Continuous glucose monitoring in diabetes

NHS Devon

Commissioning policy

The routine commissioning of Continuous Glucose Monitoring is accepted in Devon in the circumstances detailed below. A process of shared decision making between members of the specialist multi-disciplinary team and the patient should be used when choosing a continuous glucose monitoring device.

Real Time Continuous Glucose Monitoring (rtCGM)

A range of rtCGM devices is available, it is expected that a **clinically appropriate device** with the **lowest cost** is chosen (taking into account acquisition and ongoing running costs).

GP prescribable systems (listed in the NHS Drug tariff)

GP prescribable rtCGM is routinely commissioned for **ALL** patients with type 1 diabetes*. GP prescribable rtCGM is also routinely commissioned in children and young people with type 2 diabetes who also meet one of the following criteria from NICE Guideline NG18:

- 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.
- Are treated with insulin

rtCGM is commissioned for patients who commenced CGM as a child following the criteria in NG18 if a clear and documented improvement in glycaemic control occurred whilst using an rtCGM.

GP prescribable rtCGM is also routinely commissioned as an alternative to intermittently scanned continuous glucose monitoring (isCGM) for patients who meet the isCGM eligibility criteria listed below if it is available for the **same or lower cost**.

Secondary care procured (non GP prescribable) systems

A 6-month trial of a secondary care procured rtCGM is routinely commissioned only for patients with type 1 diabetes* who meet **one or more** of the following criteria:

1) Are ineligible for a suitable GP prescribable rtCGM or isCGM device due to the absence of a device authorised for use at their age

   OR

2) Are incapable of self-management of their diabetes and have an inability to recognise, or communicate about, symptoms of hypoglycaemia

   OR

3) Patients who receive insulin via a pump **and** who have been deemed likely to benefit from integration between CGM and pump by members of the specialist secondary care diabetes team

   OR

4) Despite a 6-month trial of GP-prescribable rtCGM are experiencing impaired awareness of hypoglycaemia or have hypoglycaemia unawareness **PLUS** have had recent episodes of severe hypoglycaemia (have experienced two or more severe hypoglycaemic episodes within 12 months where they have been unable to take oral treatments)

Continuation criteria for all secondary care procured rtCGM systems

The use of secondary care procured (non GP prescribable) rtCGM systems is expected to be assessed by the specialist team at 6 months (and then annually) against the following continuation criteria:

- A clinically relevant improvement from baseline must be observed in either
  - Glycaemic control (HbA1C or time spent in a pre-defined glucose range), or
  - The frequency or severity of hypoglycaemic events, or
  - A reduction in the patients fear of hypoglycaemia, or
  - An improved awareness of hypoglycaemia

  and

- Secondary care procured rtCGM should cease if the patient is persistently non-engaged with the secondary care clinic

If the continuation criteria are met the patient may continue to use a procured (non GP prescribable) rtCGM device.

It is expected that at each review consideration is given to stepping down to lower cost (e.g. GP prescribable) forms of glucose monitoring wherever clinically appropriate or where the ability to recognise and/or communicate about symptoms of hypoglycaemia has significantly improved.

Intermittently Scanned ("Flash") Continuous Glucose Monitoring

A 6-month trial of intermittently scanned continuous glucose monitoring (isCGM) is routinely commissioned for patients who meet one of the criteria outlined below:

1) Patients with type 1 diabetes* who based on their individual preferences, needs, characteristics, or the functionality of the devices show a preference to use isCGM over a real time continuous glucose monitor.

    Continuation criteria: A clinically relevant improvement must be observed in either glycaemic control (HbA1C or time spent in a pre-defined glucose range) **OR** the frequency / severity of hypoglycaemic events **OR** a reduction in the patients fear of hypoglycaemia **OR** an improved awareness of hypoglycaemia.

