Surrey Heartlands Integrated Care System
Area Prescribing Committee (APC)

Integrated Care Partnership - Surrey Downs, Guildford & Waverley, North-West Surrey, and East Surrey Places & associated partner organisations.

NICE Technology Appraisals (TA) briefing paper for local implementation

NICE TA Guidance name and number	Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes (NICE TA943)		
Available at	https://www.nice.org.uk/guidance/ta943		
Date of issue	19 December 2023	**Implementation deadline**	The normal period of compliance has been extended to 5 years for this technology because NHS England submitted a funding variation request, which was accepted by NICE after a period of public consultation

Medicine details[1]	
Name and brand name	Hybrid Closed Loop (HCL) Systems

Available devices	NHS England in partnership with NHS Supply chain, have concluded their negotiations with industry and a range of cost effective HCLs have been agreed as follows:
	• **CamAPS FX hybrid closed loop uses** a
	  ○ DANA I insulin pump and Dexcom 6 CGM, or an
	  ○ Ypsopump insulin pump and Dexcom 6 or FreeStyle Libre 3 CGM
	• **Medtronic 780G plus Guardian 4 sensors hybrid closed loop uses** a
	  ○ Medtronic insulin pump and Guardian 4 sensors.
	• **Control IQ hybrid closed loop uses a**
	  ○ Tandem t:slim insulin pump and Dexcom G6 or G7 CGM. Licenced for those aged 4+
	• **Omnipod 5 tubeless (patch) system uses an**
	  ○ Omnipod 5 controller (PDM) with a pre-loaded app and pods plus Dexcom 6 or FreeStyle Libre 2 plus CGM
	• **Medtrum A8 Touch Care Nano (patch) system uses a**
	  ○ Medtrum Touch Care Nano insulin pump, CGM (TouchCare Nano) & the Medtrum APGO algorithm
	These are the current available Hybrid Closed Loop systems on the framework. Any additions/alterations to the framework can be noted through APC and updates made. HCLs not on the framework will not be automatically funded and will need to be considered by the Area Prescribing Committee prior to use.

NICE TA recommendations[2]

1. **Recommendations**

1.1. Hybrid closed loop (HCL) systems are recommended as an option for managing blood glucose levels in type 1 diabetes for adults who have an 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 insulin infusion (CSII)
- real-time continuous glucose monitoring
- intermittently scanned continuous glucose monitoring.

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.

1.2. 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.

1.3. HCL systems are recommended as an option for managing blood glucose levels in type 1 diabetes for women, trans men and non-binary people who are pregnant or planning to become pregnant. 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.

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

1.5. 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.

1.6. These recommendations are not intended to affect use of HCL systems that was started in the NHS before this guidance was published. People using HCL systems outside these recommendations may continue until they and their NHS clinician consider it appropriate to stop. For children and young people, this decision should be made jointly by them, their clinician and their parents or carers.

Why the committee made these recommendations.

Standard care for type 1 diabetes involves regularly measuring blood glucose levels by self-monitoring (blood testing) or by using a continuous glucose monitor (real-time or intermittently scanned). Blood glucose levels are managed with multiple daily insulin injections or by using a pump to inject insulin under the skin (CSII). The aim of treatment is to decrease blood glucose levels and keep them within a healthy range.

Continuously managing blood glucose levels is a substantial mental burden for people with type 1 diabetes and their families or carers. HCL systems deliver insulin automatically using a calculation based on continuous glucose measurements. The systems do not need as much input from the person, but manual insulin dosing is still needed sometimes, for example, around mealtimes. So, they may reduce the mental burden and improve people's quality of life.

Clinical trial and real-world evidence shows that HCL systems are more effective than standard care at maintaining blood glucose levels within a healthy range.

There is uncertainty in the economic model, so the systems need to be procured at a cost-

effective price agreed by the companies who manufacture HCL systems and NHS England. This will mean the HCL systems are likely to be cost effective for adults who have an HbA1c level of 58 mmol/mol (7.5%) or more or have disabling hypoglycaemia (when hypoglycaemia occurs frequently or without warning, so the person is constantly anxious about having hypoglycaemic episodes). So, HCL systems are recommended for these people. HCL systems are likely to be more cost effective for children and young people than adults, so they are also recommended for children and young people irrespective of their HbA1c level. And because blood glucose levels are harder to manage in pregnancy, they are also recommended for women, trans men and non-binary people with type 1 diabetes who are pregnant or planning to become pregnant.

