Continuous Glucose Monitoring (CGM) for Type 1 Diabetes Mellitus (T1DM) in children under 18.

Background

Most people with type 1 diabetes manage their blood glucose levels by regular daily self-monitoring of blood glucose (SMBG) and insulin injections. However, a small number of people have problems maintaining optimal blood glucose levels by self-administration of insulin therapy, and so are at risk of the severe complications associated with diabetes. Short-term complications of type 1 diabetes are hypoglycaemia and diabetic ketoacidosis. The longer-term complications of type 1 diabetes, such as neuropathy, nephropathy, retinopathy and cardiovascular events, are related to hyperglycaemia.

Although many people effectively self-manage their diabetes with conventional insulin therapy or insulin pumps, there is a specific minority group of patients who have hypoglycaemic unawareness and/or recurrent disabling hypoglycaemia. This group meets the NICE criteria both for an insulin pump and for continuous glucose monitoring.

Automated continuous glucose monitoring (CGM) and sensor augmented pump therapy (SAPT) have the potential to reduce the incidence of complications associated with hypoglycaemia for these patients.

Interstitial glucose monitoring takes two forms:
1. Continuous glucose monitoring with alarms (CGM)
2. Intermittent interstitial glucose monitoring (iGM) (e.g. Freestyle Libre®)

CGM devices consist of a subcutaneous glucose-sensing electrode which sends interstitial glucose levels to a paired receiver and/or insulin pump via a transmitter. There are different models available, but all systems provide 3 pieces of information:
   - current interstitial fluid glucose
   - expected future trend
   - glucose history over the preceding hours, days and weeks

All devices give an updated result every 5 minutes (equivalent to 288 tests daily).

The use of iGM (e.g. Freestyle Libre) is excluded from the scope of this document.

NWL CCGs have had a position statement and policy for funding continuous glucose monitoring (CGM) for T1DM adults resident in the 8 NW London CCGs since 2016. However, there is no commissioning policy in place for T1DM children under 18.

Present policy development taking into account the evidence

Clinical Effectiveness

1. **NICE TA151** published in July 2008¹ states that continuous subcutaneous insulin infusion (CSII or insulin pump therapy) is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus (T1DM) provided that:
   - Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. (NB for the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life; OR HbA 1c levels have remained high (that is, at
8.5% [69 mmol/mol] or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

- CSII therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that MDI therapy is considered to be impractical or inappropriate, and children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.
- It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.
- Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.
- CSII therapy is not recommended for the treatment of people with type 2 diabetes mellitus.

2. This TA has now been incorporated into NICE NG18 on diabetes in children and young people published in 2015\(^2\). The full guideline states that CGM may be useful where unidentified hypoglycaemia occurs, especially at night-time, but further research is needed before such systems can be recommended for routine use for optimisation of glycaemic control.

NICE NG18 on diabetes in children and young people\(^2\), recommends the use of Continuous Glucose Monitoring (CGM) in certain patient groups as follows:

**Offer** ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have:
- frequent severe hypoglycaemia
  OR
- impaired awareness of hypoglycaemia associated with adverse consequences (for example, seizures or anxiety)
  OR
- Inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).

**Consider** ongoing real-time continuous glucose monitoring for:
- neonates, infants and pre-school children
  OR
- children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level)
  OR
- Children and young people who have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult. [new 2015]

**Consider** intermittent (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support.

Critique of the NICE clinical criteria above:
- NICE makes two separate sets of recommendations for clinical criteria under the headings ‘offer’ and ‘consider’. NB NICE National Guidelines such as NG18 make recommendations
which are not mandatory. This means that commissioners may decide on the implementation of individual recommendations on the basis of local funding priorities.

