

Policy for Hybrid Closed Loop Systems

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Department:	Medical Directorate

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.
	1.0		
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1. Category: Threshold

This commissioning policy has been produced in order to provide and ensure equity, consistency and clarity relating to the use of hybrid closed loop systems within Coventry & Warwickshire 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. Where the threshold criteria for a procedure or treatment has not been met, an application can be made to the Individual Funding Request Panel if there are clinically exceptional circumstances.

2. Background

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 Plan¹ made a commitment for the NHS to ensure that: 'in line with clinical guidelines², 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-known³.

The NICE technology appraisal (TA) 943⁴ 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.³

3. Indication

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

4.1 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 Coventry & Warwickshire is in line with the recommendations of NICE TA 943⁴ 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:
 - CSII
 - real-time continuous 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

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-funding

HCL systems are only recommended if they are procured at a cost-effective price agreed by the companies and NHS England. Coventry & Warwickshire will develop a preferred prescribing list for HCL systems selected from the NHSE procurement list.

4.2 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 & wellbeing.

The patient or their family or their carer must meet the following requirements to qualify for HCL:

- Is able to use the HCL systems, and
- Is offered approved face-to-face or digital structured education programmes or
- Is competent in insulin dosing and adjustments.

4.3 Initiation

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

Adults

Priority Number	Priority
1	Pregnancy
2	Severe hypoglycaemia
2	Hypoglycaemia unawareness (e.g. unable to drive)
2	Planning pregnancy
3	Already on an insulin pump and HbA1c \geq 58mmol/mol
3	HbA1c >86mmol/mol
4	HbA1c 75-85mmol/mol
5	HbA1c 64-74mmol/mol
5	HbA1c 58-63mmol/mol

Children & Young People

Priority Number	Priority
1	Already on an insulin pump and HbA1c $>$ 58mmol/mol
1	Hypoglycaemia unawareness in under 5 years
2	HbA1c >86mmol/mol
2	HbA1c 75-85mmol/mol
3	HbA1c 64-74mmol/mol
3	HbA1c <63mmol/mol
4	Hypoglycaemia unawareness in over 5 years
4	Already on an insulin pump and HbA1c $<$ 58mmol/mol
5	Severe hypoglycaemia

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

When choosing the HCL system:

- a shared decision making will be used to identify the person's needs and preferences
- the choice of HCL systems will be made from the Coventry & Warwickshire Netformulary preferred prescribing list (when available)

Prior approval as per agreed process (e.g. Blueteq), will be required from the Integrated Care Board before any treatment proceeds in secondary care, unless an alternative contract arrangement has been agreed with the ICB.

The supply of the insulin pump, consumables and CGM will be provided by secondary care. However if the CGM is on the CW Netformulary ([CW 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 [Coventry and Warwickshire 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, the ICB will only consider funding the treatment if an Individual Funding Request (IFR) detailing the patient's clinical presentation is submitted to the ICB.

4.4 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

If the device is not being worn consistently by the patient, or there are concerns about how they are using their device, support should be offered to improve use of their HCL system.

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.

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.

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 system withdrawn if the patient does not meet the eligibility criteria stated in section 4.1.

5. Guidance/References

1. National Health Service (NHS): The NHS long term plan (2019). Available at: <https://www.longtermplan.nhs.uk/> [Accessed 16/04/2024]
2. 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> [Accessed 16/04/2024]
3. NHS England Hybrid Closed Loop technologies: 5-year implementation strategy. Publication reference: PRN01097
4. 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 [Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes \(nice.org.uk\)](https://www.nice.org.uk/guidance/TA943) [Accessed 15/04/2024]

Equality and Quality Impact Assessment Tool

The following assessment screening tool will require judgement against all listed areas of risk in relation to quality. Each proposal will need to be assessed whether it will impact adversely on patients / staff / organisations.

Insert your assessment as positive (P), negative (N) or neutral (N/A) for each area.

Record your reasons for arriving at that conclusion in the comments column. If the assessment is negative, you must also calculate the score for the impact and likelihood and multiply the two to provide the overall risk score. Insert the total in the appropriate box.

