

## Commissioning Policy

### Hybrid Closed Loop Technology

### Criteria Based Access Policy (CBA)

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## Authorisation and document control

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<b>Job title of author:</b>	Senior Programme Manager Clinical Programmes Diabetes – Corinne Robinson
<b>Name of sign off group:</b>	Commissioning Policy Review Group

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## 1.0 Background

The integrated care board will provide funding for hybrid closed loop technology for patients who meet the criteria defined within this policy in line with a 5-year implementation plan as set out by NHSE and in line with NICE TA policy 943.

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.

The NHS Long Term Plan (1) made a commitment for the NHS to ensure that: 'in line with clinical guidelines (2), 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 continuous glucose monitoring (CGM), helping to improve neonatal outcomes.' Hybrid closed loop (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. This is because the benefits of HCL, including the potential to reduce mental burden and improve quality of life, are well-known (3). The NICE technology appraisal (TA) 943 was published in December 2023 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. 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.

This commissioning policy has been produced to provide and ensure equity, consistency and clarity relating to the use of hybrid closed loop systems within the Gloucestershire integrated care system. Threshold procedures and therapies are those in which a clinical threshold has been set which needs to be met before funding will be made available for treatment.

## 2.0 Policy statement

### Policy details

#### Indication

Managing blood glucose levels in Type 1 diabetes in adults, children, and young people.

#### Eligibility Criteria/ Commissioning position

The eligibility for funding of HCL systems for the management of blood glucose levels in people with Type 1 diabetes within Gloucestershire is in line with the recommendations of NICE TA 943 and is as follows:

**Adults** who meet the following criteria:

- HbA1c of 58 mmol/mol (7.5%) or more, or
- Have disabling hypoglycaemia, despite best possible management with at least 1 of the following:
  - Continuous subcutaneous intensive insulin therapy (CSII)
  - Real-time Continuous Glucose Monitoring (CGM) or intermittently scanned CGM.

### **Pregnancy/Planned Pregnancy**

- All women, trans men and non-binary people who are pregnant or planning to become pregnant.

### **Children and Young People**

- All children and young people with a diagnosis of Type 1 diabetes.

### **Current Self-Funders**

- Patients who have obtained an HCL systems through clinical trials; private treatment; or who have been self-funding and are now seeking NHS supply, will be required to demonstrate that they:
  - Satisfied the eligibility criteria **and**
  - Have shown improvement in one or more of the eligibility criteria since self-fundingHCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England. Gloucestershire will develop a preferred prescribing list for HCL systems selected from the NHSE procurement list.

### **Other requirements**

Patients with diabetes are central in developing and agreeing their personalised care and support plan including deciding who is involved in the process. They should be supported to have proactive, personalised conversations which focus on what matters to them, paying attention to their diabetes needs and wider health and wellbeing. If a decision is made to proceed with HCL prescribing, then the patient/family/carer must meet the following requirements to qualify for HCL:

- can use the HCL systems and demonstrate technology competence.
- have attended approved face-to-face or digital structured education programmes or
- are competent in insulin dosing and adjustments.
- demonstrate a commitment to engaging with ongoing clinical reviews.
- commitment to share pump data with clinical teams.

### **Prioritisation**

Implementation for adults and children/young people will be phased over a 5-year period in line with NICE and according to the locally agreed clinical prioritisation. The prioritisation list is detailed below in order of priority.

Where significant complications of diabetes, e.g. severe/progressive retinopathy or neuropathy are present, and the clinical team feel immediate optimisation of HbA1c will delay/prevent further progression of these complications, following multi-disciplinary team discussion, a clinical decision can be made for these patients to commence HCL outside of strict HbA1c prioritisation order.

### **Adults**

Priority Number	Priority
1	Pregnancy
1	Already on an insulin pump and HbA1c $\geq$ 58mmol/mol
1	Severe Hypoglycaemia
1	Hypoglycaemia unawareness (e.g. unable to drive)
1	Planning pregnancy
2	HbA1c >86mmol/mol
3	HbA1c 75-85mmol/mol

4	HbA1c 64-74mmol/mol
5	HbA1c 58-63mmol/mol

## Childrens and Young People

Priority Number	Priority
1	Already on an insulin pump and HbA1c >58mmol/mol
1	All under 5 years
1	Already on an insulin pump and HbA1c <58mmol/mol
2	Children: based on clinical assessment of with consideration of social/psychological/additional needs including ethnicity and deprivation to reduce health inequalities'

## Initiation

Initiation will be undertaken by the diabetes multidisciplinary team who are trained and experienced in using HCL systems in type 1 diabetes.

