Placename CCG

Policies for the Commissioning of Healthcare

Policy for the funding of insulin pumps and continuous glucose monitoring devices for patients with diabetes

1	**Introduction**
1.1	This document is part of a suite of policies that the CCG 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 polices in that suite.
1.2	This policy is based on the CCG's Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted).
2	**Scope and definitions**
2.1	Most patients with Type 1 diabetes are managed by insulin which is given by injections once or more each day. For short term control, patients monitor their blood glucose levels periodically by testing the glucose level in a blood droplet. Long term control is monitored by clinicians measuring the HbA1c level in the blood. The aim of diabetic control is to avoid short and long term complications by achieving a blood glucose level as close as possible to normal. In particular excessively low levels (hypoglycaemia) can be a medical emergency (albeit a relatively easy one to treat) and persistently high levels accelerate the development of the complications of diabetes, especially in relation to the circulatory system, the kidneys, eyesight and the peripheral nervous system. In some patients with type 1 diabetes, good blood glucose control is difficult to achieve through injections and self-monitoring. Technologies including insulin pumps and continuous glucose monitoring devices may be considered as part of a management plan for patients with poor blood glucose control.
2.2	An insulin pump is a device that delivers a continuous infusion of insulin subcutaneously. Most devices are programmable so that the amount of insulin can be changed throughout the day, allowing the patient to adjust the insulin dose to account for periods of exercise or mealtimes.
2.3	A continuous blood glucose monitoring device provides a real time measurement of the glucose levels. There are three types of device: • A basic device which is used periodically to show how glucose levels vary throughout the day, and enable more accurate programming of an insulin pump. • A device with an alarm that alerts the patient (or their companions) to hypoglycaemia. • A device that is linked to an insulin pump, and seeks to achieve the most appropriate rate of insulin delivery by the pump. Devices in the latter two groups are more expensive than the basic device.

2.4	The scope of this policy includes requests for insulin pumps and continuous blood glucose monitoring devices in patients of any age who have type 1 diabetes. The policy also indicates that such devices will not normally be considered for patients who do not have this diagnosis.
2.5	The scope of this policy does not include other aspects of the management of diabetes.
2.6	The CCG recognises that a patient may suffer diabetes, wish to have NHS funded devices to achieve better control and have advice that they are clinically suitable. Such features place the patient within the group to whom this policy applies and do not make them exceptions to it.
2.7	This policy makes reference to guidance of The National Institute for Health and Care Excellence (NICE), and in particular to TA151 (published 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 & young people respectively). Some extracts from those guidance documents are in Appendix 1.
2.8	Terms and abbreviations used in this policy are explained and defined in Appendix 2. Throughout this policy any terms is used with the meaning described in that appendix.
3	**Appropriate Healthcare**
3.1	The purpose of devices in scope of this policy is to assist in the management of diabetes. Diabetes is a health problem, and good control prevents or delays the onset of complications. Those complications can be disabling or life limiting. Therefore the CCG regards the provision of these devices in accordance with the Principle of Appropriateness.
3.2	If a patient is considered exceptional in relation to the criteria that rely on other Principles, the CCG 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 CCG recognises that the devices in scope of this policy are effective in controlling the blood glucose level, and in turn that good control of blood glucose is effective in preventing or delaying the onset of complications of diabetes.
4.2	The CCG is aware of no major clinical dis-benefits arising from the use of these devices, although it does recognise that they need the patient to carry the devices continuously, with needles being in place. That may represent discomfort or inconvenience and many patients will choose not to use these devices. The CCG recognises that for patients who satisfy the criteria in this policy the actual decision to use a device will be driven by patient choice with