- The following points need to be taken into account in relation to the recommendations under ‘consider’
  
  ▪ A review of CGM in neonates carried out in 2017 concluded that the use of CGM in neonates is in the research phase and is still evolving. (McKinlay JD et al. Continuous glucose monitoring in neonates: a review. Oct 2017. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5644070/)
  
  ▪ In 2018, the Endocrine Society of USA Clinical Practice Guidelines stated, “We make no recommendations for or against the use of RT-CGM by children with T1DM who are less than 8 years of age” (see Section 2.3 in Table 1). (Peters AL et al. Advances in Glucose Monitoring and Automated Insulin Delivery: Supplement to Endocrine Society Clinical Practice Guidelines. 2018. https://www.endocrine.org/-/media/endosociety/files/guidelines/resources/diabetes-tech-supplement-november-2018.pdf)
  
  ▪ In considering the question of whether continuous glucose monitoring should be recommended for coverage in children and adolescents with type 1 diabetes mellitus, the Oregon Health Evidence Review Commission (HERC) stated that published CGM studies generally did not include the youngest children with type 1 diabetes and did not address long-term developmental concerns. Their recommendation for coverage of these children is a weak recommendation that needs to be supplemented by further studies of CGM use in this population. (HERC. Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus. August 2017. https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-CGM-DM-2017.pdf)
  
  ▪ The Association of Children’s Diabetes Specialists UK considered the evidence around CGM in 2017, and stated that the evidence base for CGM was weak with many studies underpowered and not definitively conclusive. Few if any studies addressed the impact on quality of life, economic impact or on aspects of CGM use such as exercise. CGM has been shown to lead to modest reduction in HbA1c both with insulin pump therapy (CSII) and in those on multiple daily injections (MDI). However, this was not demonstrated universally in all studies. (The Association of Children’s Diabetes Specialists UK. A Practical Approach to the Management of Continuous Glucose Monitoring (CGM) / Real-Time Flash Glucose Scanning (FGS) in Type 1 Diabetes Mellitus in Children and Young People Under 18 years. 2017. https://www.bsped.org.uk/media/1551/cgm-fgs-practical-approach-acdc-guideline-oct-2018.pdf)
  
  ▪ The clinical commissioning policy on CGM of the Essex CCGs does not fund the category of patients which NICE has mentioned under ‘consider’.

3. The **NICE QS125** Quality Standard for Diabetes in Children and Young People, published in July 2016³ includes a quality statement regarding CGM stating that T1DM children who have frequent severe hypoglycaemia should be offered ongoing real-time continuous glucose monitoring with alarms.

4. **NICE DG21** on integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes¹¹ states that the Vibe and G4 PLATINUM CGM system shows promise but there is currently insufficient evidence to support its routine adoption in the NHS for managing blood glucose levels in people with type 1 diabetes. Robust evidence is needed to show the clinical effectiveness of using the technology in practice.
5. A National Institute for Health Research (NIHR) systematic review and economic evaluation\textsuperscript{12} states that the Veo system appears to be better than the other systems considered at reducing hypoglycaemic events. However, in adults, it is unlikely to be cost-effective. Integrated systems are also generally unlikely to be cost-effective given that stand-alone systems are cheaper and, possibly, no less effective. Evidence in this regard is generally lacking, in particular for children. Future trials in specific child, adolescent and adult populations should include longer term follow-up and ratings on the European Quality of Life-5 Dimensions scale at various time points with a view to informing improved cost-effectiveness modelling.

6. A Health Technology Assessment (HTA) was published by Health Quality Ontario in 2018\textsuperscript{4,5} for the purpose of determining whether or not children with T1DM should be publicly funded by the government of Ontario, based on the detailed evidence from the HTA and from public consultation. Ontario Health Technology Advisory Committee (OHTAC) made the following final recommendations:
   - Public funding of continuous glucose monitoring in patients with type 1 diabetes who are willing to use continuous glucose monitoring for the vast majority of the time and who meet one or more of the following criteria:
     - Severe hypoglycemia without an obvious precipitant, despite optimized use of insulin therapy and conventional blood glucose monitoring
     - Inability to recognize, or communicate about, symptoms of hypoglycemia
   These recommendations confirm the previous guidance from NICE. The government of Ontario is currently considering the funding and implementation of these recommendations.

