NHS
Shropshire, Telford and Wrekin
Clinical Commissioning Group

Commissioning Policy: Continuous Subcutaneous Insulin Infusion (CSII) without continuous glucose monitoring (CGM) in adults and children with Type 1 Diabetes

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Version No.	Date	Brief Description
Version 5	11/11/21	Review of previous version and updated to new CCG format. Included additional section on use of CSII in pregnant women with Diabetes.

The formally approved version of this document is that held on the NHS Shropshire, Telford and Wrekin CCG website: www.shropshiretelfordandwrekinccg.nhs.uk

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1 Introduction

Continuous subcutaneous insulin infusion (CSII) is often called 'insulin pump' therapy. The pump is a small device worn outside the body, which continuously delivers insulin into the body through a very thin tube or needle inserted under the skin. The insulin can be delivered at a set rate throughout the day, which can be increased when it is needed, for example at meal times.

There is a range of insulin pumps available. Their approximate annual costs are based on a four year assumed life of the pump. This policy does not cover integrated sensor-augmented pump therapy systems. Sensor-augmented pump systems, with integrated CGM, will only be considered via Blueteq in line with NICE [DG21] criteria.

There has been a substantial amount of evidence demonstrating the clinical and economic effectiveness of using CSII therapy to manage type 1 diabetes mellitus compared to multiple daily injections (MDI therapy) based on people with following characteristics:

- MDI therapy to manage HbA1c levels has resulted in the person experiencing disabling hypoglycaemia
- HbA1c levels have remained high on MDI therapy (above 69mmol/mol) despite a high level of care
- Children under 12 years where MDI is considered to be impractical or inappropriate[1]

Monitored continued use in these groups results in a sustained improvement in glycaemic control through reduced HbA1c level or reduced hypoglycaemic episodes.

NICE guidelines [TA151] identified that the use of CSII therapy is only likely to be cost effective when used appropriately, with ongoing support from a specialist team. The guideline also states that there is no clinical evidence that one make of pump necessarily leads to better diabetes control compared to another however, as there are variations in features which may lead to a reduced chance of effective use e.g. ease of seeing the screen or refilling the pump. The choice of pump for an individual should therefore be based on clinical need.[2]

2 Purpose

The purpose of this policy is to provide clear criteria for the commissioning of continuous subcutaneous insulin infusion (CSII) without continuous glucose monitoring (CGM) in adults and children with Type 1 diabetes.

3 Eligibility criteria for CSII (without CGM)

CSII (without CGM) for children younger than 12 years

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 the child / family accepts that the child on CSII therapy would be expected to undergo a trial of MDI therapy between the ages of 12 and 18 years.[1]

OR

- MDI therapy has been tried for at least 6 months with good compliance and appropriate adjustments to the dosage (including using long-acting insulin analogues if appropriate) and it has been impossible to find a dosage regime, which will achieve the target HbA1c level without disabling hypoglycaemia (see definition).

CSII (without CGM) for adults and children aged 12 and over

CSII therapy should be initiated and supported following assessment by NHS specialist and multidisciplinary team, which provides structured education programmes and advice on diet, lifestyle and exercise appropriate for patient using CSII.[1]

CSII therapy is recommended as a treatment option for adult and children 12 and over with type 1 diabetes mellitus provided that:

- MDI therapy has been tried for at least 6 months with good compliance and appropriate adjustments to the dosage.[3]

AND

- HbA1c levels have remained high (8.5% or [above 69 mmol/mol] or above) with MDI (including using long-acting insulin analogues if appropriate) despite the person and/or their carer carefully trying to manage their diabetes.[1]

OR

- Attempts to reach target HbA1c levels with MDIs result in the person experiencing disabling hypoglycaemia[1] (see definition below).

CSII (without CGM) for pregnant women with insulin-treated diabetes[4]

Offer continuous subcutaneous insulin infusion (CSII; also known as insulin pump therapy) to pregnant women with insulin-treated diabetes who:

- are using multiple daily injections of insulin and
- do not achieve blood glucose control without significant disabling hypoglycaemia.

Definition: Disabling hypoglycaemia

Disabling hypoglycaemia is defined as a pattern of hypoglycaemic episodes which comprises:

- Two episodes or more 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

- 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 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.

4 Continuation criteria for CSII (without CGM)

Appropriate targets for such improvement should be set by secondary care, in discussion with the person receiving the treatment or their carer. CSII therapy should be reviewed annually and should be discontinued if the agreed targets are not being met.[3]

CSII therapy can be continued in adults and children aged 12 years and older provided that they demonstrate:

- A sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels.[1]

OR

- A sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvement should be set by the specialist, in discussion with the person receiving the treatment and/or their families or carers (if appropriate).[1]

If more than one insulin pump device is considered appropriate, the most cost-effective device should be used. Switching devices within the original warranty period is **not normally funded**. When devices become due for replacement funding will only be considered if continuing clinical benefit is evidenced in line with the criteria above.

NHS funding is not available for consumables or replacements following initial private provision or purchase of a pump.

NHS Shropshire, Telford and Wrekin CCG and have agreed to fund CGM (Continuous Glucose Monitoring) in addition to the use of CSII therapy, in accordance with the CGM commissioning policies.

5 Application for funding CSII

Clinicians wishing to apply for funding for CSII for a patient meeting the criteria in this policy should do so via the Blueteq system. On discontinuation of CSII, Blueteq should be updated.

6 Exceptional circumstances

The CCG recognises that there may be exceptional circumstances where it is clinically appropriate to fund CSII outside the terms of this policy. Funding for such cases will be considered by the CCG following application to the CCG's Individual Funding Request Panel, whereby the IFR process will be applied.

Guidance regarding IFRs, and an application form, can be found on the CCG website, here.

7 Related documents

The following documents contain information that relates to this policy:

- Commissioning Policy: Continuous Glucose Monitoring (CGM) for Type 1 Diabetes in Children and Young People aged up to 19 years.

8 References

1. NICE guidance [TA151], Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus, Published July 2008, Available at: https://www.nice.org.uk/guidance/TA151/chapter/1-Guidance (Accessed: November 2021)

2. Specialist Pharmacy Service (May 2018) Comparative table of insulin pumps, Available at: https://www.sps.nhs.uk/articles/comparative-table-of-insulin-pumps-2/ (Accessed: November 2021)

3. Thames Valley Priorities Committee Commissioning Policy Statement (April 2018) Continuous subcutaneous insulin infusion (insulin pumps) for adults with type 1 diabetes, Available at: https://www.oxfordshireccg.nhs.uk/professional-resources/documents/commissioning-statements/288-insulin-pumps-adults.pdf (Accessed: November 2021).

4. NICE guidance [NG3], Diabetes in pregnancy: management from preconception to the postnatal period, Published February 2015, Updated December 2020, Available at: https://www.nice.org.uk/guidance/ng3/chapter/Recommendations (Accessed: November 2021)