	the patients balancing the advantages of excellent control of the diabetes, against the discomfort and inconvenience associated with the devices.
4.3	Therefore this policy does not rely on the principle of effectiveness, and the issue of effectiveness has not been considered further in developing the policy. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG 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	The CCG considers that the use of additional resources such as insulin pumps and continuous blood glucose monitoring devices to improve the control of diabetes in patients who can achieve satisfactory control by other means, does not represent a good use of resources when compared with other demands on its budget. The CCG has made use of the NICE guidance quoted in section 2 above and in Appendix 1, to define the circumstances under which it will regard insulin pumps and continuous glucose monitoring devices as cost effective in patients with Type 1 diabetes.
5.2	The CCG is aware that he NICE guidance in question does not relate to patients with other conditions such as Type 2 diabetes. These devices are unlikely to be of comparable benefit to such patients and it is on the basis of cost effectiveness that this policy does not enable the commissioning of devices for them.
6	**Ethics**
6.1	This policy does not rely on the principle of ethics, and therefore the issue of ethics has not been considered in developing the policy. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG 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	This policy does not rely on the principle of affordability, and therefore the issue of affordability has not been considered in developing the policy. Nevertheless if a patient is considered exceptional in relation to the principles on which the policy does rely, the CCG may consider whether the treatment is likely to raise affordability concerns in this patient before confirming a decision to provide funding.
8	**Policy**
8.1	Funding for devices in accordance with this policy will be only for patients with a diagnosis of Type 1 diabetes.

8.2	Before being considered for any of the devices in scope of this policy, the patient and clinician must have agreed a target HbA1c level that is within the range 48mmol/mol to 69 mmol/mol and must be realistic in the context of the patient's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of hypoglycaemia.
8.3	Continued funding for any device offered under this policy will be subject to the patient complying with the use of the machine, and to evidence that the device is continuing achieve its objectives.
	Insulin Pumps – children under 12
8.4	Insulin pumps may be funded for children under 12, provided that: • it accords with the preference of the family, taking due account of any preference that the patient is able to express, and • without a pump, the diabetic control to the target HbA1c level would require injections at least three times a day and at times that would interfere with schooling, childcare, or specific activities that the child wishes to undertake, and • the reasons for, and the nature of, that interference are clear and documented, and there is no reasonable alternative means of alleviating them, and • the child / family accepts that the child will be expected to undergo a trial of multiple daily injection therapy at some time between the age of 12 and 18.
8.5	Insulin pumps may also be funded for children under 12, provided that multiple daily injection therapy has been tried for at least 6 months with good compliance and appropriate adjustments to the dosage, and it has been impossible to find a dosage regime that will achieve the target HbA1c level without disabling hypoglycaemia. (See appendix 2 for definition of disabling hypoglycaemia.)
8.6	Insulin pumps may also be funded for children under 12, provided that the CCG has agreed to fund a glucose monitoring device in accordance with section 8.9 below and that device needs to be linked to a pump to achieve its purpose.
	Insulin Pumps – children between 12 and 18
8.7	Insulin pumps may be funded for young people aged 12 or more, but under age 18, provided that: • they are using a pump that was supplied to them before the age of 12, that pump remains functional, and they have not yet had the trial of MDI therapy that is required between ages 12 and 18, OR • having been newly diagnosed, or having undertaken a trial of MDI therapy, or being in need of a replacement pump, they satisfy the criteria for the provision of a pump to adults, OR • the CCG has agreed to fund a glucose monitoring device in accordance with section 8.9 below and that device needs to be linked

