NHS
Lancashire and South Cumbria
Integrated Care Board

Policy for the Provision of Insulin Pumps for Patients with Diabetes Mellitus

Ref:	LSCICB_Clin35
Version:	1.1
Purpose	This document is part of a suite of policies that the Integrated Care Board (ICB) uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite.
Supersedes:	1
Author (inc Job Title):	
Ratified by: (Name of responsible Committee)	LSCICB Board (adopted 1 July 2022)
Cross reference to other Policies/Guidance	
Date Ratified:	1 July 2022
Date Published and where (Intranet or Website):	July 2022 (Website)
Review date:	5 October 2021
Target audience:	All LSCICB Staff

This policy can only be considered valid when viewed via the ICB website or ICB staff intranet. If this document is printed into hard copy or saved to another location, you must check that the version number on your copy matches that of the one published.

Document control:		
Date:	**Version Number:**	**Section and Description of Change**
October 2018	V1	Policy ratified by Healthier Lancashire and South Cumbria's Joint Committee of Clinical Commissioning Groups.
July 2022	V1.1	Policy adopted by Lancashire and South Cumbria ICB – references to CCG replaced by ICB where relevant

1. Policy Criteria

1.1 Insulin pump therapy must be initiated and continually supplied / prescribed by specialist clinicians (Diabetologists, Paediatricians with a special interest in diabetes, Diabetes Specialist Nurses) in limited and controlled settings where patients are attending for type 1 diabetes mellitus care, as part of strategies to optimise a patient's HbA1c levels and reduce the frequency of hypoglycaemic episodes

Insulin Pumps – adults and children 12 years and older

1.2 The ICB will commission insulin pump therapy in accordance with the criteria specified in NICE TA151 for adults and children 12 years and older, which states:

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 or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production provided that:

1.2.1 Attempts to achieve target haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia. For the purpose of this guidance, disabling hypoglycaemia is defined as the repeated and unpredictable occurrence of hypoglycaemia that result in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life

OR

1.2.2 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 Pumps – Children under 12 years

1.3 The ICB will commission insulin pump therapy for children under 12 years when:

EITHER

ALL OF THE FOLLOWING CRITERIA ARE MET:

1.3.1 provision of an insulin pump concurs with the preference of the patient or parent(s) / guardian(s) and takes into account any preference that the patient may be able to express,

AND

1.3.2 multi-disciplinary teams planning to commence a patient on insulin pump therapy must ensure that the disadvantages of therapy have been discussed with the patient or guardian(s) and the patient or parent(s) / guardian(s) have expressed a continued wish to initiate insulin pump therapy,

AND

1.3.3 the patient or parent(s) / guardian(s) must have demonstrated appropriate levels of competence to perform carbohydrate counting (e.g. level 3 carbohydrate counting such as DAFNE regimen; or have been judged by their specialist supervising clinician to have demonstrated an equivalent level of competence through the prior management of the patient's glycaemic control), blood glucose monitoring and the patient or parent(s) / guardian(s) must be able to interpret this data to competently adjust insulin doses,

AND

1.3.4 the patient or parent(s) / guardian(s) must have performed frequent blood glucose self-monitoring (ONLY if the patient has previously received insulin therapy) at least 5 times daily (as described in NICE NG18)

AND

1.3.5 the patient or parent(s) / guardian(s) must demonstrate a willingness to engage in all necessary training.

OR

1.3.6 The patient has a definitive diagnosis of needle phobia. The diagnosis must have been made by a specialist with expertise in behavioural therapy and all therapeutic interventions to manage the phobia have failed.

1.4 At the point of device renewal (4 years after the issue of the device) all patients must show:

1.4.1 appropriate device use and compliance with associated testing regimens

AND

1.4.2 a clearly documented achievement of targets for glycaemic control measures including:

a. HbA1c levels
b. Rate and severity of hypoglycaemic and hyperglycaemic episodes (including episodes of DKA)
c. Quality of Life measures (e.g. NICE referenced EQ-5D assessment and / or DQoL questionnaire)

All targets must be agreed by the responsible specialist clinician.

1.4.3 Children under the age of 12 who have been initiated on an insulin pump would be expected to undergo a trial of MDI therapy ONCE between the ages of 12 and 18. This trial must be conducted at the point after their twelfth birthday when their current pump warranty comes to an end. This is required to secure continued funding in accordance with NICE TA 151.

The timing of such a trial will be agreed with the responsible clinician to suit the individual needs of the patient. Should the responsible specialist clinician believe a trial of MDI to be inappropriate, the basis for not conducting such a

trial must be clearly documented to enable continued funding of the insulin pump device.

