

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

## Policy for Continuous Sub-Cutaneous Insulin Infusion (CSII) Therapy (Insulin Pump Therapy)

Diabetes mellitus is a chronic metabolic disorder caused by insufficient activity of the hormone insulin and a subsequent loss of control of blood glucose levels. There may be a lack of the hormone itself or resistance to its action, or both. Insulin is produced by the beta cells of the pancreas in response to rising blood glucose levels and primarily regulates the metabolism of carbohydrates, but also that of proteins and fats. There are two main types of diabetes mellitus; Type 1 diabetes mellitus is caused by the destruction of insulin-producing cells, leading to an absolute lack of the hormone and requires life-long insulin treatment. Within this policy, patients who have had a pancreatectomy and therefore have an absence of insulin are subject to the same eligibility criteria as patients with Type 1 diabetes. Type 2 diabetes mellitus is characterised by insulin resistance and is often associated with obesity.

A number of patients with cystic fibrosis also develop diabetes as a result of build-up of secretions surrounding the pancreas and delayed/blunted 1<sup>st</sup> phase insulin release.

In Type 1 Diabetes or after pancreatectomy, insulin is administered subcutaneously as injections, or it may be given via an insulin pump as a 'continuous subcutaneous insulin infusion' (CSII). CSII therapy makes use of an external pump that delivers insulin continuously from a refillable storage reservoir by means of a subcutaneously placed cannula. The pump is programmed to deliver a continuous 'background' insulin infusion to cover basal insulin requirements, with higher infusion rates triggered by the push of a button at meal times or to correct high blood glucose levels. Basal insulin requirements often vary throughout the 24 hour period and are individualised according to patient need. Insulin boluses may be administered 'immediately', or over a longer period of time according to factors including meal composition.

Insulin pump therapy is recommended by NICE TA151 as a treatment option for some patients with Type 1 Diabetes with the following objectives:

- Improved glycaemic control (reduced HbA1c)
- Reduced rate of hypoglycaemia

Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.

Criteria from the current 2014/15 Cheshire and Merseyside commissioning policy	
Intervention	
Policy Statement	
<b>Minimum eligibility criteria</b>	Not Applicable as there is currently no policy in place for Continuous Sub-Cutaneous Insulin Infusion

Proposed criteria for the revised, future policy		High level summary of changes
Intervention	Continuous Sub-Cutaneous Insulin Infusion	
Policy Statement	Restricted	
<b>Minimum eligibility criteria</b>	<p>NICE technology appraisal TA151 on insulin pump therapy states that continuous subcutaneous insulin pump therapy is recommended as a treatment option for adults and children 12 years and older with type 1 diabetes mellitus provided that:</p> <ul style="list-style-type: none"> <li>Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. NICE guidance defines disabling hypoglycaemia 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.</li> </ul> <p>or</p> <ul style="list-style-type: none"> <li>HbA1c 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.</li> </ul> <p>Insulin pump therapy is recommended as a treatment option for children younger than 12 years with type 1 diabetes mellitus provided that:</p> <ul style="list-style-type: none"> <li>MDI therapy is considered to be impractical or inappropriate, and</li> <li>Children on insulin pumps would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.</li> </ul> <p>Insulin pump therapy is also recommended as a treatment option for</p>	<p><b>Reason for proposed policy</b></p> <p>The policy has been aligned with NICE Guideline [NG] 17 'Type 1 diabetes in adults: diagnosis and management' 2015 (updated 2016) <a href="https://www.nice.org.uk/guidance/NG17">https://www.nice.org.uk/guidance/NG17</a></p> <p>Insulin pump therapy is recommended by NICE TA151 as a treatment option for some patients with type 1 diabetes to improve control of blood sugar and reduce the rate of hypoglycaemia (low blood sugar levels).</p> <p>Haemoglobin A1c (HbA1c) is an unreliable measure of glycaemia in patients with cystic fibrosis-related diabetes owing to their increased red cell destruction. Guidelines recommend that decisions are not based on HbA1c but are based on glycaemic variability, especially hypoglycaemia.</p>

