NHS
Nottingham and Nottinghamshire

# Hybrid Closed Loop Technology for People Living with Type 1 Diabetes Mellitus - Commissioning Policy

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| Version No. | Description of Change | Author | Date |
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| 1.0 | New policy developed in response to the release of NICE Technology Appraisal TA943 published December 2023. | Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes | 12/06/2024 |
| 2.0 | Updated with implementation section | Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes | 08/01/2025 |
| 3.0 | Updated with priority cohorts | Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes | 24/04/2025 |
| 4.0 | Updated priority cohorts to reflect pumps due for renewal, added self-funding statement, added blood glucose monitoring testing strips statement | Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes | 14/07/2025 |
| 5.0 | Updated to improve clarity, consistency and governance, including refinement of eligibility criteria, prioritisation framework, MDT responsibilities, prescribing guidance, and inclusion of equality considerations. | Laura Stokes-Beresford, Senior Commissioning Manager for Diabetes | 15/04/2026 |

**Contributors/Reviewers:**

| Name | Last Date of Review | Versions Reviewed |
|---|---|---|
| Dr Rahul Mohan, GPwSI Diabetes, CDA Lead | April 2026 | 1.0,2.0,3.0,4.0,5.0 |
| Laura Catt, Prescribing Interface Advisor | April 2026 | 1.0,2.0,3.0,4.0.5.0 |
| Diabetes and Technology Task and Finish Group | April 2026 | 1.0,2.0,3.0,4.0,5.0 |
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| Nottingham and Nottinghamshire Area Prescribing Committee | April 2026 | 4.0, 5.0 |
| Medical Director, Nottingham and Nottinghamshire ICB | September 2025 | 4.0 |

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| | This document is part of a suite of policies that the ICB uses to drive its commissioning of healthcare. Each policy in that suite is a separate public document in its own right but will be applied with reference to other policies in that suite. |
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| **1** | **Policy Criteria** |
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| **1.1** | **Background** |
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| **1.1.1** | Hybrid closed loop (HCL) systems use a mathematical algorithm to deliver insulin automatically in response to continuously monitored interstitial fluid glucose levels. They use a combination of real-time glucose monitoring from a continuous glucose monitor (CGM) device and a control algorithm to direct insulin delivery through continuous subcutaneous insulin infusion (CSII). Different HCL systems are available, and some are built by combining interoperable components from different companies. |
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| **1.1.2** | The NHS Long Term Plan made a commitment for the NHS to ensure that: 'in line with clinical guidelines, patients with Type 1 diabetes benefit from life changing flash glucose monitors from April 2019, ending the variation patients in some parts of the country are facing. In addition, by 2020/21, all pregnant women with Type 1 diabetes will be offered CGM, helping to improve neonatal outcomes.' |
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| **1.1.3** | HCL technologies are the next phase of technical advancement linking CGM and insulin pump technology to provide people living with Type 1 diabetes with support 24 hours a day. Sometimes referred to as an 'artificial pancreas', HCL has led to high levels of interest in the technology from people living with Type 1 diabetes. These benefits include improved glycaemic outcomes, reduced treatment burden, and enhanced quality of life. |
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| **1.1.4** | NICE technology appraisal TA943 published 19 December 2023 recommends HCL systems as an option for managing blood glucose levels in Type 1 diabetes. |
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| **1.1.5** | This policy adopts NICE TA943 as the primary commissioning framework, with local interpretation applied to support safe, equitable, and phased implementation within system capacity |
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| **1.1.6** | The NICE technology appraisal TA943 was published with a 5-year implementation period to allow the NHS time to train and build specialist competencies within the clinical workforce, and to procure HCL technologies at cost-effective prices.<br><br>It is not possible to provide HCL in a shorter timeframe given the demand, management pressures and capacity constraints that diabetes services are currently experiencing. |
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| **1.1.7** | HCL must be initiated and overseen by specialist diabetes multi-disciplinary teams (MDTs) with demonstrable expertise in insulin pump therapy (CSII) and continuous glucose monitoring (CGM).<br><br>This ensures a holistic approach to care, enabling teams to assess psychological readiness, support self-management, and tailor interventions beyond HbA1c metrics. |
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| **1.1.8** | HCL systems should only be initiated where the person (or their carer):<br>• Is able and willing to use the system safely; and<br>• Has completed, or is actively undertaking, approved structured education; or<br>• Demonstrates competence in insulin dose adjustment and self-management. |
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| **1.1.9** | **Eligibility Criteria and Commissioning Position**<br><br>HCL systems are commissioned for the management of blood glucose levels for people living with Type 1 diabetes in Nottingham and Nottinghamshire.<br><br>Eligibility reflects NICE Technology Appraisal TA943 and is subject to clinical assessment and system capacity.<br><br>• **Adults**<br>Eligible if:<br>○ HbA1c ≥ 58 mmol/mol (7.5%) despite optimal therapy, or<br>○ Experiencing disabling hypoglycaemia<br>AND receiving at least one of the following:<br>○ CSII.<br>○ Real-time or intermittently scanned CGM.<br><br>• **Pregnancy**<br>Eligible if:<br>○ Pregnant or planning pregnancy<br>○ Includes women, trans men, and non-binary people with Type 1 diabetes<br><br>• **Children and Young People**<br>Eligible irrespective of HbA1c level. |
| **1.1.10** | **Initiation Pathway and Prioritisation**<br><br>To support equitable and phased implementation, the following prioritisation categories will apply in Nottingham and Nottinghamshire:<br><br>**Category 1 – High priority (Years 1 to 3)**<br>1. All children and young people <=18 years.<br>2. Pregnant individuals or those planning pregnancy within 12 months.<br>3. Young adult <25 years with HbA1c >58mmol/mol or disabling hypoglycaemia<br>4. Adults >25 years who:<br>○ Are on a pump with HbA1c >58mmol/mol or disabling hypoglycaemia |