Quality Impact Assessment –Quality and Equality Impact Assessment

Scheme Title:	Implementation of the NICE Technology Appraisal (TA) 943 Hybrid closed loop (HCL) systems for managing blood glucose levels in type 1 diabetes		
Project Lead:	Medicines Optimisation: Natasha Jacques	Senior Responsible Officer:	Angela Brady
	Long Term Conditions: Yasser Din	Quality Sign Off:	Quality Team members below
Intended impact of scheme:	<p>To support the implementation across Coventry and Warwickshire Integrated Care System (CWICS) of NICE TA943 HCL systems for managing blood glucose levels in type 1 diabetes. This NICE TA recommends HCL systems (only if purchased at cost-effective price) for patients with Type 1 diabetes including all children and young people (CYP), all patients who are pregnant or planning pregnancy and defined adult cohorts.</p> <p>NHSE will make annual capped funding for 5 years, available to all ICBs from which they can request reimbursement for 75% of the estimated incremental costs of HCL as a contribution to the cost of the technology and operational delivery of the service.</p> <p>A paper has been submitted to the CWICS prioritisation panel requesting for system wide support and identification of funding streams for HCL implementation in line with the local 5 year implementation plan. If this is agreed then a hybrid closed loop policy will be developed in line with NICE TA943.</p>		

How will it be achieved:

A system wide implementation plan phased over 5 years was developed by CW ICB and clinical diabetes teams at SWFT, GEH and UHCW. 2781 adults and 498 CYP across the ICS have been identified as requiring initiation on HCL. A clinical prioritisation list (see table below) has been developed for adults and children to support the onboarding of patients onto the HCL systems.

Adult Priority List		CYP Priority List	
1	Pregnancy	1	Already on an insulin pump and HbA1c > 58mmol/mol
2	Severe hypoglycaemia	1	Hypoglycaemia unawareness in under 5 years
2	Hypoglycaemia unawareness (e.g. unable to drive)	2	HbA1c >86mmol/mol
2	Planning pregnancy	2	HbA1c 75-85mmol/mol
3	Already on an insulin pump and HbA1c ≥58mmol/mol	3	HbA1c 64-74mmol/mol
3	HbA1c >86mmol/mol	3	HbA1c <63mmol/mol
4	HbA1c 75-85mmol/mol	4	Hypoglycaemia unawareness in over 5 years
5	HbA1c 64-74mmol/mol	4	Already on an insulin pump and HbA1c <58mmol/mol
5	HbA1c 58-63mmol/mol	5	Severe hypoglycaemia

Name of person completing assessment:

Natasha Jacques*
Yasser Din**

Position:	*Lead Medicines Optimisation Pharmacist **Long Term Conditions Transformation Manager
Date of Assessment:	15/05/2024

Quality Review by:	Anna Crane, Annette Walker, Micaela Loveridge, Dawn Baker, Sam Collier
Position:	Quality leads
Date of Review:	23.05.24

High level Quality and Equality Questions

The risk rating is only to be done for the potential negative outcomes. We are looking to assess the likelihood of the negative outcome occurring and the level of negative impact. We are also seeking detail of mitigation actions that may help reduce this likelihood and potential impact.

AREA OF ASSESSMENT		OUTCOME ASSESSMENT (Please tick one)			Evidence/Comments for answers	Risk rating (For negative outcomes)			Mitigating actions
		Positive	Negative	Neutral		Risk impact (I)	Risk likelihood (L)	Risk Score (IxL)	
Duty of Quality Could the scheme impact positively or negatively on any of the following:	Effectiveness – clinical outcome	✓			Use of HCL will support patients with Type 1 diabetes to effectively manage their blood glucose levels. Full details of the efficacy of HCL on glycaemic control and outcomes is detailed in NICE TA943				
	Patient experience	✓			The offer of HCL will support patients to effectively manage their blood glucose levels and will essentially remove the need to routinely use				

					finger prick blood glucose testing and injecting insulin.				
	Patient safety	✓			HCL systems help to reduce the incidence of hypoglycaemia and supports patients to more effectively manage their blood glucose levels and reduce the burden of everyday decision making for the patient/parents. . See NICE TA943 for full details.				
	Parity of esteem	✓			Identification of our underserved communities has been considered within the implementation plan. Strategies have been identified to help support the uptake of this technology in these communities and to reduce health inequality and inequity in provision of HCL systems.				
	Safeguarding children or adults			✓	Maintenance of current safeguarding arrangements as per ICB Local Authority and/or Provider safeguarding policies and procedures. A systemwide approach to care with a collaborative, integrated				

