

# Clinical Pathway for the use of diabetes technologies in all patients with Type 1 Diabetes



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# Clinical Pathway for the use of diabetes technologies in all patients with Type 1 Diabetes

## 1 Introduction

For patients with Type 1 diabetes who have challenging diabetes control despite all reasonable measures on standard insulin therapy and self-blood glucose monitoring, timely and appropriate access to diabetes technologies can transform lives, reduce burden of care to the patients and health services and be very cost effective.

Diabetes technology covers the following:

- Continuous Glucose Monitoring (CGM) (NICE NG3, NG17 and NG18)
  - Intermittently scanned Continuous Glucose Monitoring (isCGM)/Flash Glucose monitoring 2
  - Real time Continuous Glucose Monitoring (rtCGM)
- Insulin Pump therapy (NICE TA151)

This guideline seeks to bring together the current available Type 1 Diabetes technology into a simple pathway which is fit for purpose and will support clinicians with joint decision making, ensuring the most appropriate use of technology to support improved glycaemic outcomes in adults, young people and children with Type 1 diabetes across BNSSG.

By adoption of these technologies there are potential savings in the system to be realised through:

- Improving management of blood glucose levels
- Reducing HbA1c/improving Time in Range in this group of patients
- Reducing hypoglycaemic severity and frequency of events
- Reducing diabetes related complications and morbidity
- Improving the quality of life for people with Type 1 diabetes.

This updated pathway will rationalise the use of technologies across the BNSSG Health Community in line with NICE guidance, NHS England guidance and in addition a recent consensus document developed by Diabetes UK in conjunction with NHS England, Type 1 Diabetes Technology: A consensus guideline<sup>1</sup>. This consensus document considers all national guidance related the use of these technologies as well as bringing together a multi-disciplinary group of experts from across England including representative groups and expert patients.

## BNSSG Type 1 diabetes technology pathway

### Optimal Standard care

Insulin basal-bolus regimen (Multiple Daily Injections (MDI)) with analogue insulins (dose optimisation)

Use of bolus advisor meters/ smartphone apps

Structured education: Group, individual, online (BERTIE)

Advanced carbohydrate counting

Specialist team support, structured clinic reviews, downloads of meters + review

**Continuous glucose monitoring (CGM)**

**NICE NG17 & NICE NG18**

#### OFFER:

#### Prescribed real-time CGM (rtCGM)

- When choosing a CGM device: use shared decision making to identify the person's needs and preferences, and offer them an appropriate device. If multiple devices meet their needs and preferences, offer device with lowest acquisition cost.
- Lowest acquisition cost <£1,000 p.a.
- Consider licensed age for use
- Sensors available on FP(10) prescription for continuation

For example:

- GlucoRx Aidex (≥14years)
- DexcomOne (≥2 years)

#### OR

#### Intermittently scanned CGM (isCGM)/ Flash Glucose Monitoring

For example:

- Free Style Libre 2 (≥4 years) If using with an app and smartphone, this also acts as rtCGM

#### OR

If cannot use or do not wish to use rtCGM or isCGM the patient should use capillary blood glucose monitoring

Not achieving Hba1c targets, troublesome hypoglycaemia, significant diabetes distress, excessive burden of diabetes care

### Specialist review

Assess for causes of raised HbA1c. Consider further education, clinical psychology support. Exclude other exacerbating condition e.g. coeliac disease, pancreatic exocrine insufficiency.

**Make an informed joint decision on best technology suited to address problem(s), educate on use and agree expected outcomes.**

### Technology options Monotherapy

#### Continuous Insulin Infusion

**NICE TA151**

Useful if:

- HbA1c >69mmol/mol despite all measures with injection therapy + FGM/CGM
- Recurrent troublesome hypoglycaemia not resolved with FGM or CGM
- Need variable basal profile e.g. dawn phenomenon
- Need for frequent, small or complex boluses
- Daily insulin dose < 20 units
- Pregnancy
- Diabetic gastroparesis
- Professional sports
- Children <12 years and MDI considered impractical/inappropriate



#### Consider procured rtCGM

- If prescribed rtCGM is unsuitable for patient needs – problematic hypoglycaemia, repeated admissions, excessive burden of care.
- High acquisition cost >£1,000 p.a. Offer device with lowest acquisition cost.
- Purchased by hospital only
- As per Diabetes Technology Formulary (in development)

If there are continuing problems, high HbA1c, troublesome hypoglycaemia, excessive burden of diabetes care. Optimise therapy and technology. Review engagement with technology, e.g. if <4 times a day SBGM,



Consider switching between technologies as monotherapy or using dual technology therapy.