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| | ○ Are on Multiple Daily Injections (MDI) with severe hypoglycaemia or persistently high time below range (TBR >10%)<br>○ Have active eye disease, CKD Stage 4-5, or neuropathic complications.<br>○ Had admissions with diabetic ketoacidosis (DKA) or severe hypoglycaemia in the past 12 months.<br>5. Individuals who are on a pump that is due for renewal and has HbA1c <58mmol/mol AND adding HCL is cost neutral.<br><br>**Category 2 – Medium Priority (Years 3-4)**<br>6. Adults on MDI with<br>○ Impaired hypoglycaemia awareness (Gold score 4-7).<br>○ HbA1c 69-86mmol/mol.<br>○ Planning pregnancy in the next 12-36 months.<br><br>**Category 3 – Standard Priority (Year 5)**<br>7. Adults on MDI with HbA1c >59mmol/mol.<br><br>**Additional Notes**<br>• Patients not meeting criteria may be placed on a holding list pending review or change in clinical status.<br>• Patients/family/carer must commit to sharing pump data with clinical teams.<br>• All patients must retain access to a blood glucose meter for device failure or ketone testing, in line with the Nottingham and Nottinghamshire preferred prescribing list for blood glucose meters.<br>• Prescribing of blood glucose test strips, insulin delivery devices, and associated consumables should be reviewed and adjusted following HCL initiation, in line with local prescribing guidance.<br>• Funding outside these criteria requires submission of an Individual Funding Request (IFR) with clinical justification to the ICB. |

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| **1.2** | **General Requirements**<br><br>Responsibility for ensuring compliance with these requirements lies with the initiating specialist diabetes service.<br><br>To ensure safe and effective use of HCL systems, the following general requirements apply:<br><br>**Structured Education**<br>All patients should be offered structured diabetes education prior to HCL initiation. This may include:<br>• Face-to-face programmes such as DAFNE or KAREN.<br>• Digital platforms such as MyWayHealth and Digibete.<br><br>**Pre-Initiation Preparation** |

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| | HCL-specific education is strongly encouraged before prescribing. As part of onboarding, patients should be supported to complete training in HCL system use. This may be delivered by the product manufacturer, subject to commercial agreements.<br><br>**Ongoing Support and Review**<br>Patients must agree to regular follow-up with their local clinical team. Reviews should assess:<br>• Device usage and adherence<br>• Clinical benefit and continued suitability<br>• Any concerns or barriers to effective use<br><br>**Shared Decision-Making**<br>Selection of the HCL system should be based on shared decision-making, considering the patient's preferences, lifestyle, and clinical needs.<br><br>**Non-Adherence and Support**<br>If a patient is not consistently using the device or is struggling with its operation, targeted support should be offered to improve engagement and outcomes**.**<br><br>**Trial Period and Continuation Criteria**<br>A formal clinical review should be undertaken following the initial trial period (as locally defined), assessing clinical benefit, engagement, and safe use.<br><br>**Withdrawal of Funding**<br>Continuation of NHS funding is dependent on ongoing clinical benefit, safe use, and engagement with follow-up. |
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| **1.3** | **Self-Funded Patients**<br>The ICB will not routinely commission the continuation of HCL therapy that was initiated privately—whether through self-funding, clinical trials, or treatment abroad.<br><br>However, exceptions may be considered where NHS-funded treatment would ordinarily be available under this policy. In such cases, the following conditions must be met:<br><br>• The patient must fully meet the eligibility criteria outlined in this policy; and<br>• There must be documented clinical benefit aligned with the eligibility criteria since the initiation of self-funded treatment. |
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| **1.4** | **Patients who are not eligible for treatment under this policy**<br>Patients who are not eligible for treatment under this policy may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.<br><br>Individual cases will be reviewed at the ICB's Individual Funding Request Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. |