8. The Royal College of Paediatrics and Child Health (RCPCH) published a report in October 2018\textsuperscript{6} which makes the case for investing in children and young people's diabetes services, pointing out that paediatric diabetes services were providing care for just over 26,000 children and young people with diabetes in England in 2017. Of these, 95% have type 1 diabetes. If not properly managed, children and young people with diabetes are at risk of developing significant clinical complications.

9. In May 2019 the South East Coast & London Paediatric Diabetes Network issued guidance on insulin pumps and continuous glucose monitoring for children and young people\textsuperscript{14}. There is reference to a local agreement which is not recommended by NICE: ‘Although NICE Guideline 18 supports intermittent CGM in children and young people who continue to have hyperglycaemia despite insulin adjustment and additional support, but does not allow for ongoing CGM. In contrast, NICE Guideline 17 for Type 1 diabetes in adults, does allow ongoing real time CGM in adults who continue to have hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. In London and South East Coast, it was therefore decided to apply the same principle to children and young people, if hyperglycaemia cannot be managed following intermittent CGM.’

Cost effectiveness

Both NICE and OHTAC conducted cost effectiveness studies which have been included in their documents. However, it is important to note that the cost effectiveness data analysis all relates to adults with T1DM. There is no cost effectiveness data analysis specifically for children. NICE and OHTAC decided that they would use the same adult data analysis in relation to CGM for children.

Demographics

Tables 1 to 3 illustrate the population characteristics of T1DM children in NWL CCGs.
**Table 1: Population of children under 18**

<table>
<thead>
<tr>
<th>CCG</th>
<th>Total population 2016/17*</th>
<th>Children under 18 years**</th>
<th>Children under 18 with T1DM registered to CCG practices***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brent</td>
<td>370000</td>
<td>77563</td>
<td>6</td>
</tr>
<tr>
<td>Harrow</td>
<td>260000</td>
<td>57825</td>
<td>81</td>
</tr>
<tr>
<td>Hillingdon</td>
<td>312600</td>
<td>72746</td>
<td>113</td>
</tr>
<tr>
<td>Central London</td>
<td>242300</td>
<td>45165</td>
<td>39</td>
</tr>
<tr>
<td>West London</td>
<td>240000</td>
<td>28475</td>
<td>60</td>
</tr>
<tr>
<td>Hammersmith and Fulham</td>
<td>231000</td>
<td>35928</td>
<td>57</td>
</tr>
<tr>
<td>Hounslow</td>
<td>305600</td>
<td>63928</td>
<td>81</td>
</tr>
<tr>
<td>Ealing</td>
<td>343000</td>
<td>31884</td>
<td>126</td>
</tr>
<tr>
<td>TOTAL</td>
<td>2304500</td>
<td>463514</td>
<td>563</td>
</tr>
</tbody>
</table>

Sources:
*From Annual Accounts for each NWL CCG for 2017-18
**ONS mid-year estimates 2017
***Whole Systems Integrated Care (WSIC) dashboards and information sharing for NHS NW London Collaboration of CCGs

**Table 2: Number of children and young people included in the audit with Type 1 diabetes by country, region and age, 2016/17 (based on PDU location)**