Comparison to NICE TA151 (2008) Continuous subcutaneous insulin infusion (CSII or insulin pump).

This NICE guidance will still be applicable for those patients that are NOT using a Hybrid Closed Loop System.

Insulin pumps are recommended in patients (12 years and older) with type I diabetes with

- Disabling hypoglycaemia or high HbA1c of 8.5% or above on MDI therapy

Insulin pumps are recommended in children under 12 with type I diabetes where:

- MDI therapy is considered to be impractical or inappropriate and
- There is a trial of MDI therapy between the ages of 12 and 18 years.

Lead author comments:

It is unknown how many patients would fall between a HbA1c of 7.5% and 8.5% and this has been difficult to quantify.

NICE TA943 recommends all children and young people use a hybrid closed loop system, where previously a young person over the age of 12 would need to have disabling hypoglycaemia or a high HbA1C of 8.5% or above.

All type I diabetes patients now have access to CGM in line with NICE NG17 & 18 and so many patients will already be closed looping using the pumps and CGMs that are already routinely funded.

Decision making framework (DMF)
National guidance and priorities
The ICS has a legal obligation to commission this medicine in line with the NICE TA. • The normal period of compliance has been extended to 5 years for this technology because NHS England submitted a funding variation request, which was accepted by NICE after a period of public consultation
Clinical effectiveness
• Clinical trial and real-world evidence shows that HCL systems are more effective than standard care at maintaining blood glucose levels within a healthy range. • Surrey Heartlands ICB are awaiting the financial framework to understand the phased funding for this technology and as soon as this is received the Hybrid Closed Loop Steering Group which is represented by diabetes teams from each local acute trust will work through the implementation of the Hybrid Closed Loop Systems.
Patient safety
• If glucose alerts and CGM readings do not match the patient's symptoms, a blood glucose meter should be used to make diabetes treatment decisions.

- Test blood glucose more frequently to account for changes in activity levels and mealtimes.
- Hybrid Closed Loop systems have limited evidence for use in pregnancy, but are recommended by NICE

Patient factors

- Patients will be required to attend liaise with their Diabetes team and attend clinic appointments as required.
- Patient should be committed to using the insulin pump safely and effectively to improve glycaemic control.
- The manufacturers pump warranty covers and includes replacement for mechanical failure but not for damage due to neglect or loss.
- Consideration should be given by the patient to insuring the pump for loss or damage (e.g. household insurance)
- After the initial HCL set up, the patient will be required to contact multiple manufacturers to obtain further supplies of consumables (Infusors, reservoirs, pods, CGM consumables etc). The patient should be provided with the URN (provided by NHS supplies) so that this can be quoted when ordering (this is to ensure that the appropriate discounts are applied to the patient's order)
- www.diabetes.org :As the amount of insulin given is calculated more precisely and given more often, this can help keep blood sugar levels more stable. As a result, this can increase the amount of time you will spend in your target blood sugar range. This can reduce hypos and lower your HbA1c and risk of diabetes complications.
- Research shows the benefits brought by closed loop systems can help give people with type 1 diabetes and people caring for them a better quality of life.

Warranties on insulin pumps

- Note that the tethered pumps (using giving sets) have a 4 year warranty and the ICB will not fund a new pump outside of warranty unless there is a clinical need to do so (safety concern or patient unable to control blood sugars on current HCL)
- The patch pumps do not have the initial outlay for the insulin pump and so there is a not a 4 year warranty unlike the tethered insulin pumps.

Environmental impact

- Additional packaging will be generated and will be an environmental impact with regards to waste management. (Medical waste)
- Deliveries of ongoing consumables – patients' home (additional carbon – increase air pollution)
- Sharps waste requires safe collection and disposal

Equality & diversity

Disability

Patients with impaired vision or hearing: the patient may not be able to see or hear the alarms, alerts or pump signals without carer support.