1.4.4 The ICB will not commission continuation of insulin pump treatment commenced in the private sector (self-funded) either in the UK or abroad. However, exceptions are permissible when NHS funded treatment would normally be made available to NHS patients within the terms detailed in this policy. The following statement(s) must apply:

- the patient must have demonstrably satisfied the initiation criteria detailed in this policy at the time of commencing the self-funded insulin pump, as confirmed and documented by the specialist clinician through a review of the patient's medical history.
- at the point of device renewal, the patient must satisfy the continuation eligibility criteria above and have previously satisfied the initiation criteria at the time of commencing the self-funded insulin pump.

2. Scope and definitions

2.1 This policy is based on the ICBs' Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).

2.2 Type 1 diabetes mellitus is a chronic metabolic disorder caused by the destruction of insulin producing cells in the pancreas that leads to an absolute lack of the hormone and subsequent loss of blood glucose control. Treatment of type 1 diabetes mellitus is by insulin therapy to achieve blood glucose control. Many patients can achieve blood glucose control through multiple daily injections of insulin (MDI) using a mixture of rapid-acting, short-acting, intermediate-acting and long-acting insulins. For those patients with type 1 diabetes mellitus who have difficulty controlling their blood glucose through MDI, insulin pump therapy provides an alternative treatment option.

Type 2 diabetes mellitus is a chronic metabolic condition characterised by insulin resistance (that is, the body's inability to effectively use insulin) and insufficient pancreatic insulin production, resulting in high blood glucose levels (hyperglycaemia). Patients with type 2 diabetes mellitus may initially be managed with lifestyle and dietary changes alone, although due to the progressive nature of the disease many patients will require interventions with medicines including insulin as glycaemic control deteriorates.

Insulin pumps are programmable devices with refillable reservoirs of short-acting insulin which deliver (pump) insulin subcutaneously through a sited cannula to provide a continuous infusion of insulin. The pump can be programmed to deliver a basal rate of insulin throughout the day, with higher infusion rates triggered by pushing a button at mealtimes. This may be as a bolus or delivered over a period of time. The pump can also deliver different basal rates of insulin at different times of the day and night.

2.3 The scope of this policy includes requests for insulin pumps for adults and children of any age with a confirmed diagnosis of type 1 or type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production (e.g. cystic fibrosis-related diabetes, post-pancreatic destruction, post-pancreatectomy diabetes) where these patients fulfil NICE TA151 criteria in every regard other than having type 1 diabetes.

2.4 The scope of this policy does not include the provision of insulin pumps for adults and children who do not have a confirmed diagnosis of diabetes mellitus or any other aspects of the management of type 1 and type 2 diabetes mellitus.

2.5 The ICB recognises that a patient may have certain features, such as:

- having type 1; type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production
- wishing to have a service provided for type 1; type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production
- being advised that they are clinically suitable for an insulin pump; and
- being distressed by having type 1; type 2 diabetes mellitus; or non-type 1, non-type 2 diabetes caused primarily by (near-) absence of insulin production
  This alone is not sufficient to meet the criteria specified in this commissioning policy.

Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.

2.6 The NICE technology appraisal guidance 151 does not recommend insulin pump therapy for patients with type 2 diabetes as a cost-effective use of NHS resource. On this basis the ICB will not routinely commission insulin pump therapy for patients with type 2 diabetes mellitus.

2.7 Terms and abbreviations used in this policy are explained and defined in Appendix 1. Throughout this policy any term is used with the meaning described in that appendix.

2.8 This policy references the guidance of The National Institute for Health and Care Excellence (NICE), in particularly TA151 (published in July 2008), which is mandatory, and NG17 and NG18 (both published in August 2015), which are not mandatory, and relate to adults and to children and young people respectively.

3. Appropriate Healthcare

3.1 The purpose of an insulin pump device is to reduce the variability of blood glucose levels in patients unable to achieve satisfactory control using MDI insulin. Improved control of blood glucose levels reduces the likelihood of short-term complications such as episodes of low blood glucose (hypoglycaemia) or high glucose (hyperglycaemia) leading to life-threatening emergencies such as diabetic ketoacidosis. The long-term microvascular and macrovascular complications of chronically elevated blood glucose levels include retinopathy, nephropathy, neuropathy and blindness, renal failure and foot ulceration respectively.

3.2 Due to the effects of insulin treatment and diabetic complications on a patient's quality of life, the ICB regards the provision of insulin pumps in accordance with the Principles of Appropriateness. The policy does not rely on the Principle of Appropriateness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider the principle of appropriateness in the particular circumstances of the patient in question before confirming a decision to provide funding.

