

## Variation to the funding period document

### NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

#### Multiple Technology Appraisal

#### GID-TA10845: Hybrid closed loop systems for managing blood glucose levels in type 1 diabetes

All relevant health bodies must comply with technology appraisal recommendations and make a health technology available for patients within 3 months of publication of final guidance. When it considers it to be appropriate, NICE can specify a longer period of compliance.

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| 1. Name of organisation:  | NHS England  |
| Please state the reason for applying to vary the funding period (please tick all that apply): | <input type="checkbox"/> The technology exceeds the Budget Impact Test (BIT) level of £20million in any of the first 3 years following implementation<br><br>The health technology cannot be appropriately administered until:<br><input checked="" type="checkbox"/> training is put in place<br><input checked="" type="checkbox"/> certain health service infrastructure requirements including goods, materials or other facilities are put in place<br><input checked="" type="checkbox"/> other appropriate health services resources, including staff, are put in place   |
| <b>Additional rationale to support the funding variation request</b>                          |  |
| 1. What is the duration of, and the justification for, the proposed variation?                | NHS England is seeking a five-year phased roll-out of Hybrid Closed Loops (HCLs) to ensure equitable, sustainable, and affordable patient access to this technology.<br><br>We are seeking this variation for the following reasons: <ul style="list-style-type: none"> <li>• <b>Clinical capacity</b> - This variation reflects a lack of clinical capacity with training needed for both staff and patients to support effective use of diabetes technologies. It will take time to train and recruit staff to deliver HCL effectively as well as supporting patients to start on insulin pumps and use HCL.</li> <li>• <b>Specialist support</b> - Effective use of insulin pumps, glucose monitors and HCL requires specialist support, training and investment in the workforce.</li> <li>• <b>Variations in access</b> - There are significant variations in the provision of relevant blood glucose monitors and insulin pumps, with the expertise and capacity to provide pump services often concentrated in larger teaching diabetes centres, with fewer resources at smaller diabetes centres and district general hospitals.</li> <li>• <b>Healthcare inequalities</b> - There are also additional complexities related to population demographics such as age, deprivation, ethnic diversity, language, income and access to technology (e.g., smartphone, internet and broadband), all which could impact the uptake of HCL systems. Without continued investment in workforce training and staffing capacity the unplanned introduction of HCL has the potential to exacerbate health inequalities.</li> <li>• <b>Patient benefit</b> - the phased rollout of HCL is not expected to adversely impact patient outcomes for people eligible for HCLs. Notwithstanding variation noted</li> </ul> |

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|  | <p>above, the National Diabetes Audit highlights the growing number of people with Type 1 diabetes achieving improved glycaemic control. Effective implementation of HCLs will represent a further advance in achieving optimal glycaemic control.</p> <ul style="list-style-type: none"> <li>• <b>Targeted to optimise outcomes</b> - the phased rollout will concentrate on those most likely to benefit. This will begin with populations where the demand is highest, specifically Children and Younger People (0-12) and their families, Children and Younger Adults (13 -19), pregnancy, existing adults who are pump users wishing to transition to HCL and then extending to new pump users over time.</li> <li>• <b>Variation in procurement</b> - Currently there is considerable variation in the procurement of diabetes technology, including insulin pumps. To resolve this variation and ensure Trusts can access nationally mandated cost-effective prices NHS England will need to develop a new commercial framework via a formal procurement process. This is expected to take time and resource to develop and test with suppliers.</li> </ul> <p>This timeline is consistent with the introduction of similar novel and complex technologies in diabetes, including insulin pumps and flash glucose monitors. It also aligns to timelines for other potentially significant new technologies.</p>   |
| <p>2. Describe any relevant provisions of any commercial arrangement reached with the company.</p> | <p>NHS Supply Chain currently manages around 60/70% of the provision of pumps to patients (via Trusts). NHS Supply Chain are the main route to market for this technology. Their current framework offers pumps and Continuous Glucose Monitors (CGMs) – the same hardware used for HCLs, but not HCL-enabled. Therefore, to support HCL roll-out changes to this framework, or a new framework, would be required (depending on the existing framework’s characteristics). This development necessitates a mandated procurement process that needs to be managed formally to be compliant with procurement law.</p> <p>To achieve cost-effectiveness at the levels specified by NICE, suppliers are required to offer a reduction on current prices. The market is very diverse with multiple suppliers of various components reflecting the complexity of the systems (pumps, algorithms and software).</p> <p>There is currently no facility within the NHS Supply Contract to manage ‘cost-effective’ pumps separately, and current pricing models are Trusts based - therefore specific work is required to facilitate ‘national cost-effective’ pricing.</p> <p>NHS England are therefore currently supporting NHS Supply Chain to run a commercial exercise with manufacturers to attempt to achieve cost-effective prices at the level specified by the NICE Appraisal Committee.</p> <p>NHSE have asked NHS Supply Chain to issue a Request for Information (RFI) to provide an opportunity to test scenarios for roll out of HCL technology to patients, including the price and requirements for the future procurement. To support this exercise there will be a number of supplier engagement opportunities planned over the summer. Further details will be published on the NHS Supply Chain website. The commercial exercise will last a maximum of 16 weeks and is expected to conclude by 13 October 2023.</p> |
| <p>3. Describe the amount and phasing of funding that will be made available and</p>               | <p>Three scenarios of possible uptake outcomes have been provided by the NHS England Diabetes National Specialty Advisor for Diabetes and diabetes programme team based on the eligibility criteria set out by the NICE Appraisal Committee (Please see <b>Appendix 1</b>).</p>  |