					approach, will enable learning from incidents to be shared across the system.				
NHS Outcomes Framework Could the scheme impact positively or negatively on the delivery of the five domains:	Enhancing quality of life	✓			The offer of HCL will support patients to effectively manage their blood glucose levels and will essentially remove the need to routinely use finger prick blood glucose testing and injecting insulin. See NICE TA943 for further details on positive impact on quality of life.				
	Ensuring people have a positive experience of care	✓			The offer of HCL across the hospital providers in Coventry & Warwickshire will ensure equity of the offer of HCL systems supporting effective, inclusive and personalised care. Audit tools including the National Diabetes Audit and National Paediatric Diabetes Audit will collate feedback. Complaints, compliments, and feedback will be sought through on-going engagement with the people and stakeholders of our system.				
	Preventing people from	✓			The use of HCL systems				

	dying prematurely				will help to reduce the incidence of hypoglycemia and diabetic ketoacidosis, both of which can lead to premature death from cardiovascular complications linked to poor diabetes management.				
	Helping people recover from episodes of ill health or following injury	✓			The real time continuous glucose monitoring (rtCGM) part of the HCL systems enables real time monitoring of blood glucose levels which are often affected by concurrent illness. In addition the automated insulin dose adjustments will minimize illness related glucose fluctuations.				
	Treating and caring for people in a safe environment and protecting them from avoidable harm	✓			Many of the rtCGM devices allow remote monitoring so will help support carers/parents to safeguard children and adults for example to identify issues such as hypoglycaemia HCL systems automatically adjust rate of insulin according to the blood glucose levels helping to prevent hypoglycaemia and hyperglycemia .				

Patient services Could the proposal impact positively or negatively on any of the following:	A modern model of integrated care, with key focus on multiple long-term conditions and clinical risk factors	✓			HCL will be offered to patients with higher risk which includes those that have multiple long term conditions that impact negatively on managing diabetes. It will be an integral part of the care pathway for patients with Type 1 diabetes				
	Access to the highest quality urgent and emergency care		✓		Clinicians working within urgent and emergency care settings are unlikely to be familiar with HCL systems	2	4	8	Within the implementation plan it has been identified that training will need to be provided for staff who do not work within diabetes to ensure a basic level of knowledge on HCL systems. In addition the escalation policy to support access to specialist advice out of hours
	Convenient access for everyone		✓		NICE TA943 states the eligibility criteria which does not include all patients with Type 1 diabetes. Due to the	2	4	8	Clinicians will use the clinical prioritization list to ensure those with the greatest

					numbers of patients that have been identified as meeting the eligibility criteria the onboarding of these patients will be phased over 5 years and will be based on the clinical prioritization described earlier.				need are offered early access to the HCL systems.
	Ensuring that citizens are fully included in all aspects of service design and change			✓	The offer and initiation of HCL systems will be part of the patient centred discussion on their management.				
	Patient Choice	✓			The offer and initiation of HCL systems will be part of the patient centred discussion on their management. NHS England are currently negotiating cost effective prices for HCL systems and once this is completed CWICS will consider developing a formulary. More than one HCL system will be available on the formulary allowing for patient choice.				
	Patients are fully empowered in their own care	✓			The offer and initiation of HCL systems will be part of the patient centred discussion on their management.				
	Wider primary care,			✓	This is a specialist only				

	provided at scale				device so the initiation and ongoing management will within secondary care diabetes services				
Access Could the proposal impact positively or negatively on any of the following:	Patient choice	✓			The choice of whether to start on a HCL system will be a shared decision making between the clinician and patient. Choice of the formulary HCL systems will allow patients to choose a device which may be more acceptable to them wearing it and their body image.				
	Access	✓			<p>HCL will be accessible based on the eligibility criteria within the NICE TA943 and the CWICS implementation plan.</p> <p>Patients known to have inequity of access to services will be identified and support planning undertaken for reaching out to these diverse and harder to reach communities.</p>				
	Integration	✓			Use of HCL systems enables clinicians in primary and secondary care to provide support to people with diabetes, facilitating care across the				