<table>
<thead>
<tr>
<th>Region</th>
<th>0-4 years</th>
<th>5-9 years</th>
<th>10-14 years</th>
<th>15-19 years</th>
<th>20-24 years</th>
<th>Total aged &lt;20 (% of total &lt;20)</th>
</tr>
</thead>
<tbody>
<tr>
<td>England and Wales</td>
<td>1670</td>
<td>6165</td>
<td>10984</td>
<td>8901</td>
<td>19</td>
<td>27720 (100%)</td>
</tr>
<tr>
<td>England</td>
<td>1590</td>
<td>5843</td>
<td>10399</td>
<td>8439</td>
<td>19</td>
<td>26271 (94.8%)</td>
</tr>
<tr>
<td>Wales</td>
<td>80</td>
<td>322</td>
<td>585</td>
<td>462</td>
<td>0</td>
<td>1449 (5.2%)</td>
</tr>
<tr>
<td>East of England</td>
<td>186</td>
<td>713</td>
<td>1190</td>
<td>1001</td>
<td>*</td>
<td>3090 (11.1%)</td>
</tr>
<tr>
<td>East Midlands</td>
<td>111</td>
<td>422</td>
<td>829</td>
<td>496</td>
<td>0</td>
<td>1858 (6.7%)</td>
</tr>
<tr>
<td>London and South East</td>
<td>408</td>
<td>1450</td>
<td>2438</td>
<td>1984</td>
<td>*</td>
<td>6280 (22.7%)</td>
</tr>
<tr>
<td>North East and North Cumbria</td>
<td>93</td>
<td>318</td>
<td>625</td>
<td>513</td>
<td>*</td>
<td>1549 (5.6%)</td>
</tr>
<tr>
<td>North West</td>
<td>205</td>
<td>781</td>
<td>1327</td>
<td>1145</td>
<td>0</td>
<td>3458 (12.5%)</td>
</tr>
<tr>
<td>South Central</td>
<td>158</td>
<td>511</td>
<td>975</td>
<td>764</td>
<td>0</td>
<td>2408 (8.7%)</td>
</tr>
<tr>
<td>South West</td>
<td>126</td>
<td>458</td>
<td>867</td>
<td>688</td>
<td>6</td>
<td>2139 (7.7%)</td>
</tr>
<tr>
<td>West Midlands</td>
<td>149</td>
<td>610</td>
<td>1086</td>
<td>972</td>
<td>*</td>
<td>2817 (10.2%)</td>
</tr>
<tr>
<td>Yorkshire and the Humber</td>
<td>154</td>
<td>580</td>
<td>1062</td>
<td>876</td>
<td>*</td>
<td>2672 (9.6%)</td>
</tr>
</tbody>
</table>

* indicates a number less than 5 which has been suppressed
The population of London is approximately 8.8 million and the population of SE England is approximately 9 million giving a total of approx. 16.8 million. The population of NW London CCGs is approximately 2.3 million, representing 14% of the popn of London and the SE. Assuming an even distribution this would translate into 785 T1DM children under 18 in NWL CCGs. However, the WSIC figures show that only 585 T1DM children are registered in NW London CCGs. This may indicate an under-registration of T1DM children in NWL. NB these figures may not be reliable because of the potentially large disparity between the resident population of the Local Authority areas (used by ONS) and the CCG-registered population.
Table 3: Total number and percentage (of the total) of all diabetes-related admissions in England, Wales and Regional Networks by audit year

<table>
<thead>
<tr>
<th></th>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>England</td>
<td>9374</td>
<td>95.1</td>
<td>9518</td>
<td>94.6</td>
<td>10240</td>
<td>94.8</td>
</tr>
<tr>
<td>Wales</td>
<td>482</td>
<td>4.9</td>
<td>540</td>
<td>5.4</td>
<td>560</td>
<td>5.2</td>
</tr>
<tr>
<td>East of England</td>
<td>1096</td>
<td>11.1</td>
<td>1075</td>
<td>10.7</td>
<td>1109</td>
<td>10.3</td>
</tr>
<tr>
<td>East Midlands</td>
<td>524</td>
<td>5.3</td>
<td>468</td>
<td>4.7</td>
<td>517</td>
<td>4.8</td>
</tr>
<tr>
<td>London and South East</td>
<td>2171</td>
<td>22.0</td>
<td>2260</td>
<td>22.5</td>
<td>2211</td>
<td>20.5</td>
</tr>
<tr>
<td>North East</td>
<td>431</td>
<td>4.4</td>
<td>417</td>
<td>4.1</td>
<td>559</td>
<td>5.2</td>
</tr>
<tr>
<td>North West</td>
<td>1642</td>
<td>16.7</td>
<td>1580</td>
<td>15.7</td>
<td>1862</td>
<td>17.2</td>
</tr>
<tr>
<td>South Central</td>
<td>970</td>
<td>9.8</td>
<td>1076</td>
<td>10.7</td>
<td>1031</td>
<td>9.5</td>
</tr>
<tr>
<td>South West</td>
<td>726</td>
<td>7.4</td>
<td>772</td>
<td>7.7</td>
<td>809</td>
<td>7.5</td>
</tr>
<tr>
<td>West Midlands</td>
<td>901</td>
<td>9.1</td>
<td>897</td>
<td>8.9</td>
<td>1063</td>
<td>9.8</td>
</tr>
<tr>
<td>Yorkshire and The Humber</td>
<td>913</td>
<td>9.3</td>
<td>973</td>
<td>9.7</td>
<td>1079</td>
<td>10.0</td>
</tr>
<tr>
<td><strong>TOTAL DIABETES-RELATED ADMISSIONS</strong></td>
<td><strong>9856</strong></td>
<td><strong>10058</strong></td>
<td><strong>10800</strong></td>
<td><strong>10800</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