	to a pump to achieve its purpose.
	Insulin Pumps – adults
8.8	Insulin pumps may be funded for adults aged 18 or more, provided that: 1. MDI therapy has been tried for at least 6 months with good compliance and appropriate adjustments to the dosage, AND 2. it has been impossible to find a dosage regime that will achieve the target HbA1c level without disabling hypoglycaemia. Disabling hypoglycaemia is defined as a pattern of hypoglycaemic episodes that: • Includes at least two episodes within the last 24 months, including at least one within the last 12 months, satisfying the definition of severe hypoglycaemia with no obvious precipitating cause, OR. • Comprises frequent (at least twice a week) and irregular (i.e. at different times of day and with no obvious precipitating factor) episodes which interfere with employment, education, social activities, regular travel sleep or reasonable levels of exercise. The nature of that interference will be substantial and documented. By itself, an inability to participate in extreme sporting activities will not satisfy this requirement. Extreme means at a level more than a brisk walk for an hour on undulating terrain. OR • Is causing extreme anxiety such that the patient is undertaking finger prick testing to an excessive frequency, or has fear of going out of the house, falling asleep or equivalent, and the patient has seen a psychologist without significant benefit.
	Continuous glucose monitoring devices
8.9	Continuous glucose monitoring devices may be funded for patients with Type 1 diabetes who: 1. have clinical advice recommending the use of such a device, AND; 2. after being fully informed by their clinician of the advantages and disadvantages of using a device, have made a clear decision to request such a device, AND; 3. are willing to commit to using it at least 70% of the time and to calibrate it as needed, AND; 4. meet at least one of the following criteria (despite optimised use of insulin therapy and conventional blood glucose monitoring where appropriate): a) have disabling hypoglycaemia. (See appendix 2 for definition of disabling hypoglycaemia.); b) have a loss of awareness of hypoglycaemia (as demonstrated either by a score of 7 on the Gold and Clarke scales, or by a score of 4 or more which has been associated with adverse consequences); c) have extreme hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day. (If a device is funded under this clause, the objective of the device (see section 8.3 above) is to sustain HbA1c at or below 53 mmol/mol and/or at a level at least 27 mmol/mol below the pre-device level.);

	d) have an inability to recognise, or communicate about, symptoms of hypoglycaemia (for example, because of cognitive or neurological disabilities); e) are of pre-school age; f) are aged under 18 and undertake high levels of physical activity (for example, sport at a regional, national or international level); g) are aged under 18 and have comorbidities (for example anorexia nervosa) or who are receiving treatments (for example corticosteroids) that can make blood glucose control difficult. NB In respect of criteria 2 and 3 for children and young people, the decision / commitment may be the responsibility of the parent or guardian, involving the child or young person as appropriate to their age and level of understanding. NB if a child or young person aged under 18 satisfies one or more of criteria 4a, 4b or 4d, the funding may include provision for a device with an alarm.
9	**Exceptions**
9.1	The CCG will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies.
	In the event of inconsistency this policy will take precedence over NICE guidance NG17 and NG18 in driving decisions of this CCG. 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.
9.2	In the event of NICE guidance quoted by 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 CCG will aspire to review and update this policy accordingly. However until it adopts a revised policy, this policy will remain in force and any references in it to the 2008 version of TA151 and to the 2015 versions of NG17 and NG18 will remain valid as far as the decisions of this CCG are concerned.