## Technology options Dual therapy

### isCGM + insulin pump

Useful if:

- HbA1c remains >69mmol/mol
- Recurrent hypos + intact or only recently impaired hypo awareness
- Children >4 years

### rtCGM + Continuous insulin infusion

- Continuing troublesome hypoglycaemia with loss of hypoglycaemia awareness
- Continuing unexplained severe hypoglycaemia

If there is ongoing severe hypoglycaemia/hypoglycaemia unawareness even on dual technology therapy an Islet cell/whole pancreas transplant may be considered.

## 2 The Pathway

### 2.1 Optimal standard care (baseline minimum standard of care)

As optimal standard care, all people living with Type 1 diabetes should be able to access structured education (face to face either individually or in groups, or online via BERTIE or [www.mytype1diabetes.nhs.uk](http://www.mytype1diabetes.nhs.uk) the NHSE procured education programme), CGM (see below), access to ketone monitoring and a specialist care team to support insulin dose optimisation and with whom they can download and review blood glucose information. This may also involve advanced carbohydrate counting and the use of bolus advisor meters and smartphone apps.

### CGM

#### Adults

Offer adults with type 1 diabetes a choice of intermittently scanned continuous glucose monitoring (isCGM) or real-time continuous glucose monitoring (rtCGM)<sup>2</sup>. Offer prescribed rtCGM in the first instance as these are the most cost-effective options (<£1,000 per patient per year) and are expected to be sufficient for most patients.

#### Children and young people

Offer rtCGM to all children and young people with type 1 diabetes<sup>3</sup>.

Use prescribed rtCGM if appropriate and device meets the patients/family needs; the device chosen depending upon the licensed age for use and additional supportive requirements such as cloud-based sharing.

Offer isCGM to children and young people with type 1 diabetes aged 4 years and over who are unable to use rtCGM or who express a clear preference for isCGM<sup>3</sup>.

#### Pregnancy

Offer rtCGM to all pregnant women with type 1 diabetes to help them meet their pregnancy blood glucose targets and improve neonatal outcomes. Offer isCGM to those who are unable to use rtCGM or express a clear preference for isCGM.

It is expected that a prescribed rtCGM is offered in the first instance due to their lower acquisition cost.

Education and support should be provided by the joint diabetes and antenatal care team

Despite access to this optimal standard of care, some patients are unable to achieve the personalised glycaemic targets set, may have troublesome or disabling hypoglycaemia, significant diabetes distress or have excessive burden of diabetes care. A specialist review and close working with the specialist team will aim to assess the causes of the raised HbA1c or hypoglycaemia issues (to exclude exacerbating conditions) and consider further education or access to clinical psychology support. A copy of the Diabetes Distress Screening Scale DDS17 can be found [here](#).

### 2.2 First Line Technology (monotherapy)

If it is felt that standard care has been optimised and that individual issues cannot be resolved, the addition of a technological support as a 'first line agent' should be agreed. This should be an informed joint decision on which technology is best suited to address the problem being experienced (in line with criteria set out in the pathway). Clear expected outcomes should be agreed between the patient and specialist care team.

Most patients would need a single technology (monotherapy). It may be appropriate to move a patient from one monotherapy to another if the desired or expected outcomes and benefits are not being achieved before adding in another technology if the Healthcare professional feels this is appropriate. While the indications for each of the technologies appear comparable, each technology has its own merits and limitations and the best choice for an individual patient (where they meet the relevant criteria) should be decided by the clinician and patient in a face to face review of current diabetes care and treatment options.

#### Adults

If adult patients have tried isCGM and/or prescribed rtCGM but this has not had the desired or expected benefit, it may be appropriate to move to another '1<sup>st</sup> line' technology e.g. procured rtCGM or Continuous Insulin Infusion (CSII) before considering adding in another technology. After joint discussion about needs and preferences, offer the device(s) with the lowest cost<sup>2</sup>.