OR

2) Patients with type 2 diabetes who are treated with multiple daily insulin injections AND who meet the following eligibility criteria set out in NICE NG28:

    2a) Have recurrent or severe hypoglycaemia, or impaired hypoglycaemia awareness

        Continuation criteria: A reduction in hypoglycaemia frequency (by more than one episode per week) **OR** severity **AND** should cease if the patient is persistently non-engaged with the secondary care clinic

    or

    2b) they have a condition or disability (including a learning disability or cognitive impairment) that means they cannot self-monitor their blood glucose by capillary blood glucose monitoring but could use an isCGM device (or have it scanned for them)

        Continuation criteria: Performing 4 or more scans a day **AND** collecting 70% of daily data **AND** should cease if the patient is persistently non-engaged with the secondary care clinic

    or

    2c) who as a result of a clinical need, have to self-monitor their blood glucose 8 times or more per day as demonstrated on a meter download/review over the past 3 months

        Continuation criteria: Performing 8 or more scans a day **AND** collecting 70% of daily data **AND** should cease if the patient is persistently non-engaged with the secondary care clinic

OR

3) Patients with type 2 diabetes on haemodialysis and who are on insulin treatment **AND** as a result of a clinical need, have to self-monitor their blood glucose 8 times or more per day as demonstrated on a meter download/review over the past 3 months

Continuation criteria: Performing 8 or more scans a day **AND** collecting 70% of daily data **AND** should cease if the patient is persistently non-engaged with the secondary care clinic

As isCGM systems have been commercially available prior to this commissioning policy, patients who have been self-funding or have received isCGM as part of a research project would be eligible for funding only if they met one of current criteria at the time they started using the device and attained the appropriate continuation criteria after 6 months.

* Patients with type 3c diabetes who are treated with insulin are considered as patients with type 1 diabetes for the purpose of this commissioning policy.

Rationale for the decision

Real time continuous glucose monitors (rtCGMs) measure interstitial glucose levels using a sensor which has a small filament sitting under the skin. Measurements are generally taken every 5 minutes and are wirelessly transmitted to a receiver. A range of rtCGM devices is available. Most systems will provide alerts to users if their glucose levels fall outside of a pre-defined glucose range. More advanced systems are able to provide predictive alerts for hypoglycaemia and may also be used in conjunction with other devices such as insulin pumps.

Intermittently scanned continuous glucose monitors (isCGM), commonly referred to as flash glucose monitors, are a technology which acts as an alternative to finger prick glucose testing for people with diabetes. Like rtCGM, these devices measure interstitial glucose levels. However, unlike rtCGM, isCGM devices require the user to bring their receiver in close proximity of the sensor to take a reading. This means that many of the automated rtCGM features are not available on isCGM devices.

National Institute for Health and Care Excellence (NICE) guidelines NG17 and NG18 recommend that all adults with type 1 diabetes, and children and young people with type 1 or type 2 diabetes are offered a rtCGM device to monitor their glucose levels. The NICE guidelines also state that if a patient with type 1 diabetes has an individual preference, need, or characteristics which are better suited to using isCGM than it should be offered. NICE NG28 recommends the use of isCGM for a small, specified group of patients with type 2 diabetes who are treated with insulin.

This policy aligns with the guidance for glucose monitoring using these technologies set out in NICE NG17, NG18 and NG28. This policy also allows for provision of these devices in patients with type 3c diabetes. This provision has been included as NICE NG104 (pancreatitis) states that patients with type 3c diabetes who are treated with insulin should be considered in line with the guidance published in NG17 (adults with type 1 diabetes).

rtCGM systems may be considerably more expensive than isCGM or self-monitoring blood glucose (SMBG). NICE found rtCGM to be a cost-effective option compared to SMBG in patients with type 1 diabetes, meaning that the greater cost associated with the technology are considered, on average, good value for the health benefits gained. There is a large variation in the cost of rtCGM systems, therefore it is expected that if multiple devices meet the needs and preferences of a patient, clinicians will only offer the device with the lowest cost.

Routine funding of secondary care procured (non GP prescribable) rtCGM for all patients with type 1 diabetes would have a significant financial impact. This policy supports access to rtCGM for all patients with type 1 diabetes; it provides clarity regarding the circumstances under which secondary care procured rtCGM devices may be made available, with the aim of achieving equitable outcomes from the use of CGM devices in patients with diabetes, within the finite resources available to the NHS in Devon.

Guidance notes on exceptionality

Where the circumstances of treatment for an individual patient do not meet the criteria described above exceptional funding can be sought. Individual cases will be reviewed by the appropriate panel of the ICB upon receipt of a completed application from the patient's GP, consultant or clinician. Applications cannot be considered from patients personally.

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