Date of adoption / Date for review

Appendix 1 Extracts from NICE guidance

Guidance	Section	Text
NG17	1.7.6	For guidance on the use of continuous subcutaneous insulin infusion (CSII or insulin pump) therapy for adults with type 1 diabetes, see continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (NICE technology appraisal guidance 151). [new 2015
NG17	1.6.06	Support adults with type 1 diabetes to aim for a target HbA1c level of 48 mmol/mol (6.5%) or lower, to minimise the risk of long-term vascular complications. [new 2015]
NG17	1.6.07	Agree an individualised HbA1c target with each adult with type 1 diabetes, taking into account factors such as the person's daily activities, aspirations, likelihood of complications, comorbidities, occupation and history of Hypoglycaemia. [new 2015]
NG17	1.6.21	Do not offer real-time continuous glucose monitoring routinely to adults with type 1 diabetes. [new 2015]
NG17	1.6.22	Consider real-time continuous glucose monitoring for adults with type 1 diabetes who are willing to commit to using it at least 70% of the time and to calibrate it as needed, and who have any of the following despite optimised use of insulin therapy and conventional blood glucose monitoring: • More than 1 episode a year of severe hypoglycaemia with no obviously preventable precipitating cause. • Complete loss of awareness of hypoglycaemia. • Fear of hypoglycaemia. • Frequent (more than 2 episodes a week) asymptomatic hypoglycaemia that is causing problems with daily activities. • Extreme Hyperglycaemia (HbA1c level of 75 mmol/mol [9%] or higher) that persists despite testing at least 10 times a day (see recommendations 1.6.11 and 1.6.12). Continue real-time continuous glucose monitoring only if HbA1c can be sustained at or below 53 mmol/mol (7%) and/or there has been a fall in HbA1c of 27 mmol/mol (2.5%) or more. [new 2015]
NG17	1.6.23	For adults with type 1 diabetes who are having real-time continuous glucose monitoring, use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen or continuous Subcutaneous insulin infusion (CSII or insulin pump) therapy. [new 2015]
NG17	1.10.2	Use the Gold score or Clarke score to quantify awareness of hypoglycaemia in adults with type 1 diabetes
NG18	1.2	(page 15) Insulin therapy for children and young people with type 1 diabetes While the insulin regimen should be individualised for each patient, there are 3 basic types of insulin regimen. • Multiple daily injection basal–bolus insulin regimens: injections of short-acting insulin or rapid-acting insulin analogue before meals, together with 1 or more separate daily injections of intermediate-acting insulin or long-acting insulin analogue. • Continuous subcutaneous insulin infusion (insulin pump therapy): a programmable pump and insulin storage device that gives a regular or continuous amount of insulin (usually a rapid-acting insulin analogue or short-acting insulin) by a subcutaneous needle or cannula. • One, two or three insulin injections per day: these are usually injections of short-acting insulin or rapid-acting insulin analogue mixed with intermediate-acting insulin. (paragraphs 1.2.18 and 1.2.19 follow immediately after this)
NG18	1.2.18	Take into account the personal and family circumstances of the child or young person with type 1 diabetes and discuss their personal preferences with them and their family members or carers (as appropriate) when choosing an insulin regimen. [new 2015]

Appendix 1 Extracts from NICE guidance

Guidance	Section	Text
NG18	1.2.19	Offer children and young people with type 1 diabetes multiple daily injection basal–bolus insulin regimens from diagnosis. If a multiple daily injection regimen is not appropriate for a child or young person with type 1 diabetes, consider continuous subcutaneous insulin infusion (CSII or insulin pump) therapy as recommended in continuous subcutaneous insulin infusion for the treatment of diabetes mellitus (NICE technology appraisal guidance 151). [new 2015]
NG18	1.2.62	Offer ongoing real-time continuous glucose monitoring with alarms to children and young people with type 1 diabetes who have: • frequent severe hypoglycaemia • 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). [new 2015]
NG18	1.2.63	Consider ongoing real-time continuous glucose monitoring for: • neonates, infants and pre-school children • children and young people who undertake high levels of physical activity (for example, sport at a regional, national or international level) • 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]
NG18	1.2.67	Explain to children and young people with type 1 diabetes and their family members or carers (as appropriate) that an HbA1c target level of 48 mmol/mol (6.5%) or lower is ideal to minimise the risk of long-term complications. [new 2015]
TA151	1.1	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 provided that: • 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 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.
TA151	1.2	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.
TA151	4.1.8	In summary, there is little evidence from the RCTs of a significant difference between CSII and MDI therapy in terms of a decrease in HbA1c levels or in the rate of severe hypoglycaemic episodes in people with diabetes mellitus. Observational studies show a much greater improvement (decrease) in HbA1c levels with CSII therapy, as well as statistically significant decreases in the rate of severe hypoglycaemia episodes. There is no clear evidence of any greater benefit of CSII over MDI therapy in pregnancy.