					interface.				
Compliance with NHS Constitution	Quality of care and environment	✓			We have a good insight into the current position and numbers of patients meeting the eligibility criteria with the NICE TA943. Using the implementation plan and clinical priority list we aim to offer eligible patients over a 5 year period. The extent to which this improves individual outcomes will be monitored via local and national audits.				
	Nationally approved treatment/drugs	✓			The implementation plan aligns with NICE TA943				
	Respect, consent and confidentiality			✓	All usual ICB and/or Provider respect, consent and confidentiality policies and mechanisms will apply				
	Informed choice and involvement	✓			The offer and initiation of HCL systems will be part of the patient centred discussion on their management.				
	Complain and redress	✓			Usual ICB and/or Provider compliment, complaint and redress policies and mechanisms will apply A number of complaints				

					have been received that the ICB are not yet offering HCL as per NICE TA943.				
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*Risk score definitions are provided in the next section.

Equality Impact Assessment

Project / Policy Details

What is the aim of the project / policy?

The proposal requests CW ICS support for the funding stream and local HCL implementation plan, to allow the hospital providers to initiate HCL in line with the NICE TA943. Subject to approval of the proposal a HCL policy will be developed to help to provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.

The cohorts of patients that are eligible to receive HCL are defined within the NICE TA943 and there is an expectation that all ICBs offer HCL from 1st April 2024. Currently HCL is offered to a limited group of patients with a significant clinical risk, but the NICE TA outlines that it should be on offer to a wider cohort and the details of proposed implementation are in the CW HCL implementation plan..

Who will be affected by this work? e.g. staff, patients, service users, partner organisations etc.

The NICE TA943 defines the cohorts of patients with Type 1 diabetes that should be offered HCL technology. These cohorts are listed below.

- 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 or intermittently scanned CGM
- Type 1 diabetes for children and young people.
- Type 1 diabetes for women, trans men and non-binary people who are pregnant or planning to become pregnant.

Implementation of HCL NICE TA943 will have a significant positive impact on the patients with Type 1 diabetes listed above, their families and carers. It will also affect the diabetes specialists as HCL will

become a more standard offer for Type 1 diabetes management

Is a full Equality Analysis Required for this project?

Yes	Proceed to complete this form.		Explain why further equality analysis is not required.
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If no, explain below why further equality analysis is not required. For example, the decision concerned may not have been made by the ICB or it is very clear that it will not have any impact on patients or staff.

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Equality Analysis Form

1. Evidence used

What evidence have you identified and considered? This can include national research, surveys, reports, NICE guidelines, focus groups, pilot activity evaluations, clinical experts or working groups, JSNA or other equality analyses.

1. National Health Service (NHS): The NHS long term plan (2019). Available at: <https://www.longtermplan.nhs.uk/> [Accessed 16/04/2024]
2. 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> [Accessed 16/04/2024]
3. NHS England Hybrid Closed Loop technologies: 5-year implementation strategy. Publication reference: PRN01097
4. 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 [Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes \(nice.org.uk\)](https://www.nice.org.uk/guidance/TA943) [Accessed 15/04/2024]

2. Impact and Evidence:

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should also include any identified health inequalities which exist in relation to this work.

Age: A person belonging to a particular age (e.g. 32 year olds) or a range of ages (e.g. 18-30 year olds)

Describe age related impact and evidence. This can include safeguarding, consent and welfare issues:

Children and Young People will be a priority group

Pregnant women are the main priority in adults in the delivery plan.

Disability: A person has a disability if he/she has a physical, hearing, visual or mental impairment, which has a substantial and long-term adverse effect on that person's ability to carry out normal day-to-day activities

Describe disability related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/ learning disabilities, cognitive impairments:

In 2019 a third of deaths of people with a learning disability were shown to have been due to

treatable causes, compared with 8% in the general population. A recommendation specific to diabetes from the Learning Disabilities Mortality Review (LeDeR) Programme reviews related to appropriate provision of support for people with diabetes, particularly in community settings. Access to Flash or other formulary FP10 CGM devices for people with a learning disability on insulin will help support them and their carers to manage their blood glucose levels.