#### Children and young people

Offer procured rtCGM when prescribed rtCGM does not meet the needs and preferences of the patient/family; offer the device with the lowest cost<sup>3</sup>.

### 2.3 Second Line Technology – dual therapy

If, despite the use of a technology monotherapy there are continuing problems for the patient including high HbA1c, disabling hypoglycaemia or excessive burden of diabetes care, the patient should be reviewed and assessed in terms of their engagement and appropriate use of the technology, ensuring this is optimised. If following the review, these issues continue, the addition of a second technology would be appropriate.

The NICE technology appraisal 'Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes' (GID-TA10845) is in development; this pathway will be reviewed on its publication, expected publication date TBC (<https://www.nice.org.uk/guidance/indevelopment/gid-ta10845>).

### 2.4 The Technologies

The three technology options are:

#### a. Continuous Glucose Monitoring

##### i. Intermittently scanned continuous glucose monitoring (isCGM)/Flash Glucose Monitoring 2

isCGM or Flash Glucose monitoring is a system which monitors glucose levels in interstitial fluid rather than capillary blood glucose levels from finger-prick testing. A sensor is worn on the upper arm to measure the interstitial glucose level every few minutes and a reader device is scanned over the sensor to read the result. It can produce a near continuous record of measurements for the last eight hours which can be accessed on demand. It is also possible to show glucose level trend over time. This technology is suitable for all patients over 4 years of age.

Initiation should not be limited to case setting and can occur via Primary Care, Secondary Care or Community Teams.

The initiating team will provide the patient with a device, if required (reader and/or transmitter) and at least 2 weeks supply of sensors on initiation.

It is expected that patients' complete education on their CGM either online where available or in person to ensure they are obtaining maximal benefit from the technology. Ongoing review of the CGM should be undertaken as part of the routine diabetes reviews and, where that review is not undertaken by the Primary care team, clearly documented and communicated to **primary care for ongoing repeat prescribing of the sensors and transmitters, if required.**

Caution is advised for prescribing of isCGM/Flash Glucose monitoring devices where there is impaired awareness of hypoglycaemia, a history of severe hypoglycaemia, or frequent asymptomatic episodes. Newer models of isCGM/ Flash Glucose monitoring do have device warnings or alarms and these would be strongly advised.

### **Review at 6 months:**

All patients should attend a review at 6 months to determine whether the isCGM/Flash Glucose monitor should be continued long term or discontinued. This review will be based on evidence of adhering to the requirements set on initiation relating to the appropriate use of the monitoring system. There must also be an improvement in the individual's diabetes self-management e.g. improved HbA1c or Time in Range, improved symptoms e.g. fewer episodes of Diabetic Ketoacidosis (DKA) or hypoglycaemia or improved psycho-social wellbeing. A validated tool e.g. Clarke score or Gold score should be used to assess improvement in hypoglycaemia, hypoglycaemia awareness as well as diabetes distress and psycho-social wellbeing. The review and outcome should be clearly documented on the relevant paperwork and communicated with primary care for ongoing prescription of the Flash Glucose sensors.

### **ii. Real-time Continuous Glucose Monitoring (rtCGM)**

Continuous Glucose Monitoring devices measure glucose in the interstitial fluid (as opposed to the blood) via a sensor inserted under the skin. This is connected to a transmitter that automatically sends continuous glucose results to a receiver device. If using Flash glucose monitoring with an app and smartphone, this also acts as real time CGM and sends glucose readings directly to a smartphone every minute. These results are presented as continuous values and trends over time. They allow for glucose values to be visible continuously, enabling immediate therapeutic adjustments on the basis of 'real time' glucose results. The real-time monitor shows trends in glucose levels on a display and indicates the rate of glucose change using arrows. They have predictive alarms for low or high glucose levels and warn of impending hypoglycaemia or hyperglycaemia. isCGM/ Flash Glucose Monitoring (above) is a form of intermittent glucose monitoring however the newer model has alarm functionality.

There are two types of rtCGM available: the newer devices that can be prescribed on the NHS via an FP(10) prescription and those that cannot be prescribed but have to be procured and purchased by the NHS hospital Trust. These are known as prescribed rtCGM and procured rtCGM respectively.

#### **Prescribed rtCGM**

These devices have the lowest acquisition cost at less than £1,000 per patient per year, are the most cost-effective option of rtCGM and should therefore be offered first.

