General Commissioning Policy

Equipment	**Flash Glucose Monitoring (FGM) systems such Freestyle Libre®**
For the management of	**Type 1 diabetes in adults and children aged four and above**
Background	This commissioning policy reflects the criteria for Flash Glucose Monitoring (FGM) systems related to the Regional Medicines Optimisation Committee position statement issued 1st November 2017. Until further trial data is available, it is recommended that audit data on the use of Freestyle Libre® is collected through its use in limited and controlled settings where patients are attending for Type 1 diabetes care. Provision of such equipment requires support and education to the person or carer. Therefore this equipment and its supplies should only be initiated and supplied by the Diabetes Specialist Team. Flash Glucose Monitoring (FGM) such as Freestyle Libre® should not be prescribed by GP practices/primary care and as such would be classed as a RED drug i.e. only for hospital specialist prescribing/supply.
Commissioning position	It is recommended that Freestyle Libre® should only be used for people with Type 1 diabetes, aged four and above, attending specialist Type 1 care using multiple daily injections or insulin pump therapy, who have been assessed by the specialist clinician and deemed to meet one or more of the following: 1. Patients who undertake intensive monitoring >8 times daily 2. Those who meet the current NICE criteria for insulin pump therapy (HbA1c >8.5% (69.4mmol/mol) or disabling hypoglycemia as described in NICE TA151) where a successful trial of FreeStyle Libre® may avoid the need for pump therapy. 3. Those who have recently developed impaired awareness of hypoglycaemia. It is noted that for persistent hypoglycaemia unawareness, NICE recommend continuous glucose monitoring with alarms and Freestyle Libre does currently not have that function. 4. Frequent admissions (>2 per year) with Diabetic ketoacidosis (DKA) or hypoglycaemia. 5. Those who require third parties to carry out monitoring and where conventional blood testing is not possible. In addition, all patients (or carers) must be willing to undertake training in the use of Freestyle Libre® and commit to ongoing regular follow-up and monitoring (including remote follow-up where this is offered). Adjunct blood testing strips should be prescribed according to locally agreed best value guidelines with an expectation that demand/frequency of supply will be reduced. Freestyle Libre® is an innovative new device that has the potential to improve quality of life for patients and support self-management. However, at the present point in time there are significant limitations in available clinical trial data and economic analysis that make it difficult to make an appropriate judgment as to its place in therapy.

	The following concerns were noted with regard to the clinical evidence and costing information supplied: • Trials contain only small numbers (n=700) of patients with well controlled Type 1 diabetes • Limited trial duration (6-12 months only) • Limited data comparing to Continuous Glucose Monitoring • Limited or no data of use in unstable patients, pregnancy, young people and children. • Projected reductions in finger-prick testing are unrealistic given the need to test before driving (current DVLA requirement) and during illness. • Costing information with regard to testing strips does not recognize significant reductions that have already been achieved in this area of prescribing. The RMOC is aware that clinics using Freestyle Libre® are already collecting audit data and would strongly support all clinics to work collaboratively (potentially through the Association of British Clinical Diabetologists) to maximize learning about this new intervention and measure its impact in individual patients. We suggest information is collected on the following: 1. Reductions in severe/non-severe hypoglycaemia 2. Reversal of impaired awareness of hypoglycaemia 3. Episodes of diabetic ketoacidosis 4. Admissions to hospital 5. Changes in HbA1c 6. Testing strip usage 7. Quality of Life changes using validated rating scales. 8. Commitment to regular scans and their use in self-management. It is recommend that if no improvement is demonstrated in one or more of these areas over a 6 month trial then the use of Freestyle Libre® should discontinued and an alternative method of monitoring used.
Effective from	December 2017
Summary of evidence / rationale	Revised in line with the Regional Medicines Optimisation Committee (RMOC) position statement and changes to FP10 to include Freestyle Libre® (FGM) November 2017.

Notes

1. This Policy will be reviewed in the light of new evidence, or guidance from NICE.
2. General Commissioning Policies are agreed by the Planning and Commissioning Committee on behalf of NHS Hull CCG and the Clinical Policy Sub Group on behalf of NHS East Riding of Yorkshire CCG.

Date	December 2017
Review Date	December 2019
Contact for this policy	William Uglow, Assistant Director of Planned & Primary Care, East Riding of Yorkshire Clinical Commissioning Group, William.uglow@nhs.net Kerry Lynn, Programme Manager Diabetes System Transformation, Hull Clinical Commissioning Group, Kerry.lynn@nhs.net

References:

NICE Medtech Innovation Briefing [MIB 110]: FreeStyle Libre® for glucose monitoring NICE July 2017. Available at https://www.nice.org.uk/advice/mib110

ABCD Type 1 Diabetes Clinical Collaborative: Information to help a formulary case for Freestyle Libre System October 2017. Available at https://abcd.care/getting-freestyle-libre-your-formulary

Diabetes UK. Diabetes Facts and Stats Version 4 Revised October 2016. https://www.diabetes.org.uk/Documents/Position%20statements/DiabetesUK_Facts_Stats_Oct16.