HCL is a computerised system involving real-time CGM and an insulin delivery system which is able to manage patients' diabetes in real time. This makes the process significantly easier for patients with learning difficulties, as it takes the ongoing decision making process away from the patient.

Gender reassignment (including transgender): Where a person has proposed, started or completed a process to change his or her sex.

Describe any impact and evidence on transgender people. This can include issues such as privacy of data and harassment.

This proposal/policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Marriage and civil partnership: A person who is married or in a civil partnership.

Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part-time working, and caring responsibilities:

This proposal/policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Pregnancy and maternity: A woman is protected against discrimination on the grounds of pregnancy and maternity. With regard to employment, the woman is protected during the period of her pregnancy and any statutory maternity leave to which she is entitled. Also, it is unlawful to discriminate against women breastfeeding in a public place.

Describe any impact and evidence on pregnancy and maternity. This can include working arrangements, part-time working, and caring responsibilities:

Women, trans men and non-binary people who are pregnant or planning to become pregnant are one of the priority groups who should be offered HCL technology.

Race: A group of people defined by their race, colour, and nationality (including citizenship) ethnic or national origins.

Describe race related impact and evidence. This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers:

Certain ethnicities have higher risk of developing diabetes and have poorer outcomes. As part of the implementation plan, we will consider ethnicities where appropriate to address health inequalities in relation to diabetes management.

This proposal/policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Religion or belief: A group of people defined by their religious and philosophical beliefs including lack of belief (e.g. atheism). Generally a belief should affect an individual's life choices or the way in which they live.

Describe any religion, belief or no belief impact and evidence. This can include dietary needs, consent and end of life issues:

This proposal/policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

The use of HCL systems can support patients during periods of fasting e.g. Ramadan

Sex: A man or a woman

Describe any impact and evidence on men and women. This could include access to services and employment:

This proposal/policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

From the current patient population on HCL technology, there is an equal split between the use of HCL/insulin pumps in males and females.

Sexual orientation: Whether a person feels generally attracted to people of the same gender, people of a different gender, or to more than one gender (whether someone is heterosexual, lesbian, gay or bisexual).

Describe any impact and evidence on heterosexual people as well as lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers:

This proposal/policy does not contain any statements which may exclude clinicians of the NHS Coventry and Warwickshire Integrated Care Board from applying this policy.

Carers: A person who cares, unpaid, for a friend or family member who due to illness, disability, a mental health problem or an addiction cannot cope without their support

Describe any impact and evidence on part-time working, shift-patterns, general caring responsibilities:

Where the eligibility criteria is met the functionality offered by some of the rtCGM devices which are part of the HCL systems will allow remote monitoring so will help support carers/parents to safeguard children and adults for example to identify issues such as hypoglycaemia.

Other disadvantaged groups:

Describe any impact and evidence on groups experiencing disadvantage and barriers to access and outcomes. This can include lower socio-economic status, resident status (migrants, asylum seekers), homeless, looked after children, single parent households, victims of domestic abuse, victims of drugs / alcohol abuse: (This list is not exhaustive)

Health inequalities will be considered when rolling out HCL.

It is recognised that there are existing health inequalities in the provision of diabetes technology across Coventry and Warwickshire and this will be addressed in the rollout of the implementation plan.

3. Human Rights

FREDA Principles / Human Rights	Question	Response
<p>Fairness – Fair and equal access to services</p>	<p>How will this respect a person’s entitlement to access this service?</p>	<p>To provide a fair, equitable and transparent process for all patients of the NHS Coventry and Warwickshire Integrated Care Board (ICB), for which the ICB has commissioning responsibility.</p> <p>This proposal/policy supports the objective to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for HCL and to ensure that HCL systems are provided within the context of the needs of the overall population and the evidence of clinical and cost</p>