Currently these devices may only be used as monotherapy as they do not have the functionality to pair with an insulin pump however it is expected that newer models will in the very near future.

Initiation should not be limited to case setting and can occur via Primary Care, Secondary Care or Community Teams.

The initiating team will provide the patient with a device, if required (reader and/or transmitter) and at least 2 weeks supply of sensors on initiation.

It is expected that patients' complete education on their CGM either online where available or in person to ensure they are obtaining maximal benefit from the technology. Ongoing review of the



CGM should be undertaken as part of the routine diabetes reviews and, where that review is not undertaken by the Primary care team, clearly documented and communicated to **primary care for ongoing repeat prescribing of the sensors and transmitters, if required.**

### **Procured rtCGM**

These devices have a much higher acquisition cost, greater than £1,000 per patient per year. They may be offered as monotherapy where the functionality of a prescribed rtCGM does not meet the requirements of the patients' needs and outcomes. They may also be used as dual therapy since they will pair with specific insulin pumps to provide a hybrid closed loop system.

Patients/carers will be required to complete education on their procured CGM to ensure they are obtaining maximal benefit from the technology and must also agree to attend regular reviews with their local clinical team.

### **Assessment for initiation of procured rtCGM**

All patients (adults and paediatrics) must be assessed and supported by a multidisciplinary specialist diabetes team during a face to face or virtual appointment with secondary care for procured rtCGM. They must fulfil the appropriate NICE criteria set out above. The patient (and family when used in paediatrics) must complete a structured training and education programme on the use of rtCGM as well as lifestyle and dietetic care. Clear expected outcomes should be agreed with the patient (and family in the case of paediatrics). Patients must agree to regularly download and share data from their diabetes technology with their diabetes specialist team and remain fully engaged with all aspects of diabetes care.

All patients with type 1 diabetes who are having rtCGM, should use the principles of flexible insulin therapy with either a multiple daily injection insulin regimen (technology monotherapy) or with continuous subcutaneous insulin infusion (CSII or insulin pump) therapy, where dual therapy is indicated.

When choosing a system to use, it is important to consider the best rtCGM system for the age of the patient and whether or not it will be linked to a continuous subcutaneous insulin infusion. Use shared decision making to identify the person's needs and preferences, and offer them an appropriate device. NICE NG17<sup>2</sup> lists the following factors to consider when choosing a CGM device:

- Accuracy of the device
- Whether the device provides predictive alerts or alarms and if these need to be shared with anyone else (for example, a carer)
- Whether using the device requires access to particular technologies (such as a smartphone and up-to-date phone software)

- How easy the device is to use and take readings from, including for people with limited dexterity
- Fear, frequency, awareness and severity of hypoglycaemia
- Psychosocial factors
- The person's insulin regimen or type of insulin pump, if relevant (taking into account whether a particular device integrates with their pump as part of a hybrid closed loop or insulin suspend function)
- Whether, how often, and how the device needs to be calibrated, and how easy it is for the person to do this themselves
- How data can be collected, compatibility of the device with other technology, and whether data can be shared with the person's healthcare provider to help inform treatment
- Whether the device will affect the person's ability to do their job
- How unpredictable the person's activity and blood glucose levels are and whether erratic blood glucose is affecting their quality of life
- Whether the person has situations when symptoms of hypoglycaemia cannot be communicated or can be confused (for example, during exercise)
- Clinical factors that may make devices easier or harder to use
- Frequency of sensor replacement
- Sensitivities to the device, for example local skin reactions
- Body image concerns<sup>2</sup>
- Whether there is carer input whereby the carer needs to have access to the data remotely

### Review of rtCGM

All patients will be given a trial of the rtCGM with clear outcomes identified. There will be a review against set criteria to enable continuation of the rtCGM. The **review and discontinuation criteria** for adults, children and young people are as follows:

#### Review at 1 month

Assess:

- that the patient is using the rtCGM correctly,
- that the patient is working towards the agreed individual outcomes,
- adjust therapy where needed.

CGM will no longer be supported if after **one month** if:

- CGM has not been used 70% of the time,
- CGM has not been calibrated as needed,
- Patient is not working towards individualised goals.