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| <p>how it is intended that this should be applied to patients eligible for treatment.</p>  | <p>The estimated additional cost to the NHS is between £72.2m - £200.9m per annum by 2031-32 depending on which of the three identified implementation scenarios is chosen.</p> <p>The cost of changes to pathways and infrastructure is not included, and it's noted that the workforce costs are not validated and likely to be higher in real terms.</p> <p>The 'highest' roll-out scenario estimates uptake of HCL at 52% of all eligible patients - by 2027-28.</p>   |
| <p>4. Provide detail of an assessment of the impact on patients, eligible for treatment under the guidance, but whose treatments will be delayed because of the funding variation, taking into account NHS England's and NICE's responsibilities under equalities legislation.</p> | <p>The rationale for phased rollout is set out under Section 5 and NHS England do not anticipate an exacerbation of any existing healthcare inequalities as a result of the phasing.</p> <p>Significant progress has been made in recent years with the introduction of CGMs, insulin pumps, and other innovative solutions, improving glucose control, reducing the risk of complications, and improving the quality of life for patients.</p> <p>The phased implementation of HCLs offers the opportunity for another step change in technological advancement in Type-1 diabetes and the potential for patients to further achieve optimal glycaemic control.</p> <p>The phased implementation of the technology is reflective of the current demand management and clinical capacity challenges facing the NHS and the need for a balanced approach. The approach is to optimise effective implementation of the technology, without putting pressure on already stretched diabetes services and clinical teams.</p> <p>NHS England will ensure that phasing is undertaken in a manner where those who can benefit the most from the technology will be prioritised. The phased introduction of HCLs will be undertaken via major clinical centres which are geographically spread across England and these are often in areas where health inequalities exist.</p> <p>NHS England has a strong record in ensuring that equality of access is central to health technology roll out and this approach can be observed in the roll out of Flash Glucose Monitoring as seen in <b>Figure 1</b> below.</p> <p><b>Figure 1: Equality in Flash Glucose Monitoring</b></p> |

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| <p>5. Provide detail of the interim commissioning policy that would be applied to phase in funding and to manage access to the technology during the extended funding variation period.</p> | <p>Setting HCL adoption up for success and enabling appropriate levels of patient care and commercial oversight will require a 'full system' operating model, mapped against indicative and high-level timeframes. This model will require significant change from national and local delivery teams, including framework setup, agreement of funding flows, development of new referral pathways and governance and clinical support.</p> <p>Based on the outputs of the commercial exercise, and the recommendation in the final guidance, NHS England will develop a 5-year national strategy to provide advice and guidance to providers on the phased uptake approach.</p> <p>The strategy will be principle led and place improving patient health outcomes and reducing health inequalities at the centre of the approach. The strategy will be comprehensive; with key elements including workforce, patient education, commercial, stakeholder engagement and data. The strategy will be transparent and have formal reporting accountability to the National Diabetes Programme Board – with stakeholder insights provided by an expert advisory group and operational excellence facilitated via a HCL delivery group.</p> <p>NHSE will develop the strategy in parallel to the commercial exercise and proposed timelines for final NICE technology appraisal guidance.</p> <p>The NHSE request for a 5-year phased roll out of HCL assumes that we are able to maintain prices at a cost-effective level.</p> |
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Appendix 1: Eligible Population Assumptions for HCL

| Uptake Outcome Scenario<br>(2022/23 - 2027-28) | Description   | Total Eligible Patients<br>(152,309)                               | Eligible Adults<br>(121,020)<br>(>19 years old, including pregnant women) | Eligible Children<br>(31,289)<br>(<19 years old) |
|--|---|--|---|--|
| Scenario 1<br>(Medium Adoption)                | Adult uptake is a 50% additional uptake on current insulin pump usage in wider Type 1 population. Child reflects expected uptake (HCLs offered to all children).            | <b>57,041</b><br><b>(37% of total estimated eligible patients)</b> | 38,349<br>(32% of estimated eligible adults)                              | 18,689<br>(60% of estimated eligible children)   |
| Scenario 2<br>(High Adoption)                  | Adult uptake is a 150% additional uptake on current insulin pump usage in wider Type 1 population. Child reflects expected uptake (HCLs offered to all children).           | <b>78,849</b><br><b>(52% of total estimated eligible patients)</b> | 60,160<br>(50% of estimated eligible adults)                              | 18,689<br>(60% of estimated eligible children)   |
| Scenario 3<br>(Low Adoption)                   | Adult uptake reflects current insulin pump uptake in wider Type 1 population after 15 years of availability. Child reflects expected uptake (HCLs offered to all children). | <b>43,621</b><br><b>(29% of total estimated eligible patients)</b> | 24,932<br>(21% of estimated eligible adults)                              | 18,689<br>(60% of estimated eligible children)   |

Proportions are presented relative to the estimated patients eligible for HCL as per NICE HTA

Eligible adults includes those with HbA1c >7.5% and pregnant women

NHSE do not have robust data on HbA1c levels of pregnant women, therefore pregnant women have been added to the HbA1c > 7.5% population. This is likely to result in some double counting of the total eligible adult population where pregnant women also have Hb1Ac levels > 7.5%

Scenario descriptions are based on the wider Type 1 adult population