Dorset Health Scrutiny Committee

Dorset County Council

Date of meeting	17 October 2018
Officer	Katherine Gough, NHS Dorset Clinical Commissioning Group
Subject of report	**Glucose Monitoring Device for individuals with diabetes**
Executive summary	This report outlines the processes followed in Dorset CCG to determine the NHS prescribing arrangements for the flash glucose monitor, Freestyle Libre®
Impact assessment:	Equalities Impact Assessment: NICE found that people with learning difficulties or certain mental health problems and pregnant women may particularly benefit from FreeStyle Libre. People with certain skin conditions or allergies may be unable to wear the sensor. An application for use in Adults was received by the CCG in March 2018, and an application for use in children received in June 2018.
	Risk Assessment: N/A - Report provided by NHS Dorset CCG.
	Other Implications: N/A
Recommendation	The Committee is asked to note and comment on the contents of this report.
Reason for recommendation	This paper is presented for information purposes following concerns raised by Councillors and members of the public regarding the availability of flash glucose monitoring to Dorset patients.
Appendices	Dorset CCG commissioning Statement Freestyle Libre August 2018
Background papers	NICE Guidance Freestyle Libre glucose monitoring

	Healthcare Improvement Scotland advice statement July 2018 www.dorsetformulary.nhs.uk
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NHS Dorset Clinical Commissioning Group

Flash Glucose Monitoring Device: Freestyle Libre®

Freestyle Libre ® is a flash glucose monitoring system which monitors glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing.

Dorset CCG has always maintained an evidence based and cost effectiveness approach to making decisions on medicines and devices. The CCG aims to adhere to the statutory requirements to fund and commission drugs and devices with NICE technology appraisals (TA) within the required timescales and advise on medicines which are most cost effective and have a strong evidence base.

In the case of Freestyle Libre®, Dorset CCG published a commissioning statement in November 2015 to state that it was not commissioned. This was developed with a multidisciplinary team (MDT) of medical and pharmaceutical support. The product had come to market, and there was little evidence available.

NICE issued an innovation briefing on Freestyle Libre® in September 2017, but recognised that the evidence had limitations and the resource impact on health systems was uncertain: https://www.nice.org.uk/advice/mib110.

In November 2017, the device became available on NHS Prescription. At that point the previous commissioning statement was reviewed by a multidisciplinary team, our Diabetes working group which is made up of diabetes consultant specialists, GPs and senior pharmacists. This group found that:

> "There is limited data to confirm that use of FreeStyle Libre® will result in better controlled diabetes, an improvement in patient oriented outcomes such as a reduction in complications due to poorly controlled diabetes, hospitalisation rates or ambulance/GP call out rates, improvement in overall long-term diabetes control or quality of life. More data is also required to confirm effectiveness of this technology in less well controlled diabetes.
>
> There is limited data to support the routine use in children and young people."

Dorset CCG therefore decided not to support prescribing at this time until a full cost and clinical effectiveness review is available or further national guidance, such as NICE technology appraisal is issued.

At that time, the Regional Medicines Optimisation Committee (RMOC) North issued some limited criteria for prescribing. This was reviewed by the Dorset group, but as they had not

used any additional evidence than was looked at by the Dorset group, the criteria were not accepted. Dorset CCG raised concerns with the South Regional Medicines Optimisation Committee on the rationale behind their published information.

A further formulary application from adult diabetes services which was presented to the Dorset Medicines Advisory Group (DMAG) in March and to the CCG Clinical Commissioning Committee in April to seek permission to put forward a business plan for funding. At that point, no formal formulary applications had been made for use in children.

The April 2018, Clinical Commissioning Committee decided that a business case should not be progressed at this time, as there was no further evidence, or positive NICE technology appraisal, and the cost to the Dorset system was still unknown. Therefore, the CCG did not support prescribing of the device at this time.

Dorset CCG was not the only CCG upholding the position not to fund the device. Across the Southwest of England there remained a mixed picture. Work was undertaken to establish potential costs, and the estimates using an evaluation by the East of England NHS, estimated costs to Dorset to be over £2+ million, without evidence of improved outcomes. Consultants and GPs evaluated potential patient numbers, and local estimates ranged between several hundred patients and half of all type one diabetics.

This decision remained under review and each month there were reviews of published data and evidence to see if there was any further information to support use of the device.

The Dorset Clinical Reference Group (CRG) which comprises of medical and nursing directors across the System, raised concerns that there were some patients who could benefit from the device, and sought a further review in July 2018.

Also in July 2018, Healthcare Improvement Scotland announced that they would be making Freestyle Libre® available to patients meeting a set criteria. Within their evaluation they recognised that there was a general lack of transparency of the published evidence and thus decided that a de-novo economic analysis would better inform the cost-effectiveness and use of Freestyle in Scotland. They also carried out a budget impact model to forecast the potential cost. Rather than using the impact on HbA1c (a measure of glucose control), they looked at the impact on health benefits. Their overall assessment was:

Based on the results of the analysis presented, the Freestyle Libre® flash glucose monitoring technology appears likely to be a cost-effective alternative to self-monitoring of blood glucose levels in both T1 DM and T2 DM patients treated with intensive insulin therapy. The incremental cost effectiveness ratio of Freestyle Libre® falls within reasonable values of the willingness-to-pay thresholds for an additional QALY. The uncertainty of the results has been captured in the probabilistic sensitivity analysis, the results of which support the base case findings. The restricted populations within the IMPACT and REPLACE trials and the heterogeneity of the populations across the other evidence sources pose challenges to the generalisability of the model results to other populations. However, it is reasonable to assume the general conclusions are applicable to the Scottish real-world diabetes population.