Although the total number of admissions increased over the three audit years, the rate remained stable as the number of children and young people with diabetes increased by a similar percentage over this period.

Data for the number of episodes and length of stay (LOS) for children under 16 years from NWL CCGs admitted as an emergency between April 2015 and March 2018 with either primary or secondary diagnosis of hypoglaecemia was provided by Whole Systems Integrated Care (WSIC) dashboards for NHS NW London Collaboration of CCGs, but it was not possible to identify the number of children who had multiple emergency admissions for hypoglaecemia. Moreover, given the well-documented rising trend in diabetes in children under sixteen years, there appears to be some under-reporting in relation to the National Paediatric Diabetes Audit 2012-2015.
Financial Impact

Gloucestershire CCG estimated the approximate cost of commissioning a Continuous Glucose Monitor as £3,000 to £3,500 per year for each child. This varies according to which manufacturer is used. Real Time CGM with alarms cost approximately £3000 – 3500 per year. This needs to be offset against an annual cost of blood glucose monitoring. For a child with unstable blood glucose levels who requires testing 20 times a day, this incurs a cost of approximately £2,500 per annum (cost of glucose test strips and lancets).

The details of different types of insulin pumps can be viewed at the website of the London Medicines Evaluation Network 2015.

Annual inpatient care, to treat short and long term complications of diabetes, is estimated at between £1,800 and £2,500 per patient.

Recent economic research (2017) suggests that the cost of CGM for NW London CCG T1DM patients with impaired awareness of hypoglycemia (IAH) (both adults and children) in the first year is £10,770,671 and in the fourth year is £11,329,095. The combined cost off-sets related to reduced hypoglycaemia admissions, SMBG strip usage and complications are £8,116,912 and £8,741,026 in years one and four, respectively. The net budget impact within the NW London CCGs is £2,653,760; £2,588,068 in years one and four respectively. This research was industry-sponsored.

Comparison of the population analysis of WSIC and the National Paediatric Audit data reveals a possible under-estimate of up to 200 T1DM children in NWL, and if so, these costs will rise proportionately.
Clinical Commissioning Policy

Clinical Criteria

The high cost of CGM devices and consumables prohibits the routine commissioning of CGM for all groups of patients for which NICE guidance state that CGM should be considered. This has been estimated as an annual cost increase of approximately £2 million\(^9\). It is therefore recommended that funding for CGM is prioritised for patients with the most severe disease, those in whom despite optimal diabetes care, experience severe episodes of hypoglycaemia which result in ambulance call outs or hospital admissions. This is reflected in the clinical criteria given below.
NWLC CGs will only fund ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have:

**Group 1**

1. Frequent* and severe** hypoglycaemia
   OR
2. Impaired awareness of hypoglycaemia (evidenced by Clarke hypoglycaemia score, see appendix 2), associated with adverse consequences (for example, seizures or anxiety)
   OR
3. Inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities).
   OR
4. Children under 4 with type 1 diabetes on an insulin pump

AND

CGM must be initiated and managed by a consultant led specialist Diabetes team who must ensure that:

- the motivation of children and their carers and their ability to manage the technology appropriately has been assessed
  AND
- children and their carers are given education and training in the use of the CGM
  AND
- CGM is being used consistently and appropriately as per the treatment plan (e.g. by downloading and analysing data from the devices)
  AND
- the aims of treatment e.g. a reduction in the number of hypoglycaemic events resulting in ambulance call outs or hospital admissions should be agreed with clinicians before commencement of treatment
  AND

  o Before commencing treatment, clinicians must inform patients that the need for ongoing CGM will be reviewed and may be discontinued at an appropriate time