#### Review at 3 – 6 months

rtCGM will no longer be supported if after **three to six months** if:

- CGM has not been used 70% of the time
- CGM has not been calibrated as needed

- There is no improvement in glycaemic control (taking into account other factors which could have affected this e.g. illness, change in other medication, worsening long term condition) – e.g. individualised treatment goals are not met or Time in Range (as agreed prior to starting CGM)
- There is no improvement in scores on fear of hypoglycaemia scales where CGM was introduced for anxiety
- There is no improvement in hypoglycaemia unawareness if introduced for hypoglycaemia unawareness (Clarke or Gold score)
- There is no reduction in frequency of hypoglycaemia – particularly nocturnal hypoglycaemia (assessed from CGM download)

### **Self-funding patients**

All patients who have been self-funding a diabetes technology must meet the NICE criteria for NHS funding. Device choices should be within the guidance of this pathway. In a joint discussion about the needs and preferences of the patient the device with the lowest cost should be offered. This may result in a change of device that offers a lower acquisition cost to the NHS but the same outcomes for the patient.

### **Blood glucose testing strips and meter**

The choice of meter and test strips should be based on the [BNSSG Blood Glucose Monitoring Guidance – Type 1 Diabetes](#).

Advise patients with type 1 diabetes who are using CGM that they will still need to take capillary blood glucose measurements although they can do this less often: to check accuracy of their CGM device and as a back-up e.g., when blood glucose levels are changing quickly or if the device stops working. Reduce blood glucose testing strip quantity to 1 box every 3 months or on request, with due consideration for [DVLA requirements for insulin treated diabetes and driving](#).

Please also note that the prescribing of adhesive remover wipes is not recommended, patients should be directed to use warm, soapy water to remove any remaining adhesive following removal of the sensor.

### **b. Insulin Pump Therapy**

Continuous subcutaneous insulin Infusions (CSII) makes use of an external pump that delivers insulin continuously from a refillable storage reservoir through a subcutaneously placed cannula. The pump can be programmed to deliver a basal rate of insulin throughout the day with higher infusion rates, as required, triggered by a push of a button at meal times. This may be a bolus or over a period of time and it can also deliver different basal rates. Pumps usually have a 4 year warranty and the cost for CSII will also include batteries, reservoirs, infusion sets and insulin on top of the pumps cost itself. The cost of monitoring glucose levels e.g. lancets, test strips and glucometers is common for all forms of insulin therapy and should follow the BNSSG Type 1 Diabetes Blood Glucose monitoring Guidance ([link](#))

Treatment with Insulin Pump therapy is covered by the NICE Technology Appraisal TA151 (adults and paediatrics) published in July 2008; Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus<sup>5</sup>.

The criteria set by NICE TA151 states that insulin pump therapy is recommended as a treatment option for all adults and children (12 years and older) provided that:

- Attempts to achieve target Haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia.

**Or**

- HbA1c levels have remained high (that is, at 69mmol/mol or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

CSII therapy is also 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 must be initiated only by a specialist team that have undertaken specialist training in insulin pump therapy and should comprise at least a physician with specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian (although other AHPs may also be included in the team). All patients will be assessed by the specialist team during a face to face appointment in secondary care. If the specialist multidisciplinary team agree that the criteria for a trial of a pump are fulfilled, the patient must undertake formal face to face structured education relating to pump therapy as well as advice on diet, lifestyle and exercise appropriate for people using pump therapy. They will also undergo a documented assessment in an insulin pump clinic. The choice of insulin pump for each patient will be determined by the insulin pump team taking into account a number of factors. Choice of pump in young children must take into account the ability to deliver a very low basal rate. All pump devices are purchased via Central Procurement.

There are a few cohorts of patients in which an insulin pump would be considered as initial technology providing they meet the NICE TA 151 inclusion criteria. These include:

- i. Where there is a need for varying and flexible basal profile (e.g. in problematic dawn phenomenon not manageable with injected basal insulins, professional sports or unpredictable lifestyle)
- ii. Where there is a need for frequent, small or complex boluses of insulin
- iii. Where there is a small total daily dose of insulin e.g. <20 units in 24 hours
- iv. In diabetes gastroparesis
- v. In professional sports players
- vi. Severe injections site problems not resolved with iPort
- vii. True insulin allergy
- viii. Painful diabetic neuropathy.

