NHS Shropshire Clinical Commissioning Group and NHS Telford & Wrekin Clinical Commissioning Group Joint Commissioning Policy:
Continuous subcutaneous insulin infusion (CSII) (without continuous glucose monitoring (CGM)) in adults and children with Type 1 diabetes

Policy statement:
NHS Shropshire CCG and NHS Telford & Wrekin CCG do NOT routinely commission Continuous Subcutaneous Insulin Infusion (CSII). Both CCGs recommend the use of CSII for adults and children with Type 1 diabetes who meet the clinical criteria specified in this policy. 
CSII requires prior approval via Blueteq at the time of initiation and can only be funded for a limited number of patients per year therefore patients must be selected carefully

CSII therapy is not recommended for treatment of people with type 2 diabetes mellitus

Background

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.

Types of CSII

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.

Summary of the evidence

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 8.5%) despite a high level of care
- Children under 12 years where MDI is considered to be impractical or inappropriate

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.

**Definition:**
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.

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<th><strong>CSII (without CGM) for children younger than 12 years</strong></th>
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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

**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.

**Completion of Blueteq form will be required at the time of initiation and it should be updated on discontinuation of the CSII.**
Initiation funding request for NEW PATIENTS currently on MDI therapy

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.3

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
- 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
- Attempts to reach target haemoglobin A1c (HbA1c) levels with MDI result in the person having ‘disabling hypoglycaemia’ (see definition)

Completion of Blueteq form will be required at the time of initiation and it should be updated on discontinuation of the CSII.

On-going funding request for CSII therapy

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
- A sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvement should be set by the secondary care, in discussion with the person receiving the treatment or their carer.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 CCG and NHS Telford & Wrekin CCG have agreed to fund CGM (Continuous Glucose Monitoring) in addition to the use of CSII therapy, in accordance with the Joint Commissioning CGM policies. Prior approval via Blueteq will be required.
This policy is based on the best available information at the time of writing.

References