Midlands and Lancashire
Commissioning Support Unit

NHS Halton Clinical Commissioning Group
NHS Liverpool Clinical Commissioning Group
NHS St Helens Clinical Commissioning Group
NHS South Sefton Clinical Commissioning Group
NHS Southport and Formby Clinical Commissioning Group
NHS Warrington Clinical Commissioning Group

Continuous Glucose Monitors (CGM)

You can see your blood glucose level every few minutes with a continuous glucose monitor (CGM). It lets you see patterns in your levels and warns you if your glucose is too high or low.

A CGM is made up of:

- a sensor – a small device you attach to your abdomen – it senses how much glucose is in the fluid under your skin
- a transmitter – attached to the sensor – it sends results to a receiver
- a receiver – a small box that displays your blood glucose level – you can carry this on your belt or in your bag

A sensor usually lasts for 14 days. Some are implanted and worn for 6 months.

The National Institute for Health and Care Excellence (NICE) states there isn't enough evidence to show CGMs are cost-effective enough for everyone with type 1 diabetes.

Criteria from the current 2014/15 Cheshire and Merseyside commissioning policy		Proposed criteria for the revised, future policy		High level summary of changes
Intervention	**Continuous Glucose Monitoring Systems for Continuous Glucose Monitoring in Type 1 Diabetes Mellitus**	**Intervention**	**Continuous Glucose Monitoring**	
Policy Statement	Not Routinely Commissioned	**Policy Statement**	**Restricted**	
Minimum eligibility criteria	Not routinely commissioned and only considered if ALL of the following criteria are met; Type I diabetes. **AND** Currently on a sensor augmented continuous subcutaneous insulin pump in strict accordance with NICE appraisal TAG 151. **AND** HbA1c which is equal to or greater than 69 (8.5%) mmol/OR experiencing severe hypoglycaemic attacks which require intervention by a carer. **AND** Selected to use an approved sensor augmented pump system of high specification with a low Mean Absolute Relative Difference (MARD) value. **AND** Managed by a recognised centre of excellence in diabetes (currently using a minimum of 20 continuous infusion pumps per annum). **AND** Motivated to comply with the requirements.	**Minimum eligibility criteria**	**<u>Adults with type 1 diabetes</u>** CGM is not routinely commissioned. CGM will only be considered for patients when the following criteria are met: Currently using a continuous subcutaneous insulin pump of high specification in strict accordance with NICE appraisal TAG 151 and the local insulin pump policy. **AND** Managed by a recognised adult specialist centre of expertise. This will have a multidisciplinary team comprising a trained diabetes nurse specialist, physician and dietician with all patients trained to count carbohydrates. **AND** Willing to commit to using CGM at least 70% of the time and to calibrate it as needed. **PLUS** HbA1c ≥75 mmol/mol (9%) that persists despite blood glucose testing at least 10 times a day** **OR** Experiencing more than one severe hypoglycaemic episode a year with no obviously preventable precipitating cause. (Severe hypoglycaemia is generally recognised as hypoglycaemia involving convulsions/ unconsciousness) **OR** Experiencing more than 2 episodes of hypoglycaemia per week that the patient has been unable to manage themselves and are causing problems with daily activities. **OR** Complete loss of awareness of hypoglycaemia **OR** Inability to recognise or communicate about symptoms of hypoglycaemia e.g.	**Reason for proposed change(s)** The National Institute for Health and Care Excellence (NICE) states there isn't enough evidence to show continuous glucose monitors are cost-effective enough for everyone with type 1 diabetes. Also see: NICE Technology Appraisal 151: https://www.nice.org.uk/guidance/ta151 NICE Guideline 17 (Type 1 diabetes in adults: diagnosis and management): https://www.nice.org.uk/guidance/ng17 **Impact of proposed change(s)** People with type 1 diabetes.