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| | Applications cannot be considered from patients personally. |
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| **2** | **Scope and definitions** |
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| **2.1** | This policy is based on the ICBs' Statement of Principles for Commissioning of Healthcare (version in force on the date on which this policy is adopted). |
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| **2.2** | **Type 1 Diabetes and HCL**<br><br>Type 1 diabetes mellitus is a chronic autoimmune condition characterised by the destruction of insulin-producing beta cells in the pancreas. This results in an absolute deficiency of insulin and subsequent loss of blood glucose control.<br><br>Standard management involves regular monitoring of blood glucose levels, either through finger-prick testing or CGM, and administration of insulin via MDI or CSII. The primary goal of treatment is to maintain blood glucose levels within a healthy range to prevent both short- and long-term complications.<br><br>Living with Type 1 diabetes imposes a significant mental and emotional burden. Patients and their families must frequently interpret complex data and make real-time decisions about insulin dosing, which can be exhausting and lead to burnout.<br><br>HCL systems—sometimes referred to as an "artificial pancreas"—combine CGM and insulin pump technology with a control algorithm that automatically adjusts insulin delivery based on glucose readings. While manual input is still required for meals and physical activity, HCL systems reduce the cognitive load and improve glycaemic control.<br><br>Clinical trials and real-world evidence demonstrate that HCL systems outperform standard care in maintaining glucose levels within target range. Benefits include improved HbA1c, increased time in range, and reduced incidence of hypoglycaemia. These systems are particularly cost-effective for:<br>• Adults with HbA1c ≥ 58 mmol/mol or disabling hypoglycaemia<br>• Children and young people, regardless of HbA1c level<br>• Pregnant individuals, including women, trans men, and non-binary people, due to the increased complexity of glucose management during pregnancy |
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| **2.3** | The scope of this policy does not include the provision of HCL systems for adults and children who do not have a confirmed diagnosis of Type 1 diabetes mellitus or any other aspects of the management of Type 1 diabetes mellitus. |
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| **2.4** | Terms and abbreviations used in this policy are explained and defined in Appendix 1. Throughout this policy any term is used with the meaning described in that appendix. |
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| **3** | **Appropriate Healthcare** |

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| **3.1** | The primary aim of HCL systems is to reduce variability in blood glucose levels and improve overall glycaemic control. These systems enable patients to respond more rapidly to fluctuations in glucose levels than traditional finger-prick testing, thanks to continuous monitoring and automated insulin delivery.<br><br>By maintaining glucose levels within the target range more consistently, HCL systems help to minimise the risk of short-term complications such as hypoglycaemia and life-threatening emergencies like DKA. This enhanced control supports safer day-to-day management and contributes to improved long-term health outcomes for individuals living with Type 1 diabetes. |
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| **4** | **Effective Healthcare** |
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| **4.1** | The ICB acknowledges the clinical effectiveness of HCL systems and therefore does not rely on the Principle of Effectiveness to determine commissioning decisions under this policy.<br><br>However, in cases where a patient is considered exceptional in relation to the principles underpinning this policy, the ICB may assess whether the intended clinical outcomes of HCL therapy are likely to be achieved without undue adverse effects before confirming funding approval. |
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| **5** | **Cost Effectiveness** |
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| **5.1** | This policy is underpinned by the Principle of Cost-Effectiveness.<br><br>To determine when HCL systems are considered cost-effective, the ICB has drawn upon guidance from NHS England (NHSE) and NICE Technology Appraisal TA943. This guidance applies to adults, children and young people, and pregnant individuals—including women, trans men, and non-binary people—with Type 1 diabetes mellitus.<br><br>HCL systems will only be commissioned if:<br>• They are procured at a cost-effective price agreed between suppliers and NHS England; and<br>• Their implementation follows the national strategy outlined in NHS England's 5-year implementation plan<br><br>All HCL technology must be sourced via the NHS Supply Chain under the national framework agreement. Pre-existing commercial arrangements outside this framework will not be supported.<br><br>Procurement and supply arrangements must comply with NHS England national frameworks and local governance processes. |
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| **6** | **Equality and Inclusion** |

