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

Document version control			
Version	**Amendment**	**By whom**	**Date amendment made**
1.0	Document Created	Laura Crompton North West Coast Strategic Clinical Network	05/09/2017
1.1	Document Amended	Dr Niall Furlong	25/10/2017
1.2	Links added to document	Laura Crompton North West Coast Strategic Clinical Network	26/10/2017
2	Document draft 1Finalised	Laura Crompton North West Coast Strategic Clinical Network	08/11/2017
3	Document Revised	Dr Niall Furlong	18/04/2018
4	Document draft 2 Finalised	Laura Crompton North West Coast Strategic Clinical Network	08/06/2018
5	Document draft 3 revised	Dr Niall Furlong	16/09/2018
6	Document revised to include additional pumps; costings revised.	Dr Niall Furlong	19/02/2019
6	Document revised to include additional pumps; costings revised.	Dr Niall Furlong	22/02/2021

This document has been commissioned by the Merseyside Insulin Pump Task and Finish Group who are a subgroup of experts from the Merseyside Diabetes Steering Group part of the North West Coast Strategic Clinical Network. The group was reformed based on concerns over the current list of approved pumps and number of IFRs that are submitted, to review the policies. This group has now evolved in the Cheshire and Merseyside Diabetes Technology 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
NHS Halton Clinical Commissioning Group
NHS Knowsley Clinical Commissioning Group
NHS Cheshire 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.
Some patients with cystic fibrosis also develop diabetes as a result of build-up of secretions surrounding the pancreas and delayed/blunted 1st 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 mealtimes 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

Intervention	Continuous Sub-Cutaneous Insulin Infusion
OPCS Code(s) [tbc]	**tbc**
Policy Statement	**Restricted**
Minimum eligibility criteria	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: • 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. or • 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. Insulin pump 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 Insulin pump therapy is also recommended as a treatment option for patients who have had a pancreatectomy and otherwise meet the criteria in NICE TA151. 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 or the CFRD MDT (Endocrinologist, Diabetes nurse specialist, Dietician) based at Alder Hey Children's Hospital for children and young people. These would be patients whose diabetes is not controlled despite carefully managed multiple daily injections and carbohydrate awareness. and/or • At least two hypoglycaemic episodes per day and/or • A complete loss of hypoglycaemia awareness 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. Insulin pump therapy is not recommended for the treatment of people with type 2 diabetes mellitus. This policy proposes that all currently available insulin pumps should be available for eligible patients defined above (see table).

Name of pump	CGM enabled?	Unit cost of pump	Annual consumables (approx.)	Typical 4-year cost
1. Roche Accu-Chek Insight	No	£2,495	£1,166.64	£7,161.56
2. Roche Accu-Chek Combo	No	£2,495	£1,274.27	£7,592.09
3. Roche Accu-Chek Solo*	No	N/A note year 1 includes handset within Solo system kit (£451)	Year 1 £2,349.00 Year 2 £2,019.00 Year 3 £2,062.00 Year 4 £2,019.00	£8,449.00
4. Medtronic 640G	Yes	£2,995	£1,898	£10,587.00
5. Medtronic 670G	Yes	£3,291	£1,898	£10,883.00
6. Medtronic 780G**	Yes	£3,456	£1,898	£11,048.00
7. Omnipod*	No	N/A note year 1 includes Dash handset (£185)	Year 1 £2,558.20 Year 2 £2,373.20 Year 3 £2,373.20 Year 4 £2,373.20	£9,677.80
8. DANA RS**	Yes	£2,400	£1,490.14	£8,360.56
9. DANA-I**	Yes	£2,570	Year 1 £1,508.40 Year 2 £1,508.40 Year 3 £1,577.74 Year 4 £1,609.29	£8,773.80
10. YpsoPump	No	£1,900	£1,678	£8,612.00
11. T-Slim X2**	Yes	£3,150 Plus £200 for control IQ where required	£1,587.95	£9,501.80
12. Medtrum A6*	Yes	N/A note year 1 includes handset (PDM) / pump base (£475)	Year 1 £2,469 Year 2 £1,994 Year 3 £1,994 Year 4 £1,994	£8,451

***Table**: Currently approved insulin pumps across Merseyside Pump Centres. Current pricing (2021) obtained from Roche Diabetes Care Ltd (1 - 3), Medtronic Ltd, (4-6) Insulet corporation (7 , Advanced Therapeutics (UK) Ltd (8-9), Ypsomed Ltd (10)) Air Liquide Homecare Ltd (11) and Medtrum Ltd (12).*

**Patch pumps (Roche Solo, Omnipod, Medtum A6) are relatively evenly priced across 4 year cycle as no large outlay for pump in year 1.*

	***Volume pricing discounts available for pump* 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 – Service Specification document attached below: NORTH%20WEST% 20COAST%20STRATI
Evidence for inclusion and threshold	1. NICE. Technology Appraisal 151. Continuous Subcutaneous Insulin infusion for the Treatment of Diabetes Mellitus. 2008. Available at: https://www.nice.org.uk/guidance/ta151 2. NICE Guideline [NG] 3. Diabetes in pregnancy: management from preconception to the postnatal period. 2015. Available at: https://www.nice.org.uk/guidance/ng3 3. NICE Guideline [NG] 18. Diabetes (type 1 and type 2) in children and young people: diagnosis and management. 2015 (updated 2016). Available at: https://www.nice.org.uk/guidance/ng18 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: http://webarchive.nationalarchives.gov.uk/20130123205838/http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4132145 5. Pickup J. Insulin pumps. Int J Clin Pract Suppl 2011; 170: 16. 6. White HD et al. The United Kingdom service level audit of insulin pump therapy in adults. Diabet Med 2014; 31 (4) 412-8. 7. Ghatak A et al. UK service level audit of insulin pump therapy in paediatrics. Diabet Med 2015; 32(12):1652-7. 8. The National Diabetes Audit Insulin Pump Report 2015-16 (Published July 2017). Available at https://www.digital.nhs.uk/catalogue/pub30027 9. NICE Guideline [NG] 17. Type 1 diabetes in adults: diagnosis and management. 2015 (updated 2016). Available at https://www.nice.org.uk/guidance/NG17 10. Moran A et al. The CFRD guidelines committee. Clinical care guidelines for cystic fibrosis-related diabetes. Diabetes Care 2010; 33: 2697-2708. 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.