OR
Group 2

Children who have episodes of severe hypoglycaemia with no obvious preventable precipitating cause, which have resulted in ambulance call outs or hospital admissions despite optimal diabetes care which includes:

- optimising insulin therapy including the use of CSII where appropriate
- comprehensive re-evaluation of insulin pump settings
- optimisation of insulin infusion sites
- exercise management
- use of long-acting carbohydrate at bed-time

Use of diagnostic intermittent glucose monitoring (iGM) or CGM where appropriate

AND

CGM must be initiated and managed by a consultant led specialist Diabetes team who must ensure that:

- the motivation of children and their carers and their ability to manage the technology appropriately has been assessed AND
- children and their carers are given education and training in the use of the CGM AND
- CGM is being used consistently and appropriately as per the treatment plan (e.g. by downloading and analysing data from the devices) AND
- the aims of treatment e.g. a reduction in the number of hypoglycaemic events resulting in ambulance call outs or hospital admissions should be agreed with clinicians before commencement of treatment AND
  o Before commencing treatment, clinicians must inform patients that the need for ongoing CGM will be reviewed and may be discontinued at an appropriate time

* ‘frequent’ is locally defined as at least 2 episodes per year

**Severe hypoglycaemia is defined internationally (Seaquist ER et al.) as any or all of the following:
  o hypoglycaemia that requires the intervention of another person to reverse
  o parenteral therapy required (intramuscular glucagon or intravenous glucose)
  o associated with coma and/or seizure.
Important notes:

1. Continuous glucose monitoring with an alarm should be provided using the most appropriate device, taking into consideration the type of pump being used by patients using CSII.

2. Commissioners should be mindful of NICE DG21 which states that there is currently insufficient evidence to support the routine adoption in the NHS of the Dexcom G4 PLATINUM CGM system. Commissioners are uncertain as to how the updated Dexcom version G6 of this pump has come to be used without prior discussion with the commissioners.

3. Intermittent short term (real-time or retrospective) continuous glucose monitoring to help improve blood glucose control in children and young people (diagnostic CGM) is included in tariff and should not be separately funded.

4. Commissioners are aware that both CGM devices and associated consumables will be coming out of NHS tariff from April 2019.

5. Transition from child to adulthood: NICE criteria for CGM in adults differs to those of children. There is an expectation that as children come up to transition into adulthood there will be trials without CGM to enable the child to take responsibility to monitor their blood glucose levels and recognise early any symptoms of hypoglycaemia. There should not be an assumption that children in receipt of CGM as a child will automatically receive a CGM as an adult.

Policy exclusions:

1. Routine funding of CGM for children for other indications is considered a low priority and is NOT recommended.

2. Co-funding, which involves both private and NHS funding for a single episode of care, is currently against Department of Health policy and is not permitted.

3. Children and young people with complex diabetes being managed by a specialized diabetic unit are covered by NHS England.

4. NWL CCGs will not routinely fund integrated sensor-augmented pump therapy systems for managing blood glucose levels in type 1 diabetes such as the MiniMed Paradigm Veo system and the Vibe and G4 PLATINUM CGM system.

5. NWL CCGs will not routinely fund CGM for children with T1DM with unexplained hypoglycaemia occurring only at night time.

Criteria for continuation/stop of funding

Funding should be provided for an initial period of 6 months and reviewed every 12 months.