When considering/choosing the HCL system clinical teams will adopt the following principles:

1. Ensure a shared decision-making approach to identify the person's needs and preferences.
2. Select the choice of HCL system **only** from the Gloucestershire Procurement Framework preferred prescribing list.
3. Will offer the device with the lowest cost to meet needs.

The supply of the insulin pump, consumables and CGM will be provided by secondary care. However, if the CGM is on formulary for prescribing in primary care then the CGM can be issued by primary care. The other essential diabetes related supplies will need to be prescribed within primary care including the rapid acting insulin vial for use in the pump, insulin cartridges/pens (both long and rapid acting) which may be required in the event of pump failure, and insulin needles.

Patients will still require a meter to test capillary blood glucose in the event of CGM device failure, and to test ketones if clinically indicated. A meter should be provided to the patient in line with the Gloucestershire preferred prescribing list for blood glucose meters.

It is expected that the frequency of using blood glucose monitoring using test strips, insulin cartridges/pens, and subsequent quantities prescribed, will significantly reduce. Prescriptions should be adjusted accordingly on initiation of HCL systems and reviewed regularly.

For patients who **DO NOT** meet the eligibility criteria or should the device of choice not be available on the procurement framework the ICB will only consider funding the treatment if an Individual Funding Request (IFR) is submitted via the ICB IFR process detailing the patient's clinical presentation.

## Review

Patients who meet the criteria for HCL systems should initially have it prescribed for a 6-month period, during which time data should be collected on the indicators below:

1. Commitment to consistent wearing of insulin pump, sensor and regular data uploads
2. Reductions in severe/non-severe hypoglycaemia
3. Changes in HbA1c
4. Quality of Life changes using validated rating scales

A review should take place with the responsible clinician at the end of the initial trial period. The use of HCL systems should be continued if the patient is likely to continue to benefit from ongoing HCL system use, and support should be offered to improve use of their HCL system if this is required.

### **Deprescribing**

NHS funding for HCL systems will be withdrawn if the patient fails to meet the policy criteria and patients, family and carers should be made aware of this at initiation. It is the responsibility of responsible clinician to inform the patient's Primary Care clinician if HCL system is to be withdrawn at any time.

At the clinical review consideration will be given to the following.

- is the HCL system being used effectively (consistent wearing of the device, insulin dosing and adjustments)
- has the individual/family/carer engaged in structured education.
- has the individual/family/carer demonstrated a commitment to engaging with ongoing clinical reviews.

If the patient/family/carer does not meet the requirements HCL may be deprescribed.

Patients who are pregnant or are planning a pregnancy will have funding for the HCL system for up to 4 years. After the 4 years the patient will need to be assessed, and the HCL prescribing will be considered in relation to the eligibility criteria as stated above.

### **3.0 Patients who are not eligible for treatment under this policy.**

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.

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. Applications cannot be considered from patients personally.

### **4.0 Connected policies**

None

### **5.0 References**

National Health Service (NHS): The NHS long term plan (2019). Available at:

<https://www.longtermplan.nhs.uk/>

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>

NHS England Hybrid Closed Loop technologies: 5-year implementation strategy. Publication reference: PRN01097

National Institute for Health and Care Excellence (NICE): Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes (TA943) 19th December 2023. Available at

<https://www.nice.org.uk/guidance/ta943/resources/hybrid-closed-loop-systems-for-managing-blood-glucose-levels-in-type-1-diabetes-pdf-82615666856389>

**Plain English Summary:**

Hybrid closed loop (HCL) systems link two wearable devices a continuous glucose monitoring (CGM) with insulin pump technology to monitor blood glucose and automatically adjust the amount of insulin given through a pump to people living with type 1 diabetes. This allows people living with diabetes to better manage their condition.

The National Institute for Health and Care Excellence (NICE) has recommended that patients should be able to access hybrid closed loop technology through the NHS in certain circumstances. This policy confirms that Gloucestershire patients can access NHS funded diabetes technology devices in line with the NICE.