	The device should be withdrawn from patients who fail to achieve clinically significant response after 6 months. All cases will be subject to individual approval by the IFR Team		because of cognitive or neurological disabilities where other forms of glucose monitoring are not appropriate. **<u>Pregnancy</u>** CGM is not routinely commissioned in pregnancy unless all criteria for CGM in adults are met. Where CGM in pregnancy is used, funding is **only** for the duration of the pregnancy. Insulin doses are reduced to pre-pregnancy levels as soon as the baby is delivered and CGM should not be continued beyond this point. **FOR ALL PATIENTS** A CGM system with a low Mean Absolute Relative Difference (MARD) value should be chosen. Where there is a CGM system with alarm function that will integrate and communicate directly with the patient's established insulin pump, then this CGM system should generally be used. However, an appropriate real-time Dexcom CGM system with alarm function may be considered for patients using other insulin pumps, or those individuals where the integrated system is not the most clinically appropriate CGM system. **The device should be withdrawn from patients who fail to achieve a clinically significant response after 6 months*.** There should also be an annual review to assure the clinically significant response is maintained and that CGM is still the most appropriate method of glucose monitoring for the patient. Consideration should be given to switching to an integrated insulin pump/CGM system when seeking to replace the insulin pump at warranty expiry, if appropriate. **Children and young people with type 1 diabetes** CGM is not routinely commissioned. CGM will only be considered for patients when the following criteria are met: Currently using a continuous subcutaneous insulin pump of high specification, in	EIA - As this is a new policy, the assessment identified that there could be possible adverse impact on protected groups (disability and those who are less able to manage their condition, e.g children and people with a learning disability and therefore recommended further engagement.

			strict accordance with NICE appraisal TAG 151 and the local insulin pump policy. **AND** When provided by a specialist centre with a multidisciplinary team including an active member who attends at least 67% (2/3) of the North West children and young people's diabetes network meetings. In addition, the specialist centre is achieving best practice tariff in paediatric diabetes and is also engaged with the national peer review programme in paediatric diabetes, to monitor the quality of its service. **AND** Willing to commit to using CGM at least 70% of the time and to calibrate it as needed. **PLUS** Experiencing more than 2 episodes per week of severe hypoglycaemia. This is defined as having low blood glucose levels that require assistance from another person to treat and that are happening often enough to have a significant impact on school work or quality of life. **OR** Inability to recognise or communicate about symptoms of hypoglycaemia e.g. because of cognitive or neurological disabilities, or less than 4 years of age. **OR** Impaired awareness of hypoglycaemia which is associated with significant adverse consequences e.g. seizures or severe anxiety. Prior to transition to adult services, the child should be counselled on the transition process and advised that their CGM will be reviewed as part of the transition and their ongoing adult diabetes care. On transition to adult services there should be a review to assure there is still a clinically significant response* and that CGM is still the most appropriate method of glucose monitoring for the patient. **Ongoing continuation of CGM** * A clinically significant response is considered to be: • When the patient demonstrates wearing the sensor for at least 70% of the time. **PLUS** • A reduction in the frequency and/or severity of hypoglycaemic	

			episodes. **OR** • A reduction in the need for third party intervention during hypoglycaemic episodes. **AND/OR** • Achievement of a clinically significant reduction in HbA1c, that demonstrates the patient is moving towards their individually agreed HbA1c target. **Where CGM is initiated due to hyperglycaemia in adults, it should only be continued longer-term 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, in accordance with NICE CG17	
		Evidence for inclusion and threshold	**1**. Benkhadra K, Alahdab F, Tamhane S, Wang Z, Prokop LJ, Hirsch IB, et al. Real-time continuous glucose monitoring in type 1 diabetes: a systematic review and individual patient data meta-analysis. *Clinical endocrinology*. 2017;**86**(3):354-60. **2**. Lind M, Polonsky W, Hirsch IB, Heise T, Bolinder J, Dahlqvist S, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. *JAMA*. 2017;**317**(4):379-87. **3**. Kesavadev J, Vigersky R, Shin J, Pillai PBS, Shankar A, Sanal G, et al. Assessing the Therapeutic Utility of Professional Continuous Glucose Monitoring in Type 2 Diabetes Across Various Therapies: A Retrospective Evaluation. *Advances in therapy*. 2017. **4**. Beck RW, Riddlesworth T, Ruedy K, Ahmann A, Bergenstal R, Haller S, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. *JAMA*. 2017;**317**(4):371-8. **5**. Ruedy KJ, Parkin CG, Riddlesworth TD, Graham C, Group DS. Continuous Glucose Monitoring in Older Adults With Type 1 and Type 2 Diabetes Using Multiple Daily Injections of Insulin: Results From the DIAMOND Trial. *Journal of diabetes science and technology*. 2017:1932296817704445. **6**. van Beers CAJ, DeVries JH, Kleijer SJ, Smits MM, Geelhoed-Duijvestijn PH, Kramer MHH, et al. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. *The lancet Diabetes & endocrinology*.	

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