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| **6.1** | This policy has been developed with regard to the need to reduce health inequalities and ensure equitable access to HCL technologies. Implementation will be monitored to ensure fair access across all population groups. |
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| **7** | **Ethics** |
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| **7.1** | The ICB does not question the ethical basis of HCL technology and therefore this policy does not rely on the Principle of Ethics to determine commissioning decisions.<br><br>However, in cases where a patient is considered exceptional in relation to the principles underpinning this policy, the ICB may assess whether the proposed treatment raises any ethical concerns before confirming funding approval. |
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| **8** | **Affordability** |
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| **8.1** | The ICB does not dispute the affordability of HCL technology and therefore this policy does not rely on the Principle of Affordability to determine commissioning decisions.<br><br>However, in cases where a patient is considered exceptional in relation to the principles underpinning this policy, the ICB may assess whether the proposed treatment is financially viable before confirming funding approval. |
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| **9** | **Exceptions** |
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| **9.1** | The ICB will consider exceptions to this policy in accordance with the Policy for Considering Applications for Exceptionality to Commissioning Policies. |
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| **9.2** | In the event of inconsistency, this policy will take precedence over any nonmandatory NICE guidelines in driving decisions of this ICB. A circumstance in which a patient satisfies NICE guidelines but does not satisfy the criteria in this policy does not amount to exceptionality. |
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| **10** | **Force** |
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| **10.1** | This policy will remain in effect until it is formally replaced by an updated version or superseded by mandatory NICE guidance relating to HCL systems or alternative treatments for Type 1 diabetes mellitus. |
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| **10.2** | If NICE guidance referenced in this policy is subsequently updated or replaced:<br><br>• Where the new NICE guidance has mandatory status, it will automatically supersede this policy from the date it becomes mandatory.<br><br>• Where the new NICE guidance is non-mandatory, the ICB will aim to review and revise this policy accordingly. Until such a revision is formally adopted, this policy will remain in force, and references to NICE guidance will continue to apply as originally stated. |
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| **11** | **References** |
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| | • National Institute for Health and Care Excellence (NICE). Technology Appraisal 943: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes. Published 20 December 2023. Available at https://www.nice.org.uk/guidance/ta943<br>• National Institute for Health and Care Excellence (NICE): Diabetes (type 1 and type 2) in children and young people: diagnosis and management (NG18) (2015; last updated 2023). Available at: https://www.nice.org.uk/guidance/NG18<br>• NHS England. Hybrid closed loop technologies: 5-year implementation strategy. Published 22 January 2024.<br>• NHS. The NHS Long Term Plan. Published 2019. Available at: https://www.longtermplan.nhs.uk |

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| **12** | **Appendix 1 – Terms and abbreviations** |
| | CKD - Chronic Kidney Disease.<br><br>ICB – Integrated Care Board.<br><br>NICE – National Institute for Health and Care Excellence.<br><br>NHSE – NHS England.<br><br>Diabetes mellitus – As defined by the World Health Organisation 2006 plasma glucose criteria (fasting plasma glucose ≥ 7.0mmol/l (126mg/dl) or 2–h plasma glucose ≥ 11.1mmol/l (200mg/dl).<br><br>DKA – Diabetic ketoacidosis.<br><br>Euglycemia – Normal concentration of glucose in the blood within an optimal range of 90–130 mg/dl (5.0 to 7.2 mmol/l).<br><br>HbA1c - Glycated haemoglobin measured using methods that have been calibrated according to International Federation of Clinical Chemistry (IFCC) standardisation. |

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| | TA943– NICE technology appraisal guideline 943 Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes.<br><br>Adult – A person over the age of 18 years.<br><br>Children and young people – People under the age of 18 years as defined by NG18. Children may be defined as people under the age of 12 years and young people defined as people between the ages of 12 and 18 years. (However, the separate definitions for children and young people are not stated in NG18 or TA151).<br><br>DAFNE – Dose Adjustment for Normal Eating (regimen for patient self-management).<br><br>Digibete – a video platform and app designed to support young people's diabetes management.<br><br>Disabling hypoglycaemia – 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.<br><br>Severe hypoglycaemia – an episode of low blood glucose levels that requires assistance from another person to treat (i.e., a person unable to swallow, convulsing or unconscious).<br><br>KAREN – Kings Mill's Adjustment for Eating Normally (regimen for patient self-management).<br><br>Continuous Glucose Monitoring – measure interstitial fluid glucose levels and automatically transmit readings to a receiver every minute if using a smartphone, or when scanned if using a reader.<br><br>Continuous subcutaneous insulin infusion (CSII) - a mode of delivering intensive insulin therapy, which usually leads to improved glucose control and reduced hypoglycaemia.<br><br>MDI – Multiple daily injections.<br><br>MyWayHealth – an online platform designed to support adults with diabetes management. |
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