4. Effective Healthcare

4.1 The ICB does not call into question the effectiveness of insulin pump therapy in improving blood glucose control or the resultant prevention/delay in onset of diabetic complications afforded by improved blood glucose management. This policy does not therefore rely on the Principle of Effectiveness. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the purpose of the treatment is likely to be achieved in this patient without undue adverse effects before confirming a decision to provide funding.

5. Cost-Effectiveness

5.1 This policy relies on the Principle of Cost-Effectiveness. The ICB recognises the provision of insulin pump therapy to improve blood glucose control would not represent a cost-effective use of NHS resources in the following patient cohorts (based on the recommendations of NICE TA151):

i. those patients that can achieve satisfactory blood glucose control (defined as agreed targets made by the specialist clinician in conjunction with the patient) by administering multiple daily injections of insulin
AND
ii. all patients with type 2 diabetes mellitus

NICE TA151 defines cost-effective uses of insulin pump therapy in adults and children 12 years and older reliant on:

- raised baseline HbA1c (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 prior to commencing insulin pump therapy or
- increased episodes of disabling hypoglycaemia in patients attempting to achieve their target HbA1c levels with MDI therapy

For the use of insulin pumps in place of MDI in children under 12 years, the ICB considers that the relative costs, expected clinical benefits and limitations of insulin pump therapy may vary from patient to patient.

There is insufficient evidence to define cost-effective use of insulin pumps in children under 12 years using thresholds for baseline HbA1c or frequency of hypoglycaemic episodes. The strongest indicator of improved clinical outcomes in patients under 12 years relates to competence in the use of the pump device and treatment compliance.

6. Ethics

6.1 The ICB does not call into question the ethics of insulin pump therapy and therefore this policy does not rely on the Principle of Ethics. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the treatment is likely to raise ethical concerns in this patient before confirming a decision to provide funding.

7. Affordability

7.1 The ICB does not call into question the affordability of insulin pump therapy and therefore this policy does not rely on the Principle of Affordability. Nevertheless, if a patient is considered exceptional in relation to the principles on which the policy does rely, the ICB may consider whether the treatment is likely to be affordable in this patient before confirming a decision to provide funding.

8. Exceptions

8.1 The ICB will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.

8.2 In the event of inconsistency, this policy will take precedence over any non-mandatory NICE guidance in driving decisions of this ICB. A circumstance in which a patient satisfies NICE guidance but does not satisfy the criteria in this policy does not amount to exceptionality.

9. Force

9.1 This policy remains in force until it is superseded by a revised policy or by mandatory NICE guidance relating to this intervention, or to alternative treatments for the same condition.

9.2 In the event of NICE guidance referenced in this policy being superseded by new NICE guidance, then:

- If the new NICE guidance has mandatory status, then that NICE guidance will supersede this policy with effect from the date on which it becomes mandatory.
- If the new NICE guidance does not have mandatory status, then the ICB will aspire to review and update this policy accordingly. However, until the ICB adopts a revised policy, this policy will remain in force and any references in it to NICE guidance will remain valid as far as the decisions of this ICB are concerned.

10. References

National Institute for Health and Clinical Excellence (2008) Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus. Technology appraisal guideline 151 (TA151) accessed at https://www.nice.org.uk/guidance/ta151

National Institute for Health and Care Excellence (2016) Type 1 diabetes in adults: diagnosis and management. NICE guideline (NG17) accessed at https://www.nice.org.uk/guidance/ng17

National Institute for Health and Care Excellence (2016) Diabetes (type 1 and type 2) in children and young people: diagnosis and management. NICE guideline (NG18) accessed at https://www.nice.org.uk/guidance/ng18

Appendix 1 – Terms and abbreviations

ICB – Integrated Care Board.

MDI – Multiple daily injections. In this policy this refers to four or more daily injections of insulin.

Diabetes mellitus – As defined by the World Health Organisation 2006 plasma glucose criteria (fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).)

NICE – National Institute for Health and Care Excellence

TA151 – NICE technology appraisal guideline 151 (Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus).

NG17 – NICE guideline 17 (Type 1 diabetes in adults: diagnosis and management).

NG18 – NICE guideline 18 (Diabetes [type 1 and type 2] in children and young people: diagnosis and management).

Adult – A person over the age of 18.

Children – To align with TA151 and for the purposes of this policy all people under the age of 18 are referred to as children.

Young people - A person between the ages of 12 and 18 years. (However, the separate definitions for children and young people are not stated in NG18 or TA151).

HbA1c - Glycated haemoglobin measured using methods that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation.

Disabling hypoglycaemia – defined by TA 151 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.

DKA – Diabetic Ketoacidosis.

EQ-5D – Validated Quality of Life measure developed by EuroQol and referenced by NICE.

DQoL – Diabetes Quality of Life measure. A validated tool designed by the Diabetes Control and Complications Research Group.