		<p>effectiveness.</p> <p>Access to CGM will be available via hospital diabetes clinics to people defined in the eligibility criteria.</p> <p>It will also ensure that the CW population have access to HCL systems that is equitable with the rest of England.</p>
Respect – right to have private and family life respected	How will the person’s right to respect for private and family life, confidentiality and consent be upheld?	<p>This proposal/policy will enable a choice of HCL systems to be offered to eligible people which will support the person’s decision to be started on HCL</p> <p>Data can be shared by the person with healthcare professionals; however each person has to give permission for their data to be shared.</p>
Equality – right not to be discriminated against based on your protected characteristics	How will this process ensure that people are not discriminated against and have	This proposal/policy is applied to all patients of the NHS Coventry and

	their needs met and identified?	Warwickshire Integrated Care Board to prioritise resources and provide interventions with the greatest proven health gain, within ICB budgetary constraints. The intention is to ensure equity and fairness in respect of access to NHS funding for HCL and to ensure that HCL systems are provided within the context of the needs of the overall population and the evidence of clinical and cost effectiveness.
Dignity – the right not to be treated in a degrading way	How will you ensure that individuals are not being treated in an inhuman or degrading way?	<p>All communication, written or verbal, will be provided in a confidential, clear, understandable, format. Individuals will have the opportunity to discuss their healthcare with the requesting clinician.</p> <p>If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.</p>

Autonomy – right to respect for private & family life; being able to make informed decisions and choices	How will individuals have the opportunity to be involved in discussions and decisions about their own healthcare?	<p>All communication, written or verbal, will be provided in a confidential, clear, understandable, format. Individuals will have the opportunity to discuss their healthcare with the requesting clinician.</p> <p>If the patient contacts the ICB of their own accord then all communication, written or verbal, will be provided in a confidential, clear, understandable, format.</p> <p>Access to HCL will be available via hospital diabetes clinics to people defined in the eligibility criteria. This proposal/policy will enable a choice of HCL systems to be offered to eligible people which will support the person's decision to be started on HCL.</p>
Right to Life	Will or could it affect someone's right to life? How?	No

Right to Liberty	Will or could someone be deprived of their liberty? How?	No
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4. Engagement, Involvement and Consultation		
If relevant, please state what engagement activity has been undertaken and the date and with which protected groups:		
Engagement Activity	Protected Characteristic/ Group/ Community	Date
n/a	n/a	n/a
For each engagement activity, please state the key feedback and how this will shape policy / service decisions (E.g. patient told us So we will):		

5. Mitigations and Changes
Please give an outline of what you are going to do, based on the gaps, challenges and opportunities you have identified in the summary of analysis section. This might include action(s) to mitigate against any actual or potential adverse impacts, reduce health inequalities, or promote social value. Identify the recommendations and any changes to the proposal arising from the equality analysis.

It is recognised that the provision of diabetes technology is currently inequitable across Coventry & Warwickshire. The introduction of this policy will help to address this as all eligible patients should be offered HCL across all the providers in Coventry & Warwickshire. Aside from the clinical need and prioritisation that has been outlined in the delivery plan, a health inequality priority process will need to be established to ensure that the population have equitable access to HCL.

6. How will you measure how the proposal impacts health inequalities?

e.g Patients with a learning disability were accessing cancer screening in substantially lower numbers than other patients. By revising the pathway the ICB is able to show increased take up from this group, this is a positive impact on health inequalities.

You can also detail how and when the service will be monitored and what key equality performance indicators or reporting requirements will be included within the contract.

Completion of the National Diabetes Audit and National Paediatric Diabetes Audit will support the data collection on ethnicity and deprivation. This will help us to monitor that the delivery plan is being effectively delivered to those hard to reach communities and to provide assurance that we are addressing health inequalities and inequity in access.

7. Is further work required to complete this assessment?

Please state what work is required and to what section. e.g additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g disability).

Work needed	Section	When	Dare completed
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Not applicable			
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8. Sign off		
The Equality Analysis will need to go through a process of quality assurance by a Senior Manager within the department responsible for the service concerned before being submitted to the Policy, Procedure and Strategy Assurance Group for approval. Committee approval of the policy / project can only be sought once approval has been received from the Policy, Procedure and Strategy Assurance Group.		
Requirement	Name	Date
Senior Manager Signoff	Altaz Dhanani	20/05/2024
Which committee will be considering the findings and signing off the EA?	Finance and Performance Committee	03/07/2024
Approved by the Policy Procedure and Strategy Assurance Group.		20/05/2024

Once complete, please send to the ICB's Governance Team.