		<p>patients who have had a pancreatectomy and meet the criteria in NICE TA151.</p> <p>Insulin pump therapy is also recommended for a small cohort of patients with cystic fibrosis-related diabetes (CFRD), as identified by the Advanced Nurse Practitioner for CFRD / CF specialist team at Liverpool Heart and Chest Hospital. These would be patients whose diabetes is not controlled despite carefully managed multiple daily injections and carbohydrate awareness.</p> <p>and/or</p> <ul style="list-style-type: none"> <li>• At least two hypoglycaemic episodes per day</li> </ul> <p>and/or</p> <ul style="list-style-type: none"> <li>• A complete loss of hypoglycaemia awareness</li> <li>•</li> </ul> <p>HbA1c is an unreliable measure of glycaemia in patients with CFRD owing to their increased red cell destruction. Guidelines recommend that decisions are not based on HbA1c but are based on glycaemic variability, especially hypoglycaemia.</p> <p>Insulin pump therapy is not recommended for the treatment of people with type 2 diabetes mellitus.</p> <p>This policy proposes that all currently available insulin pumps should be available for eligible patients defined above (see table).</p> <table border="1" data-bbox="945 1098 1830 1356"> <thead> <tr> <th>Name of pump</th> <th>CGM enabled?</th> <th>Cost of pump</th> <th>Annual consumables</th> <th>4 year cost</th> </tr> </thead> <tbody> <tr> <td>1. Roche Accu-Chek insight</td> <td>No</td> <td>£2,495</td> <td>£1,514.64</td> <td>£8,553.56</td> </tr> <tr> <td>2. Roche Accu-Chek Combo</td> <td>No</td> <td>£2,495</td> <td>£1,300.32</td> <td>£8,443.27</td> </tr> </tbody> </table>	Name of pump	CGM enabled?	Cost of pump	Annual consumables	4 year cost	1. Roche Accu-Chek insight	No	£2,495	£1,514.64	£8,553.56	2. Roche Accu-Chek Combo	No	£2,495	£1,300.32	£8,443.27	<p>EIA – The assessment identified that there could be a possible adverse impact and recommended further engagement before carrying out a stage 2 assessment.</p>
Name of pump	CGM enabled?	Cost of pump	Annual consumables	4 year cost														
1. Roche Accu-Chek insight	No	£2,495	£1,514.64	£8,553.56														
2. Roche Accu-Chek Combo	No	£2,495	£1,300.32	£8,443.27														


3. Medtronic 640G	Yes	£2,995	£1,746	£9,979
4. Cellnovo	No	Starter kit £1,100	£2,040	£9,430
5. Omnipod	No	1 <sup>st</sup> year £2,558.20	£2,373.20	£9,677.80
6. DANA RS	No	£2,595	£1,605.63 (approx.)	£9,083.03
7. YpsoPump	No	£1,900	£1,068	£6,172
8. Animas Vibe*	Yes	£2,800	£1,464	£8,656

*Table: Commonly used insulin pumps across Merseyside Pump Centres (2018). Insulin pump costs excluding VAT - 2018 financial data provided by UK insulin pump company representatives for (1) & (2) Roche Diabetes Care Ltd, (3) Medtronic Ltd, (4) Cellnovo Ltd, (5) Insulet corporation), (6) Advanced Therapeutics (UK) Ltd and (7) Ypsomed Ltd. Animas data (8) historical (Animas UK & Ireland) – 2017.*

\*NB ANIMAS Vibe pumps are being withdrawn so no new patients are to be started on these pumps. Existing patients will be supported until they transfer to an alternative system.

This service will only provide pumps from the agreed list in this policy. Any amendments to this list will need to be approved by the respective CCGs prior to any changes being made. Where one of these pumps is not suitable and the service wishes to use an alternative pump a request must be made via the individual patient commissioning route.

This policy is to be reviewed in conjunction with the Insulin Pump –

		<p>Service Specification document attached below:</p>  <p>Insulin%20pump%20service%20spec%20</p>	
		<p><b>Evidence for inclusion and threshold</b></p> <ol style="list-style-type: none"> <li>1. NICE. Technology Appraisal 151. Continuous Subcutaneous Insulin infusion for the Treatment of Diabetes Mellitus. 2008. Available at: <a href="https://www.nice.org.uk/guidance/ta151">https://www.nice.org.uk/guidance/ta151</a></li> <li>2. NICE Guideline [NG] 3. Diabetes in pregnancy: management from preconception to the postnatal period. 2015. Available at: <a href="https://www.nice.org.uk/guidance/ng3">https://www.nice.org.uk/guidance/ng3</a></li> <li>3. NICE Guideline [NG] 18. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. 2015 (updated 2016). Available at: <a href="https://www.nice.org.uk/guidance/ng18">https://www.nice.org.uk/guidance/ng18</a></li> <li>4. Department of Health, Child Health and Maternity Services Branch. Transition: getting it right for young people. Improving the transition of young people with long term, conditions from children's to adult health services (2006). Available at: <a href="http://webarchive.nationalarchives.gov.uk/20130123205838/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4132145">http://webarchive.nationalarchives.gov.uk/20130123205838/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4132145</a></li> <li>5. Pickup J. Insulin pumps. Int J Clin Pract Suppl 2011; 170: 16.</li> <li>6. White HD et al. The United Kingdom service level audit of insulin pump therapy in adults. Diabet Med 2014; 31 (4) 412-8.</li> <li>7. Ghatak A et al. UK service level audit of insulin pump therapy in paediatrics. Diabet Med 2015; 32(12):1652-7.</li> <li>8. The National Diabetes Audit Insulin Pump Report 2015-16 (Published July 2017). Available at <a href="https://www.digital.nhs.uk/catalogue/pub30027">https://www.digital.nhs.uk/catalogue/pub30027</a></li> <li>9. NICE Guideline [NG] 17. Type 1 diabetes in adults: diagnosis and management. 2015 (updated 2016). Available at</li> </ol>	

		<p><a href="https://www.nice.org.uk/guidance/NG17">https://www.nice.org.uk/guidance/NG17</a></p> <p>10. Moran A et al. The CFRD guidelines committee. Clinical care guidelines for cystic fibrosis-related diabetes. Diabetes Care 2010; 33: 2697-2708.</p> <p>11. The Diabetes Control; Complications Trial Research Group. (1993).The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin--dependent diabetes mellitus. N Engl J Med 1993; 329 (14): 977-86.</p>	
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