Appendix 2	Glossary and definitions
	This glossary explains and defines terms and abbreviations used in this policy, and also for ease of reference includes some terms that do not appear in this policy but are used in the related NICE guidance.
Adult	A person over the age of 18
CCG	Clinical Commissioning Group
Children and young people	People under the age of 18 (with children being people under the age of 12). Although the NICE guidance itself does not necessarily define the age of people to whom it applies, the NICE website (https://www.nice.org.uk/guidance/ng18) does confirm that NG18 applies to children and young people aged under 18.
Clarke score	A tool for measuring awareness of hypoglycaemia. A score of 4 or more implies an impaired awareness of hypoglycaemia. (Although the threshold for concluding that there is impaired awareness is the same, this is a different tool to the Gold Score). See also Appendix 3 for the way in which those scores are applied in this policy.
CSII	Continuous subcutaneous insulin infusion (i.e. supplied by an insulin pump)
Disabling hypoglycaemia *(see also "Severe hypoglycaemia")*	A pattern of hypoglycaemic episodes that: • Includes at least two episodes within the last 24 months, including at least one within the last 12 months, satisfying the definition of severe hypoglycaemia with no obvious precipitating cause, OR. • Comprises frequent (at least twice a week) and irregular (i.e. at different times of day and with no obvious precipitating factor) episodes which interfere with employment, education, social activities, regular travel sleep or reasonable levels of exercise. The nature of that interference will be substantial and documented. By itself, an inability to participate in extreme sporting activities will not satisfy this requirement. Extreme means at a level more than a brisk walk for an hour on undulating terrain. OR • Is causing extreme anxiety such that the patient is undertaking finger prick testing to an excessive frequency, or has fear of going out of the house, falling asleep or equivalent, and the patient has seen a psychologist without significant benefit.
Gold score	A tool for measuring awareness of hypoglycaemia. A score of 4 or more implies an impaired awareness of hypoglycaemia. (Although the threshold for concluding that there is impaired awareness is the same, this is a different tool to the Clarke Score). See also Appendix 3 for the way in which those scores are applied in this policy.
MDI	Multiple daily injection. For the purposes of this policy this would mean insulin injections on at least four separate occasions each day.
NICE	The National Institute for Health and Care Excellence. Guidance TA151; NG17; and NG18 are issued by NICE.
Severe hypoglycaemia *(see also "Disabling hypoglycaemia")*	Severe hypoglycaemia is defined as having low blood glucose levels that requires assistance from another person to treat. (http://www.diabetes.co.uk/severe-hypoglycemia.html). For the purposes of this policy severe hypoglycaemia must also include at least one of Confusion and disorientation; Convulsions / fitting / seizures; Intense nightmares whilst asleep; Loss of consciousness; Coma.
Young People	People under the age of 18. Although the NICE guidance itself does not necessarily define the age of people to whom it applies, the NICE website (https://www.nice.org.uk/guidance/ng18) does confirm that NG18 applies to people aged under 18.

Appendix 3 Awareness of hypoglycaemia

Much of the literature, e.g. Diabetes Care July 2007 vol. 30 no. 7 1868-1870, refers to a Gold score or Clarke score of 4 or more as indicating "impaired awareness" of hypoglycaemia. It is difficult to find a published definition of a "complete loss of awareness", although it is rational to suppose that a score below 7 could be worse and therefore the loss of awareness is less than complete.

NG18 (1.2.62) sets a criterion for children and young people for continuous monitoring devices of "impaired awareness of hypoglycaemia" and although that guidance does not specifically refer to Gold or Clarke scales it is reasonable to assume that this criterion would be satisfied by a score of 4 or more on those scales. Additionally however NG18 requires a history of adverse consequences associated with this lack of awareness.

NG17 (1.6.21) sets a tighter criterion for adults of "complete loss of awareness of hypoglycaemia" and does recommend the use of the Gold or Clarke score to determine this. However it is not specific about the point on the scale that needs to be met. Indeed sections 1.10.4 to 1.10.9 suggest that it is impaired awareness rather than complete lack of awareness that should be the trigger from clinical concern. However, unlike NG18 this guidance does not require a history of adverse consequences.

It seems reasonable to combine these two requirements into a single criterion. This policy therefore requires "Loss of awareness of hypoglycaemia (as demonstrated either by a score of 7 on the Gold and Clarke scales, or by a score of 4 or more which has been associated with adverse consequences)". This policy apples that criterion to people of any age. A pragmatic approach may need to be taken in young children for whom scoring may be difficult.