### **Review:**

All pump therapy should be reviewed on a regular basis as part of the multidisciplinary review, specifically against the initiation criteria and whether discontinuation of the pump would lead to recurrence of original symptoms/issues.

### **3 Transition from paediatrics to adults**

The ongoing use of all the technologies in people with type 1 diabetes aged 16 to 19 should be reviewed by the multidisciplinary specialist diabetes team at regular reviews, with a focus on outcomes including HbA1c, frequency and severity of hypoglycaemia, and quality of life. The most appropriate technology for these patients should be continued in line with the guidance and clinical judgement of their specialist clinical team.

## 4 Definitions/explanations of terms used

**Hypoglycaemia:** defined as Blood glucose level below 4mmol/L

**Disabling hypoglycaemia** – 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 (NICE TA151)

**BERTIE** – online Type 1 Diabetes Education Program developed by Royal Bournemouth Hospital

**Severe hypoglycaemia:** An episode of hypoglycaemia that cannot be managed by the patient with diabetes and requires third party assistance or hypoglycaemia causing impaired consciousness.

**Impaired awareness of hypoglycaemia:** Reduced awareness of the onset of hypoglycaemia. On the type 1 diabetes pre-consultation questionnaire hypo questions scored as blood/ sensor glucose usually below 3 when feels hypo **AND** Gold score 4-6.

**Longstanding impaired hypo awareness:** More than 3 months. **Recent onset:** Within 3 months.

**Complete loss of awareness of hypoglycaemia:** The person with diabetes has no symptoms nor awareness of hypoglycaemia and scores this as such on the type 1 diabetes pre-consultation questionnaire hypo question **AND** GOLD score of 7.

## 5. Audit and Monitoring of the Pathway

Yearly usage figures for all diabetes technologies and outcome data will be required to be provided to the CCG to enable a yearly review of this technology pathway. This will ensure that the pathway continues to meet the needs of the patient and the wider system and enable demonstration of the system wide savings through improved patient outcomes. Review of patient initiations against the criteria included in the pathway will also be reviewed.

All specialist clinical teams should submit data to the National Pump Audit in order that usage across BNSSG can be reviewed with the rest of England data.

For paediatric patients, data will be submitted to the National Pump Audit which will include the use of rtCGM and CSII.

## 6. References

1. Type 1 Diabetes Technology: A consensus Guideline – February 2019:  
<https://www.diabetes.org.uk/professionals/position-statements-reports/specialist-care-for-children-and-adults-and-complications/type-1-technology-guidelines>
2. Type 1 diabetes in Adults: diagnosis and management (NG17):  
<https://www.nice.org.uk/guidance/ng17>
3. Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NG18): <https://www.nice.org.uk/guidance/ng18>
4. Diabetes in pregnancy:management from preconception to the postnatal period (NG3)  
<https://www.nice.org.uk/guidance/ng3>
5. NICE TA 151 - Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus: <https://www.nice.org.uk/Guidance/TA151>

## **Appendix 1: Criteria for starting CGM**

1. Agreement on individualised goals for treatment and outcomes.
2. Education has been provided (online or in person)
3. Patient/Carer must agree to regular reviews with the local clinical team.
4. Previous attendance, or due consideration given to future attendance, at a Type 1 diabetes structured education programme (DAFNE or equivalent if available locally)



## **Appendix 2: Criteria for initiating Continuous subcutaneous Insulin infusion (taken from NICE TA151)**

### **Continuous subcutaneous insulin infusions to be considered for patients meeting the criteria below:**

1. Where attempts to achieve target Haemoglobin A1c (HbA1c) levels with multiple daily injections (MDIs) result in the person experiencing disabling hypoglycaemia.

**Or**

2. HbA1c levels have remained high (that is, at 69mmol/mol or above) on MDI therapy (including, if appropriate, the use of long-acting insulin analogues) despite a high level of care.

**Or**

3. In children younger than 12 years where MDI therapy is considered to be impractical or inappropriate.

Some specific circumstances where the use of CSII may be considered are:

- HbA1c >69mmol/mol despite all measures with injection therapy + FGM/CGM (as above)
- Recurrent troublesome hypoglycaemia not resolved with FGM or CGM
- Need variable basal profile e.g. dawn phenomenon
- Need for frequent, small or complex boluses
- Daily insulin dose < 20 units
- Pregnancy
- Diabetic gastroparesis
- Professional sports players