

Pathway for initiating Hybrid Closed Loop Insulin pumps for children and young people with Type 1 Diabetes in Frimley ICS

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| **Key Points**   * To provide clear guidance on the criteria for initiating hybrid closed loop insulin pump therapy. * To provide clear guidance on actions necessary at each stage of initiating insulin pump therapy * To provide clear guidance on what resources are required for a pump start. * Previous NICE guidelines TA151 * Current NICE guidelines for Hybrid Closed Loop TA943 * Cross site guidance |

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| **Version:** | 6 |
| **Date Issued:** |  |
| **Review Date:** | August 2025 |
| **Key words:** | Insulin Pump, hybrid closed loop |
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**Abbreviations**

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| HCL | Hybrid Closed Loop |
| HbA1c | Haemoglobin A1c |
| MDIs | multiple daily injections |
| MDT | Multiple Daily Injections |
| PDSN | Paediatric Diabetes Specialist Nurse |
| CYP | Child and Young Person |
| CGM | Continuous Glucose Monitor |
| PDM | Personal Medical Device |
| GP | General Practitioner |

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# Purpose

NICE issued a technology appraisal guideline in 2023, the TA943 (NICE, 2023) and it has a five-year implementation plan. The details of which are below:

# Insulin Pump Therapy

An insulin pump can mimic more closely the action of the pancreas than injection therapy and can give more flexibility to the user. An insulin pump is a battery operated, programmable device that is worn on the outside of your body. It delivers insulin through a soft cannula which sits just under the skin, typically around the stomach area.

# Continuous Glucose Monitor (CGM)

A continuous glucose monitor is a device used for monitoring blood glucose on a continual basis instead of monitoring glucose levels periodically by drawing a drop of blood from a finger.

**Hybrid Closed Loop** (HCL) systems deliver insulin automatically using a calculation based on CGM readings. The systems are designed to improve glycaemic control, reduce the mental burden of Type 1 Diabetes and improve people's quality of life. HCL systems use an algorithm to support automated delivery of insulin, in response to the linked continuous glucose monitor (CGM) readings, which monitors interstitial fluid glucose levels.

**NICE TA943** for HCL (December 2023) stipulated that:

*‘HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for children and young people. HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England and implemented following NHS England's implementation plan’.*

*‘Only use HCL systems with the support of a trained multidisciplinary team experienced in CSII and continuous glucose monitoring in type 1 diabetes’.*

*‘Only use HCL systems if the person or their carer:*

* *is able to use them, and*
* *is offered approved face-to-face or digital structured education programmes, or*
* *is competent in insulin dosing and adjustments’.*

[Overview | Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes | Guidance | NICE](https://www.nice.org.uk/guidance/ta943)

# Service Design

1. The person with type 1 diabetes should be seen in a Specialist Diabetes Service which includes:
   1. A defined type 1 diabetes lead, a multidisciplinary core comprising medical, specialist nursing and dietetic team members who are trained in and understand principles of flexible insulin therapy (i.e. carbohydrate counting, how to adjust insulin to carbohydrate ratios and how to adjust insulin sensitivity factors and basal insulin in response to glucose data).
   2. Experience and training in the use of diabetes technology.
   3. A regular multi-disciplinary team (MDT) meeting to review complex individual cases and review decisions around diabetes technology.
   4. Regular submission of data to the National Paediatric Diabetes Audit– so that on a national scale we can assess the effectiveness of pump therapy compared to MDI.
2. It is expected that the CYP with diabetes and their parent should:
   * 1. Be attending all their 3 monthly clinic appointments, including annual review, and engaging with the keyworker.
     2. Have completed their structured education goals sheet appropriate to their age and received individual self-management education adapted to suit their needs.
     3. Be motivated to self-manage to a safe and acceptable level (assessed via a member of the technologies MDT).
     4. Have a plan for weekly downloading and reviewing data.
     5. Have completed their yearly retinopathy screening (if over 12 years, or CYP already under ophthalmology for retinopathy) and have had the results discussed and agreed by their diabetes team and if necessary, ophthalmology/eye screening service (please refer to ‘Pathway for diabetic eye disease when starting HCL’).

# Management And Treatment

Key skills include:

1. Correct recommended frequency of monitoring glucose levels via CGM.
2. Best practice with bolusing before eating carbohydrate and using calculations that include carbohydrate counting, insulin: carbohydrate ratios and correction factors or a good level of carbohydrate awareness.
3. Be competent at using a bolus advisor app (e.g Mylife).
4. Understanding the impact of exercise, illness and alcohol and the principles of adjusting therapy in response to these.
5. Attendance of pre pump education which may need to be adapted to suit the individual’s needs.
6. Understanding the principles of how to adjust basal and/or bolus insulin in response to glucose patterns.

Throughout the process the PDSN should be liaising with the CYP and/or family to assess their knowledge and understanding. This ensures that all areas have been taught and tested and should ensure that the young person is competent and able to manage CSII.