Being pregnant or on maternity leave

Limited evidence for use in pregnant patients but recommended by NICE TA943

Place in therapy relative to available treatments

The following insulin pumps have the technology to close loop with Continuous Glucose Monitoring (CGM) and they are already routinely funded by NHS Surrey Heartlands and are likely to be used as such in a proportion of patients that meet the criteria in NICE TA 151 (2008) for both an insulin pump and CGM. These pumps are also able to be used as stand-alone insulin pumps.

- Medtronic 780g insulin Pump (Medtronic) – Implicitly funded in September 2021 (tethered)
- T-Slim insulin Pump (Air Liquide Healthcare Ltd) – Free App available for closed looping – Explicitly funded in January 2021 by the APC (tethered)

CamAPS FX as part of a hybrid closed loop system.
Recommended by NICE as part of a closed loop system but the algorithm (CamAPS FX), to enable looping, has not been considered to date.
This algorithm links with the Ypsopump insulin pump (Ypsomed Ltd) (tethered) & Dana I (Advanced Therapeutics (UK) Ltd) and CGM as part of a closed loop system. These pumps and CGM are already funded by Surrey Heartlands for patients that meet the previous NICE TA 151 guidance.

Medtrum A8 Touchcare HCL system
Recommended by NICE as part of a closed loop system but the algorithm (Medtrun APGO), to enable looping, has not been considered to date.
This algorithm links with the Medtrum A8 Touchcare Nano Insulin pump and Touch care Nano CGM as part of closed loop system. This insulin pumps is already funded by Surrey Heartlands for patients that meet the previous NICE TA 151 guidance.

This CGM to enable looping with this system is not currently routinely funded because the Medtrum A8 Touchcare Nano CGM was given a traffic light status of NON-FORMULARY in April 2023 for the following reasons

- Has accuracy concerns
- There is no publicly available data in children
- Requires calibration

The APC will be asked for a change in traffic light status for this CGM to enable this pump, CGM and algorithm to be used as a HCL as recommended by NICE TA943

Note that the Medtrum APGO algorithm is Free of Charge and will link with the Medtrum A8 Touchcare Nano (patch) pump (Medtrum Ltd) and the Medtrum A8 Touchcare Nano CGM as a Hybrid Closed Loop System.

Phased approach to implementation:
NHS England have published (January 24) a 5-year implementation strategy and the APC considered the recommendations for implementation of this NICE TA in March 24. NHS England 5 year implementation strategy.
The Hybrid Closed Loop Steering group will work together to implement this NICE guidance ensuring that the patients with the highest clinical need are provided with this technology in a phased approach.

Stakeholder views

The paper was sent out for consultation and comments are listed on the front sheet. Comments to be included in the front sheet.

Cost-effectiveness

- There is uncertainty in the economic model, so the systems need to be procured at a cost-effective price agreed by the companies who manufacture HCL systems and NHS England.
- This will mean the HCL systems are likely to be cost effective for adults who have an HbA1c level of 58 mmol/mol (7.5%) or more or have disabling hypoglycaemia (when hypoglycaemia occurs frequently or without warning, so the person is constantly anxious about having hypoglycaemic episodes). So, HCL systems are recommended for these people.
- HCL systems are likely to be more cost effective for children and young people than adults, so they are also recommended for children and young people irrespective of their HbA1c level. And because blood glucose levels are harder to manage in pregnancy, they are also recommended for women, trans men and non-binary people with type 1 diabetes who are pregnant or planning to become pregnant.