Funding will be continued where there is evidence of:

- Reduction of severe hypoglycaemic episodes resulting in fewer ambulance call outs or hospital admissions
- Evidence for need for continuation of treatment e.g. continuing episodes of severe hypoglycaemia as agreed with commissioner prior to commencement of treatment.
Funding for treatment will be discontinued where:

- Family have not attended all structured education sessions (unless extenuating circumstances are present)
- OR
- Patient/carers are unable to cope with sensor/managing technology despite intensive support by the diabetic team
- OR
- Failure to wear the sensor >70% of the time for a minimum period of 5 days a week
- OR
- No reduction of severe hypoglycaemic episodes:
  - HbA1c did not improve by >0.5% (5.5 mmol/mol, 0.8 mmol/L) if it was >7.5% (9.4mmol/L, 58.5mmol/mol) at start of CGM therapy
  - OR
  - resulting in repeated ambulance call outs or hospital admissions

Important Note:
- NICE criteria for CGM in adults differs to those of children. There is an expectation that as children come up to transition into adulthood there will be trials without CGM to enable the child to take responsibility to monitor their blood glucose levels and recognise early any symptoms of hypoglycaemia. There should not be an assumption that children in receipt of CGM as a child will automatically receive a CGM as an adult.
Review of other NHS England CCG policies

The following CCG clinical commissioning policies for CGM in children have been reviewed and taken into consideration:


SWL CCGs in line with NICE TA151 have devised a tick box form for insulin pumps for children under 12 and children between 12 and 18 years. SWL CCGs do not have a separate policy for CGM. See: https://www.swlmcg.nhs.uk/Policies/Pages/Tick-Box-Forms.aspx

NE London CCGs do not have a policy for CGM, but are in the process of developing one.

Essex CCGs have a policy for funding CGM for T1DM children under 18. Available at: https://westessexccg.nhs.uk/your-health/medicines-optimisation-and-pharmacy/high-cost-drug-policies-and-pro-formas/insulin-pumps/212-continuous-glucose-monitoring-interim-decision-children/file

Erewash, Hardwick, North Derbyshire & South Derbyshire CCGs have a policy got CGM which applies to both adults and children. Continuous Glucose Monitoring and Sensor Augmented Pump Policy November 2018 Available at: http://www.southernderbyshireccg.nhs.uk/easysiteweb/getresource.axd?assetid=6416&tipo=0&servicetype=1

References

2. NICE NG18. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. 26 August 2015. Available at: https://www.nice.org.uk/guidance/ng18
Available at: http://www.cypdiabetesnetwork.nhs.uk/index.php?cID=672 (accessed on 30/05/2019)


Appendix 1: Clinical Coding

Greater Manchester CCGs have specified the clinical coding applicable to continuous glucose monitoring\(^3\).

<table>
<thead>
<tr>
<th>GM039 - Real-Time Continuous Glucose Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>OPCS-4 procedure codes</strong></td>
</tr>
<tr>
<td>Insertion of diagnostic device into subcutaneous tissue</td>
</tr>
<tr>
<td><strong>With the following ICD-10 diagnosis code(s):</strong></td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with coma</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with ketoacidosis</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with renal complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with ophthalmic complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with neurological complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with peripheral circulatory complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with other specified complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with multiple complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - with unspecified complications</td>
</tr>
<tr>
<td>Type 1 diabetes mellitus - without complications</td>
</tr>
<tr>
<td>Hypoglycaemia, unspecified</td>
</tr>
<tr>
<td>Hyperosmolality and hypernatraemia</td>
</tr>
</tbody>
</table>

**Exceptions (ICD-10); the following in a primary diagnostic position:**

- Pre-existing type 1 diabetes mellitus (assuming this is still related to diabetes patient that are pregnant) | Q24.0
- Pre-existing type 2 diabetes mellitus                              | Q24.1
- Pre-existing malnutrition-related diabetes mellitus                | Q24.2
- Pre-existing diabetes mellitus, unspecified                        | Q24.3
- Diabetes mellitus arising in pregnancy                            | Q24.4
- Diabetes mellitus in pregnancy, unspecified                       | Q24.9
Appendix 2: Implementation of NICE recommendations

NHS commissioners need to be mindful of the following points in relation to implementation of NICE recommendations, especially given the Rose vs Thanet CCG High Court judgement (2014), which is sometimes cited by NHS providers as a justification for mandatory implementation of all NICE recommendations:

a. It is the role of NICE to give advice or guidance, provide information or make recommendations about any matter concerning or connected with the provision of NHS, public health or social care services in England.