Once the MDT is satisfied that the CYP with diabetes has achieved all the above, they should continue to progress through the pathway.

# Pump education:

The PDSN will organise the pump information education, which are usually held 2-3 times a year. The CYP and family will be invited to attend a virtual pump information session via teams and then a face-to-face pump fair will be organised 1 week afterwards. The PDSN will liaise with the pump representatives to organise this event. These sessions aim to provide families with an idea of what an insulin pump is and its differences from injections. During the pump fair the CYP and parent will be able to visit each pump representative for the opportunity to see a demo pump and ask any questions they may have. Following the completion of both sessions, the parent and/or CYP will be asked to inform the team within 2 weeks of their pump choice.

The dietitian will provide the CYP with a pre pump assessment via email. This will be sent out with the invitations for the 2 pump session invites, and we would require it to be completed and returned prior to the pump start. This will ensure that any area of weakness in knowledge is highlighted and an education session is organised, prior to the pump start date, to focus on these specific areas.

# Preparing for the pump start:

Once all the pump information session participants have informed the team of their pump choice, they will start to organise the pump starts with the relevant representatives. Pump starts may be held in a group session with CYP of the same age and learning capacity. It is expected that if the CYP is under 5 or has a high HbA1c, they may be asked to agree to an admission onto the Paediatric ward overnight for observation and support. The pump start may be virtual if it is an upgrade. The young person will receive a letter via email advising them of time, date, and running of the pump start day. They will also receive a GP letter so they can request any new medications, or consumables.

In preparation for the pump start we will ask CYP and their parents to confirm their current insulin doses. This will allow the team to use the pump settings calculator to determine insulin settings to be used for the pump.

If the CYP is unable to fund their own phone and it is a requirement for the HCL pump they have chosen, their keyworker will attempt to access funding for the phone via known charities.

The PDSN will order the pump and inform the family. This will be delivered to the CYP’s home address.

# Pump start Management:

The pump start will be conducted by a pump representative and a PDSN will also be available if required. The CYP and/or family should be asked to read and sign the CYP agreement. They should also be informed of the team’s expectations. The CYP and/or parent should bring their insulin and new pump with them to the pump start, as they will be shown how to set it up and start using it. The CYP and their family will familiarise themselves with the pump functions; they will set up their basal rates, carbohydrate ratios and insulin sensitivity factor, set out by their PDSN. The CYP and/or parent will be shown how to set up downloading or sharing of data to the cloud.

The PDSN will make sure that the emergency phone number is given and that the person holding the emergency phone knows who has attended the pump start. They will also provide the CYP and family with the relevant hypoglycaemia and hyperglycaemia guidelines including sick day rules and ABCC.

# Support following the pump start:

A PDSN will contact the CYP on the next working day to ensure they are managing well on the pump and have no issues. Changes to rates and settings should be made slowly and only when able to view downloads.

Arrangements should have been made for training to be carried out in school and a pump care plan should be provided.

The CYP and family will be expected to attend the advanced pump information session, 3 months following the pump start.

Following the advanced session, the team will use the ‘pump knowledge checklist’ to identify any areas requiring further training.

# PUMP PATHWAYS (Recommended DTN - Pump pathway)

**Assessment**

* Does the CYP have Type 1 Diabetes and using a basal bolus (MDI) insulin regimen?
* Is the CYP attending all their clinic appointments?
* Do they engage with the team and communicate appropriately?

**No**

**Yes**

**Skills assessment/review by PDSN**

Is the CYP:

* carbohydrate counting and using a bolus calculator (e.g. my life app)?
* Testing glucose appropriately and using a continuous glucose monitoring?
* Understands the impact of exercise, illness, and alcohol and applies the principles.
* Displays an understanding of how to adjust basal and/or bolus insulin in response to glucose patterns?
* Understands when and how to carry out ketone testing and interpret results using sick day rules.

**PDSN or Diabetologist to:**

* Explain that these are requirements to initiate insulin pump therapy safely.
* Set a goal for their next clinic appointment to reassess.

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**Yes**

**No**

**MDT Discussion**

Has the CYP been discussed at MDT and agreed that they are suitable and have met the education goals?

If they have a high HbA1c (69mmol/mol) has safety management been discussed?

Will they require an admission to the Paediatric ward?

**PDSN to:**

* Identify gaps in knowledge.
* Organise and deliver education.
* Assess knowledge and understanding

**Yes**

Progress to Insulin Pump Therapy

Pump fair and information session

# Flowchart for commencing Insulin Pump Therapy

CYP with Type 1 Diabetes meets criteria for HCL/upgrade.

Eligible pumps will be available to order from NHS Supply Chain.

CYP or parent to confirm DEVICE CHOICE with HCP

Mode of training and start date agreed and letter sent via email to CYP and/or parent.

GP letter sent to parent, CYP and GP.

Device ordered from company.

Face to face/Virtual training

CYP and parents to attend pump start with the pump Rep.