Cost Impact of Hybrid Closed Loop Implementation

The costs of Hybrid Closed Loop Systems above have been considered to be cost effective by NHS England in partnership with NHS Supply chain, who have concluded their negotiations with industry and a range of cost effective HCLs have been agreed as follows:

- **CamAPS FX hybrid closed loop uses** a
  - DANA I insulin pump and Dexcom 6 CGM, or an
  - Ypsomed insulin pump and Dexcom 6 or FreeStyle Libre 3 CGM
- **Medtronic 780G plus Guardian 4 sensors hybrid closed loop uses** a
  - Medtronic insulin pump and Guardian 4 sensors.
- **Control IQ hybrid closed loop uses a**
  - Tandem t:slim insulin pump and Dexcom G6 or G7 CGM. Licenced for those aged 4+
- **Omnipod 5 tubeless (patch) system uses an**
  - Omnipod 5 controller (PDM) with a pre-loaded app and pods plus Dexcom 6 or FreeStyle Libre 2 plus CGM
- **Medtrum A8 Touch Care Nano (patch) system uses a**
  - Medtrum Touch Care Nano insulin pump, CGM (TouchCare Nano) & the Medtrum APGO algorithm

Surrey Heartlands ICB are awaiting the financial framework to understand the phased funding for this technology and as soon as this is received the Hybrid Closed Loop Steering Group which is represented by diabetes teams from each local acute trust will work through the implementation of the Hybrid Closed Loop Systems.

A paper may need to be considered by CCC due to the estimated financial impact of implementing this TA when the financial framework is released.

The Surrey Heartlands Director of Pharmacy has delegated authority to enable the Committee to be a decision-making committee providing the impact of any single decision does not exceed £100,000 within an individual Place per annum. Decisions with a cost impact of over £100,000 within an individual Place per annum require authorisation from Surrey Heartlands Commissioning, Contracting and Commercial sub-committee (CCC) at their next available meeting.

Traffic light status

NHS Payment Scheme (NHSPS) excluded high-cost drug: see NHS England » 2023-25 NHS Payment Scheme
Yes

Recommended traffic light status and rationale:
e.g., **RED Traffic Light Status:**

- **CamAPS FX hybrid closed loop uses** a
  - DANA I insulin pump and Dexcom 6 CGM, or an
  - Ypsomed insulin pump and Dexcom 6 or FreeStyle Libre 3 CGM
- **Medtronic 780G plus Guardian 4 sensors hybrid closed loop uses** a
  - Medtronic insulin pump and Guardian 4 sensors.
- **Control IQ hybrid closed loop uses a**
  - Tandem t:slim insulin pump and Dexcom G6 or G7 CGM. Licenced for those aged 4+
- **Omnipod 5 tubeless (patch) system uses an**
  - Omnipod 5 controller (PDM) with a pre-loaded app and pods plus Dexcom 6 CGM
- **Medtrum A8 Touch Care Nano (patch) system uses a**
  - Medtrum Touch Care Nano insulin pump, CGM (TouchCare Nano) & the Medtrum APGO algorithm

BLUE (with information sheet) –

- FreeStyle Libre 2 plus for use with the Omnipod 5 hybrid closed loop system
- Reviewed and updated information sheet (from April 23) to include FreeStyle Iibre 2 plus as part of Omnipod 5 HCL

Implementation
Primary care • These are devices that are excluded from the National Tariff payment system and are commissioned by ICSs for use in secondary care. • To continue to prescribe FreeStyle Libre 2 plus following initiation by the specialist teams as part of Omnipod 5 Hybrid Closed Loop System. • Primary care prescribers should be aware that their patient is using this device and ensure that this is recorded in the patient's notes to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will also ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication. **Secondary care** • Providers are NHS hospital trusts. • Trusts to follow internal governance procedures to add to their formulary. • Ensure all orders are made through the NHS Supplies framework and the patients are provided with the URNs for each part of their HCL system to ensure that they are able to access the nationally agreed cost-effective prices. • To initiate freestyle libre 2 plus in line with NICE guidance in patients using the Omnipod 5 Hybrid Closed Loop System. • The initiation, administration and on-going treatment is managed by secondary care. • Specialists will be required to notify the high-cost drugs teams of initiation using the Blueteq® system. **ICS** • This technology is commissioned by integrated care systems. • There will be a phased implementation in line with NHS England recommendations (agreed at APC in March 24) **PAD and Joint Formulary** • The PAD will need to be updated and consideration will need to be given to a profile page for HCLs.
Proposed tick box forms
Blueteq® forms will be updated.

References:

1 NICE Technology Appraisal Guidance: . Available at: Accessed <insert date here>

2 NICE Resource Impact Template: . Available at: Accessed <insert date here