the person or their carer are also considerable and not every person or family may be able to fulfill them. They must □ agree to use the sensors for at least 70% of the time □ understand how to use it, to calibrate it as needed, and be physically able to use the system □ agree to use the system while having a structured education programme on diet and lifestyle, and counselling. □ only continue to use it if they have a decrease in the number of hypoglycaemic episodes that is sustained. Appropriate targets for such improvements should be set. Robust evidence is still needed to show the clinical effectiveness of using such alternative technology in practice. **Uncertainties about cost-effectiveness** This depends on many factors, including comparison with standard monitoring with finger prick blood glucose tests, the frequency of which can vary greatly. NICE CG18 points out that "Excessive testing can be more expensive than continuous glucose monitoring, and clinicians can use

	excessive testing as a rationale for requesting funding for continuous monitoring systems."2 The NICE guideline development group also considered the clinical and cost effectiveness of real-time continuous glucose monitoring systems compared to 5 or more capillary blood glucose tests per day in children aged 5 years or younger with type 1 diabetes who use insulin pump therapy. Their recommendation was to "consider" ongoing real-time continuous glucose monitoring systems (CGMS) for neonates, infants and pre-school children with type 1 diabetes. This weak recommendation reflected a lack of evidence of effectiveness of CGMs in such children (only a few studies having been conducted in this age group) – e.g reduction in adverse neurodevelopmental consequences of type 1 diabetes. One committee looked at the cost-effectiveness analyses of integrated systems in the severe hypoglycaemia population and concluded that they could not be considered cost effective when compared with capillary blood testing with multiple daily injections or continuous subcutaneous insulin infusion because of the high incremental cost of the technology4. A systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes was reviewed by CRD, who concluded that real-time, but not retrospective, continuous glucose monitoring could be more effective than self-monitoring of blood glucose, for children with type 1 diabetes5.
Date:	
Review Date:	July 2023
Contact:	Dr C Ives, Governing Body GP, North Yorkshire CCG

Additional Information/References:

1. Type 1 diabetes in adults: diagnosis and management NG 17 Aug 2015 https://www.nice.org.uk/guidance/ng17

2. Diabetes (type 1 and 2) in children and young people: diagnosis and management. NICE guideline NG18 August 2015 https://www.nice.org.uk/guidance/ng18

3. Flash glucose monitoring system (FreeStyle Libre) commissioning statement NYCCG 1st July 202. https://www.northyorkshireccg.nhs.uk/

4. DG 21 Resource impact report https://www.nice.org.uk/guidance/dg21/resources/resource-impact-report-2312936173

5. Systematic review and meta-analysis of the effectiveness of continuous glucose monitoring (CGM) on glucose control in diabetes CRD review Nov 2014
http://www.crd.york.ac.uk/crdweb/ShowRecord.asp?LinkFrom=OAI&ID=120130418005