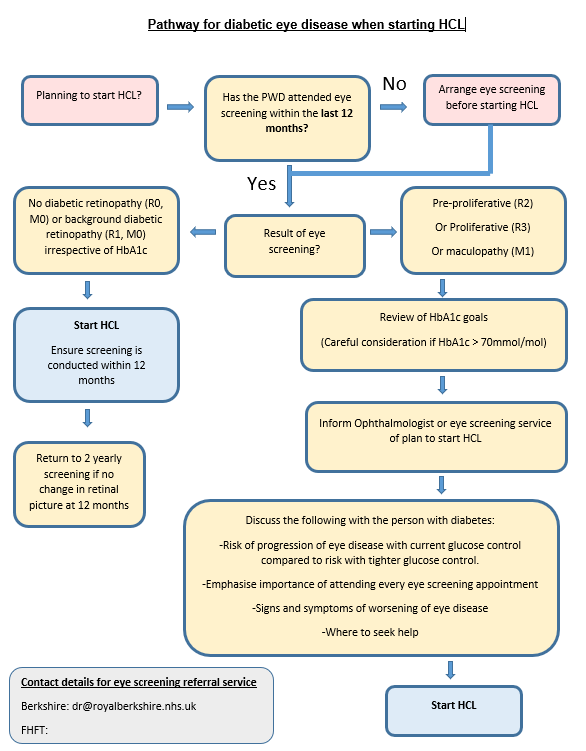
PDSN to support if required.

PDSN to deliver hypoglycaemia, sick day rules and ABCC advice.

PDSN to ensure the parent and CYP have all contact details including the emergency phone.

**Appointment: Follow Ups**

* Week 1: Review CYP on the next wroking day.
* Week 2: Review pump download and and advise on any additional pump features.
* Week 3: Review pump download and make adjustments.
* Every 1-2 weeks: CYP & parent to communicate with PDSN to review data and agree changes
* Week 12: Consultant pump follow up within 3 months.



Scanlon, P. and Karr, P. (2024)

# Reference

NICE (2023) *Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes.* TA943. Available at: [Hybrid close https://www.nice.org.uk/guidance/ta943/resources/hybrid-closed-loop-systems-for-managing-blood-glucose-levels-in-type-1-diabetes-pdf-82615666856389d loop systems for managing blood glucose levels in type 1 diabetes (nice.org.uk)](https://www.nice.org.uk/guidance/ta943/resources/hybrid-closed-loop-systems-for-managing-blood-glucose-levels-in-type-1-diabetes-pdf-82615666856389). (Accessed: 24th April 2024).

NICE (2023) *Diabetes (type 1 and type 2) in children and young people: diagnosis and management*. NG18. Available at: <https://www.nice.org.uk/guidance/ng18/resources/diabetes-type-1-and-type-2-in-children-and-young-people-diagnosis-and-management-pdf-1837278149317>. (Accessed: 24th April 2024).

Scanlon, P. and Karr, P. (2024) Diabetic eye disease and starting hybrid closed loop (HCL) systems. *NHS Diabetic Eye Screening Programme Board.* Available at: [HCL Considerations for Diabetic eye disease 2024 03 14 - The National Diabetes Programme - FutureNHS Collaboration Platform](https://future.nhs.uk/NationalDiabetesProgramme/view?objectId=201997957). (Accessed: 24th April 2024).

# Full version control record

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| --- | --- |
| **Version:** | 1.0 |
| **Guidelines Lead(s):** | Carolyn Hill, Lead Paediatric Diabetes Specialist Nurse |
| **Contributor(s):** |  |
| **Lead Director / Chief of Service:** | Dr Rekha Sanghavi |
| **Library check completed:** | TBC |
| **Ratified at:** | Paediatric Clinical Governance |
| **Date Issued:** |  |
| **Review Date:** | August 2025 |
| **Pharmaceutical dosing advice and formulary compliance checked by:** |  |
| **Key words:** | Insulin Pump, CSII |
| This guideline has been registered with the Trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt, contact a senior colleague or expert. Caution is advised when using guidelines after the review date.  This guideline is for use in Frimley Health NHS Foundation Trust hospitals only. Any use outside this location will not be supported by the Trust and will be at the risk of the individual using it. | |

**Version Control Sheet**

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| **Version** | **Date** | **Guideline Lead(s)** | **Status** | **Comment** |
| 5.0 | August 2022 |  | Final |  |
| 5.1 | August 2022 | Clinical Guidelines Administrator | Interim | Transferred to new Clinical Guidelines Template |
| 1.0 | June 2024 | Carolyn Hill, Lead Paediatric Diabetes Specialist Nurse | Final |  |

**Related Documents**

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| Document Type | **Document Name** |
| PIL Local | Sick Day Rule Pamphlet |
| PIL Local | ABCC SOP |
| PIL Local | Hypoglycaemia advice |
| PIL Local | CYP Agreement for Continuous Subcutaneous Insulin Therapy  (Pump Therapy) Insulet Omnipod |
| PIL Local | GP Letter |
| PIL Local | Pump knowledge Checklist |