Introduction

This policy review is part of a wider project to review and update more than 100 health policies by six Clinical Commissioning Groups in Merseyside. The review is to ensure that the latest clinical guidance is being applied consistently across the area and that the latest treatments are made available to patients.

Name of treatment or procedure

Continuous glucose monitors (CGM)

Description of treatment or procedure

A CGM is made up of a small sensor usually attached to the abdomen which measures blood glucose (blood sugar) levels every few minutes. It sends the information to a 'receiver' device which alerts the patient if the level is too high or low. The patient can carry this on their belt or in their bag.

Patients with diabetes need to watch their blood sugar levels carefully, but there are other methods for patients to monitor and adjust their blood sugar levels such as continuous insulin pumps or regular finger-prick tests.

Current policy – CGMs are not routinely commissioned and are only considered if ALL of the following criteria are met:

- The patient has type 1 diabetes
- AND is using a sensor augmented continuous subcutaneous insulin pump (in strict accordance with NICE appraisal TAG 151)
- AND has haemoglobin levels (HbA1c) of at least 69 (8.5%) mmol OR is experiencing severe hypoglycaemic attacks (low blood sugar) which need intervention by a carer
- AND is using an approved sensor augmented pump system of high specification with a low Mean Absolute Relative Difference (MARD) value
- AND is managed by a recognised centre of excellence in diabetes (currently using at least 20 continuous infusion pumps each year)
- AND is motivated to comply with the requirements.

The device will be withdrawn from patients who fail to get a clinically significant response after six months.

Proposed changes – the policy for commissioning CGMs is restricted.

- CGMs with a low Mean Absolute Relative Difference (MARD) value should be chosen.
- If possible, CGMs with an alarm function that communicate directly with the patient's established insulin pump should be chosen. However, an appropriate real-time Dexcom CGM system with alarm function may be considered for patients using other insulin pumps, or where the integrated system is not the most clinically appropriate CGM system.
- Patients who fail to achieve a 'clinically significant response'* after six months should have the device taken away. An annual review should be held to check that CGM is still the most appropriate method for the patient. When the insulin pump warranty expires, an integrated insulin pump / CGM

should be considered (if appropriate), rather than replacing with the same system.

CGMs will only be considered for children and young people with type 1 diabetes if ALL the following criteria are met:

- The patient is currently using a continuous subcutaneous insulin pump of high specification (in strict accordance with NICE Technology Appraisal 151 and the local insulin pump policy) which has been provided by a leading specialist centre.
- AND is committed to using CGM at least 70% of the time and to calibrate it as needed.
- AND is experiencing more than two severe hypoglycaemic attacks (low blood sugar) per week. These are defined as needing assistance from another person to treat and happening often enough to have a significant impact on school work or quality of life.
- OR is unable to recognise or communicate about their hypoglycaemic symptoms e.g. because of cognitive or neurological disabilities, or less than 4 years of age.
- OR has impaired awareness of hypoglycaemia which is associated with significant adverse consequences, e.g. seizures or severe anxiety.

Before being transferred to adult services, the child should be counselled on the process and advised that this will include a review of their CGM. This will be to check it is still the most appropriate method for the patient and that there is still a 'clinically significant response'*.

Notes:

* A clinically significant response is defined as:

- When the patient has worn the sensor for at least 70% of the time
- AND there is a reduction in the frequency and/or severity of hypoglycaemic episodes (low blood sugar)
- OR there is a reduction in the need for intervention during hypoglycaemic episodes
- AND/OR there is a significant reduction in haemoglobin levels (HbA1c), showing the patient is moving towards their individually agreed target.

** Where a patient begins to use CGM due to hyperglycaemia (high blood sugar) in adulthood, it should only be continued longer-term if haemoglobin levels can be kept at 53 mmol/mol (7%) or below, and/or there has been a fall of 27 mmol/mol (2.5%) or more (in accordance with NICE Guideline 17).

Reason for proposed changes

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

Summary of proposed changes

- The revised policy for CGM provides far greater clarity for patients and clinicians than the current policy.
- For adults with type 1 diabetes the criteria remain largely aligned with the current policy, with the addition of the following criteria:
    - Willing to commit to using CGM at least 70% of the time and to calibrate it as needed.
    - Complete loss of awareness of hypoglycaemia
    - Inability to recognise or communicate about symptoms of hypoglycaemia e.g. because of cognitive or neurological disabilities where other forms of glucose monitoring are not appropriate.
- The revised policy now takes account of both pregnant patients and children with diabetes. This will ensure pregnant women as well as children receive CGM where appropriate, where previously this would have required an IFR application.
- Additional clarity has also been provided around ‘a clinically significant response’ which is not captured in the current policy.