London Guidance: Recommended Commissioning Arrangements for CSII or Insulin Pumps in Adults with Type 1 Diabetes

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Prepared by: London Diabetes Clinical Network and NHS London Procurement Partnership

Summary

This guidance, developed by the London Diabetes Clinical Network and NHS London Procurement Partnership, provides recommended arrangements for the commissioning and provision of continuous subcutaneous insulin infusions (CSII) or insulin pumps in adults with type 1 diabetes.

1. Background

In 2016, NHS London Procurement Partnership (LPP) established a specialist stakeholder group to support the clinical aspects of a pan London procurement framework agreement for insulin pump and continuous glucose monitoring (CGM) devices. Prior framework agreements from across the country focused solely on insulin pumps and did not include the multiple CGM devices which are now widely available. LPP's work – along with other national events, such as changes to paediatric insulin pump commissioning in 2017 – has prompted London organisations to review best practice and their local arrangements.

An initial scoping exercise by LPP in 2017 showed that whilst a NICE Technology appraisal exists for insulin pump provision, the method by which this is implemented is not consistent. This may – and reports anecdotally suggests does – lead to variation in the services and devices provided.

Current barriers of provision

Current barriers to effective provision of insulin pumps and associated services across London include:

- Lack of formal arrangements for insulin pump provision
- Lack of fit for purpose documentation to ensure efficient and consistent provision of insulin pumps by services
- Some areas do not have "local" centres, meaning patients have to travel further to access this technology
- Inconsistent choice of brands provided across the region (mainly dependent on cost)

2. Recommendations for London

The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals. The NHS Constitution states that patients have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if their doctor believes they are clinically appropriate. TA151, *Continuous subcutaneous insulin infusion for the treatment of diabetes mellitus*, clearly states initiation criteria for insulin pumps.

The London Diabetes Clinical Network and NHS London Procurement Partnership suggest that all areas should review the arrangements for insulin pump provision in their area and consider how this is managed. Patients eligible as per the recommendations below should have access to local specialist services where they can discuss the appropriateness of these devices as part of their treatment plan.

2.1. 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.

2.2. 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.

For further information, please see the South East Coast and London Paediatric Diabetes Network's guidance.

2.3. It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.

2.4. Following initiation in adults and children 12 years and older, CSII therapy should only be continued if it results in a sustained improvement in glycaemic control, evidenced by a fall in HbA1c levels, or a sustained decrease in the rate of hypoglycaemic episodes. Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer.

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

2.6. Continuation parameters should be agreed on initiation and reviewed annually. These should include current and target values for:

- HbA1C level [mmol/mol]
- Number of hypoglycaemic episodes per week (average)
- Number of disabling hypoglycaemic episodes within last 12 months

Appropriate targets for such improvements should be set by the responsible physician, in discussion with the person receiving the treatment or their carer. An increase in HbA1C is

acceptable if there is an improvement in the number of hypoglycaemic episodes per week (average) and/ or number of disabling hypoglycaemic episodes within last 12 months, providing that HbA1C is within the target agreed between the responsible physician and the patient or their carer.

3. Suggested actions for commissioners and providers

3.1. Commissioners and providers should discuss current arrangements for insulin pump provision and provide a standardised route wherever possible.

3.2. Local agreement should be reached on which pumps will be commissioned.

3.3. The appropriate paperwork and pumps available should be understood and agreed (see section 6 for recommended forms).

3.4. Trust procurement teams should consult LPP for the pricing of devices as per their service requirements and ensure local choices are clearly stated.

For more information, please see LPP's *briefing on procurement arrangements*.

4. Where does this fit in with other regional guidance on the use of technologies in diabetes?

Some insulin pumps are "sensor-augmented", meaning the technology is presented in conjunction with the ability to continuously monitor interstitial glucose levels. London guidance referring to the use of CGM both in patients with type 1 diabetes using MDI and patients with type 1 diabetes who use an insulin pump should be referred to.

FreeStyle Libre® (flash glucose monitoring) is a form of intermittent glucose monitoring that measures glucose levels in the interstitial fluid. It has a number of indications outlined in the London implementation guidance and indication two most closely matches scenarios where insulin pumps and/or CGM are also considered: "Recommended implementation of FreeStyle Libre® prescribing for patients with type 1 diabetes with HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycaemia who would be eligible for insulin pump therapy as per TA151".

The members of the clinical networks discussed the place of FreeStyle Libre® in treatment pathways involving insulin pumps and CGM and considered where Libre® should feature. They noted the need to comply with TA151 and provide the option to all eligible patients and that the Libre® device is not a like-for-like alternative to pump therapy. Therefore, patients eligible under TA151 should always be considered for an insulin pump if this is the most appropriate choice for the individual patient. There may be some circumstances where the patient and clinician feel that Libre® should be trialled prior to pump therapy and the suggested pathway for Libre® allows for this. This guidance should be considered alongside all other guidance for the use of technology in diabetes (i.e. use of CGM and use of Libre®). Particular caution is advised for prescribing of Flash where there is impaired awareness of hypoglycaemia, a history of severe hypoglycaemia (defined as requiring the assistance of another person), or frequent asymptomatic episodes; in these cases the use of a device with warnings or alarms (real-time continuous glucose monitoring) is strongly advised. Each technology has its own merits and limitations, and the best choice should be decided by the

clinician and the patient in a face to face review of current diabetes care and treatment options. These devices are therefore not necessarily interchangeable and direct comparisons are not appropriate.

5. Additional information for commissioners and providers

List of devices available on the LPP procurement framework agreement. Please note that Insulet (Omnipod), Advanced Therapeutics (DANA R, DANA RS) and Tandem (t:slim X2) devices can be accessed via arrangements with NHS Scotland; all contacts for any pump (including these) should be with LPP who will facilitate any additional access agreements as needed. There is no additional cost to fully paid NHS LPP member trusts to access this framework agreement. The Animas pump from Johnson & Johnson has been discontinued and some suppliers are offering changeover deals in the innovative offers section of their bid.

Supplier	Lot 1 – Standalone insulin pumps and associated consumables	Lot 2 – Insulin pumps with integrated continuous glucose monitoring (CGM) and associated consumables
Cellnovo	Cellnovo	
Medtronic	Minimed 640G Paradigm Veo	Minimed 640G Paradigm Veo
Medtrum	A6 System	A6 System
Roche	Accu-Chek Insight Accu-Chek Combo	
Ypsomed	Ypsopump	

- For information on the use of CGM in integrated devices, please see the London commissioning guidance for CGM.
- Specialist Pharmacy Service (SPS) has a comparative table the various insulin pumps on the market.
- A best practice guide for adult diabetes services is available from the Association of British Clinical Diabetologists. Providers are advised to ensure they are able to provide all aspects covered by this guide, prior to initiating insulin pump clinics. This document should also be reviewed by existing centres to ensure that their services align with this document.

6. Templates

It is recommended that standardised forms are used between providers and commissioners (one for initiation and one for continuation). These help ensure that initiation is as per defined indications. Additionally, completed forms can provide useful information for future follow up and audits. Please find example forms below (adapted from South West London

Health and Care Partnership). These may be uploaded onto electronic systems (such as Blueteq) to provide ease of access and transfer. Please contact South West London Health and Care Partnership for appropriate versions of these.


Diabetes type 1-Insulin Pump 17_18 T


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It is recognised that not all areas implement such forms for insulin pump initiation and continuation. The use of these – or similar – is recommended in order to provide clear communication between providers and commissioners, with sufficient information to confirm compliance with this guidance for appropriate reimbursement (as locally agreed).