b. NICE publishes different forms of guidance, of which NICE NGs (National Guideline) is only one type. Other forms of NICE guidance include Technology Appraisal Guidance (TAGs) which usually apply to specific drugs or interventions, and Interventional Procedure Guidance (IPGs).

c. NICE makes “technology appraisal recommendations” (regulation 7) and “highly specialised technology recommendations” (regulation 8), with which CCGs and/or NHS England must comply, usually within three months of the date of publication.

d. However, the advice and recommendations contained in NICE Clinical Guidelines (CGs) or National Guidelines (NGs) are classified as regulation 5 generic advice.

e. Therefore there is no explicit statutory obligation upon NHS England and/or CCGs, to comply with the “regulation 5” type of advice or guidance in relation to the recommendations of NICE Clinical Guidelines (CGs) or National Guidelines (NGs), such as NG18.

f. There is no explicit statutory duty upon CCGs to ‘have regard’, even, to guidance issued by NICE under regulation 5, still yet to implement it in full with all the concomitant costs implications, as if it were a technology appraisal (TAG) recommendation.

g. The High Court Thanet CCG judgment attempted to go against the Higher Court of Appeal judgment of Sir Thomas Bingham in 1995: “I have no doubt that in a perfect world any treatment which a patient, or a patient’s family, sought would be provided if doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one’s eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. They cannot pay their nurses as much as they would like; they cannot provide all the treatments they would like; they cannot purchase all the extremely expensive medical equipment they would like; they cannot carry out all the research they would like; they cannot build all the hospitals and specialist units they would like. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this Authority can be fairly criticised for not advancing before the court.” (R v. Cambridgeshire Health Authority ex parte B [1995])
h. The High Court considered in the Rose versus Thanet CCG judgement that the CCG was under an implied obligation to give reasons for any general policy not to fund a particular intervention, including a reasoned explanation of why a NICE recommendation made under regulation 5 is not being followed.

Appendix 3: Clarke score to categorise aware or having reduced awareness of hypoglycaemia in adults

1. Check the category that best describes you: (check one only)
   - I always have symptoms when my blood sugar is low (A)
   - I sometimes have symptoms when my blood sugar is low (R)
   - I no longer have symptoms when my blood sugar is low (R)

2. Have you lost some of the symptoms that used to occur when your blood sugar was low?
   - Yes (R)
   - No (A)

3. In the past six months how often have you had moderate hypoglycemia episodes? (Episodes where you might feel confused, disoriented, or lethargic and were unable to treat yourself)
   - Never (A)
   - Once or twice (R)
   - Every other month (R)
   - Once a month (R)
   - More than once a month (R)

4. In the past year how often have you had severe hypoglycemic episodes? (Episodes where you were unconscious or had a seizure and needed glucagon or intravenous glucose)
   - Never (A)
   - 5 times (R)
   - 9 times (R)
   - 1 time (R)
   - 6 times (R)
   - 10 times (R)
   - 2 times (R)
   - 7 times (R)
   - 11 times (R)
   - 3 times (R)
   - 8 times (R)
   - 12 or more times (U)

5. How often in the last month have you had readings < 3.5 mmol/l with symptoms?
   - Never (A)
   - 1 to 3 times (R)
   - 1 time/week (R)
   - 2 to 3 times/week (R)
   - 4 to 5 times/week (R)
   - Almost daily (R)

6. How often in the last month have you had readings < 3.5 mmol/l without any symptoms?
   - Never (A)
   - 1 to 3 times (A)
   - 1 time/week (A)
   - 2 to 3 times/week (A)
   - 4 to 5 times/week (A)
   - Almost daily (A)

7. How low does your blood sugar need to go before you feel symptoms?
   - 3.1 – 3.5 mmol/l (A)
   - 2.8 – 3.0 mmol/l (A)
   - 2.2 – 2.7 mmol/l (R)
   - < 2.2 mmol/l (R)

8. To what extent can you tell by your symptoms that your blood sugar is low?
   - Never (R)
   - Rarely (R)
   - Sometimes (R)
   - Often (A)
   - Always (A)

Four or more R responses = reduced awareness; 2 or fewer R responses = aware.