Both CCGs recommend the use of CGM for adults with Type 1 diabetes who meet the clinical criteria specified in this policy.
Both CCGs will consider the use of CGM for Pregnant women with Type 1 or Type 2 diabetes on insulin therapy who meet the clinical criteria specified in this policy.
In line with NICE guidance it would be expected that CGM will only be required for a limited number of patients per year. CGM will require prior approval via Blueteq at the point of initiation. If the number of requests is higher than expected then this policy will be reviewed.

Background
CGM systems are available for use in Type 1 diabetes, as a ‘temporary diagnostic tool’ to help patients better manage their blood glucose levels (short-term CGM) or as a ‘continuous aid in glycaemic control’ (long-term CGM).
CGM systems use a sensor placed under the skin, which continuously measures glucose levels. It measures the amount of glucose in the interstitial fluid, which lags behind the glucose level in the blood by up to 15 minutes and this lag time is increased if blood glucose levels are changing rapidly e.g. after eating or if exercising. For this reason, a finger prick blood glucose check is recommended if changing treatment (e.g. taking more insulin or treating a hypo). The cost of commissioning a CGM is £3,000 to £3,500 per patient per year.

Summary of the evidence
NICE issued clinical guidance (NG17) in August 2015 concerning the diagnosis and management of Type 1 diabetes in adults. This covered a wide range of issues affecting clinical care, such as diet, exercise and insulin regimes. It states that real-time CGM should not be routinely offered to adults with Type 1 diabetes, only that it should be “considered” in certain circumstances.
NICE guidance (NG 3) also states that real-time CGM should not be routinely offered to pregnant women with diabetes, only that it should be ‘considered’ for pregnant women on insulin therapy in certain circumstances.

Current CGM systems were not found to be cost-effective in the de-novo analysis carried out for NICE clinical guidance NG17, even in people with impaired awareness of hypoglycaemia. The guidance stated that in adults with Type 1 diabetes with high HbA1c values, there may be some value in using CGM systems but further research would be needed to determine whether newer technologies would prove to be cost-effective, particularly in this group.

A study of CGM in 2012 reported that there is limited evidence for the effectiveness of real-time CGM use in children, adults and patients with poorly controlled diabetes. The largest improvements in glycaemic control were seen for sensor-augmented insulin pump therapy in patients with poorly controlled diabetes who had not used an insulin pump before. The risk of
severe hypoglycaemia or ketoacidosis was not significantly increased for CGM users but as these events occurred infrequently these results have to be interpreted cautiously. There are indications that higher compliance with using the CGM device improves glycosylated haemoglobin A1c level (HbA1c) to a larger extent.

Developing technologies in glucose monitoring and insulin delivery have not been rigorously tested in adults with Type 1 diabetes and impaired awareness of hypoglycaemia. Further research is needed to establish the extent to which existing technologies can help adults with Type 1 diabetes and impaired awareness of hypoglycaemia, to avoid hypoglycaemic episodes and regain awareness for occasional episodes.

Robust evidence is still needed to show the clinical effectiveness of using this technology in practice.

<table>
<thead>
<tr>
<th>Funding criteria for CGM in adults and pregnant women with Type 1 or Type 2 diabetes on insulin therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CGM should only be offered where there is a clear expectation of clinical benefit, and it is the clinician’s judgement that no other technology will meet the need of the patient. It is recognised that patients and parents/carers may have strong opinions regarding the use of CGM, but the final decision must rest with the clinician and be on clinical grounds.⁶</td>
</tr>
<tr>
<td><strong>Consider</strong> real-time CGM in adults with Type 1 diabetes and pregnant women with Type 1 or Type 2 diabetes on insulin therapy who:</td>
</tr>
<tr>
<td>- Have been informed of the advantages and disadvantages of continuous glucose monitoring and expressed a continued wish to initiate CGM.</td>
</tr>
<tr>
<td>- Have demonstrated appropriate levels of competence to perform carbohydrate counting (e.g. DAFNE regimen), blood glucose monitoring and to interpret this data in order to competently adjust insulin doses.</td>
</tr>
<tr>
<td>- Demonstrate a willingness to engage in all necessary training regarding the optimal use of CGM and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered)</td>
</tr>
<tr>
<td>- Are willing to commit to using CGM at least 70% of the time <strong>OR</strong> for a minimum of 5 days per week and to calibrate it as needed</td>
</tr>
<tr>
<td><strong>AND</strong></td>
</tr>
<tr>
<td>Who meet <strong>ONE OR MORE</strong> of the following criteria despite optimal use of insulin therapy and the understanding of conventional blood glucose monitoring 10 or more times per day to check for hypoglycaemia:</td>
</tr>
<tr>
<td>- More than one episode a year of severe hypoglycaemia² with no obvious preventable cause and requires third party intervention (assistance from another person) to treat</td>
</tr>
<tr>
<td>For this policy, severe hypoglycaemia is defined as having low blood glucose levels (&lt;4.0mmol/litre) that precipitates recognised signs of severe hypoglycaemia (confusion and disorientation, convulsions/fitting/seizures, intense nightmares, loss of consciousness, coma)³</td>
</tr>
<tr>
<td><strong>OR</strong></td>
</tr>
<tr>
<td>- A complete loss of awareness of hypoglycaemia²</td>
</tr>
</tbody>
</table>
| OR | • Frequent episodes of asymptomatic hypoglycaemia (more than 2 episodes a week) which is causing problems with daily living or performance impairment.\(^4\)  
  o Precipitating causes must be excluded  
  o This assessment must be made using a blinded diagnostic CGM (Navigator system)  
  o Hypoglycaemia is defined as <4mmol/L  
| OR | • Pregnant women with Type 1 or Type 2 diabetes on insulin therapy who have problematic severe hypoglycaemia (with or without impaired awareness of hypoglycaemia).\(^7\) |

**Continuation criteria for CGM in adults and pregnant women with Type 1 or Type 2 diabetes on insulin therapy**

| • Clinically appropriate, objective measures of improvement should be agreed and documented for each patient individually prior to application for funding via blueteq.\(^6\)  
| • Patients using CGM will be assessed by their specialist at **one month** and **three months** to ensure that the benefits of CGM are demonstrated (i.e. reduction in frequency of hypoglycaemia assessed by CGM downloads\(^4\))  
| • The CGM device will be withdrawn in patients where the device has not been used for at least 70% of the time (5 days a week) and/or the agreed measures for improvement have not been achieved.  
| • Patients should be kept under regular review (**at least annually**), and consideration given to stepping down to less intensive forms of glucose monitoring wherever clinically appropriate.  
| • Pregnant woman with Type 1 or Type 2 diabetes using insulin should re-assume their routine (non-pregnant) glucose monitoring regime within; six months of delivery if breast-feeding  
| or three months of delivery if not breastfeeding  
  
**Patients who do not meet the criteria for continuation should be updated on blueteq**

This policy is based on the best available information at the time of writing.

**References**

Adopted from North West London, Vale of York, Gloucestershire and Greater Preston and Birmingham and Solihull CCG