The full comprehensive assessment can be found:

http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_advice_statements/advice_statement_009-18.aspx.

The Scottish evaluation was the first full cost effectiveness recognised that there would be an additional cost impact for the system in using the new device. They looked at both type one and type two diabetes, though in England, the use at present is advised in type one only.

In addition, Health Technology Wales issued a clinical consensus statement that said: "Consider as an option for patients testing eight or more times a day".

Initial forecasting in Dorset was informed by a comprehensive analysis and commissioning statement developed by the East of England. It is understood that although it has not yet been approved and published, the regional team and CCGs in that area are considering a restricted cohort based on a refinement of the RMOC North guidance, and that it would be restricted to Consultant prescribing only in adults and children with fixed funding arrangements and audit.

Initially the new device was not suitable for drivers, who also had to use blood glucose strips before driving. However, the DVLA in April 2018 agreed that they would update their guidance to include monitoring of interstitial glucose levels, but until this is published, recommend only blood glucose test strips. This update is awaited.

In August 2018, RMOC North, indicated that they will soon begin to evaluate the audits from the use of the device following publishing of their criteria. This is awaited.

In August 2018, the CCG Chief Officer, CCG Medical Director and the Head of Medicines Optimisation met with the Associate National Clinical Director, Diabetes, NHS England to discuss this product.

As a result, a revised proposal for use of Freestyle Libre was developed with the clinicians that led the first proposal. This was presented to the Clinical Commissioning committee and approved for a limited cohort of patients, and for initiation by specialists only. This was supported by the CRG.

The current approved use for adults is detailed in appendix 1.

The full detail of the Dorset position is published on the formulary website: www.dorsetformulary.nhs.uk.

A further application for use in children has been presented to the Dorset medicines Advisory Group (DMAG) in September 2018 from paediatric consultants in the county, led by a Dorset County Hospital clinician. This was favourably received by the DMAG and a recommendation is going forward.

The number of CCGs that have made this device available is increasing, however most are with restricted criteria, often more restricted than the RMOC North and many are restricting prescribing to specialists, and for a limited period pending audit. This applies to the majority of the south west. Dorset CCG is not a major outlier in the approach taken.

COMMISSIONING STATEMENT ON THE USE OF FREESTYLE LIBRE® SENSORS

SUMMARY
The NHS Dorset Clinical Commissioning Group commissions the use of FreeStyle Libre® sensors for a restricted group of adult* patients with Type 1 diabetes.

BACKGROUND	FreeStyle Libre® is a flash glucose monitoring system which monitors glucose levels using interstitial fluid levels rather than capillary blood glucose from finger prick testing. • It consists of a handheld reader and a sensor, which is sited on the back of the arm. When the reader unit is passed over the sensor, the reader shows a reading based on interstitial fluid glucose levels. The sensor lasts for up to 14 days and then needs to be replaced. • The reader can show a trace for the last eight hours and displays an arrow showing the direction the glucose reading is heading. Flash glucose monitoring is not the same as continuous glucose monitoring (CGM). • A finger-prick test using a blood glucose meter is still required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels (i.e. acute illness such as Influenza, diarrhoea and vomiting), if hypoglycaemia or impending hypoglycaemia is reported, or the symptoms do not match the system readings. • FreeStyle Libre® users will still need to perform finger-prick blood tests prior to and during driving to meet current DVLA requirements, as FreeStyle Libre®, like CGM, measures interstitial fluid levels and not capillary blood glucose levels, though new legislation is anticipated and this may change when published.
RELEVANT NICE GUIDANCE	NICE MedTech Innovation Briefing https://www.nice.org.uk/advice/mib110 "A key uncertainty around the evidence is that the randomised controlled trial of people with type 1 diabetes included only adults whose diabetes was well controlled. The resource impact is uncertain, and depends upon the extent to which improved glucose control through the adoption of FreeStyle Libre® translates into fewer complications, reduced emergency admissions and less use of glucose test strips." http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_advice_statements/advice_statement_009-18.aspx *"Based on the results of the analysis presented, the Freestyle Libre® flash glucose monitoring technology appears likely to be a cost-effective alternative to self-monitoring of blood glucose levels in both T1 DM and T2 DM patients treated with intensive insulin therapy. The incremental cost effectiveness ratio of*

	Freestyle Libre® falls within reasonable values of the willingness-to-pay thresholds for an additional QALY. The uncertainty of the results has been captured in the probabilistic sensitivity analysis, the results of which support the base case findings. The restricted populations within the IMPACT and REPLACE trials and the heterogeneity of the populations across the other evidence sources pose challenges to the generalisability of the model results to other populations. However, it is reasonable to assume the general conclusions are applicable to the Scottish real-world diabetes population."
FORMULARY STATUS	RED- for the following patient groups only 1. Type 1 Diabetic adult patients who are pregnant 2. Type 1 Diabetic adult patients with loss of hypoglycaemia awareness who have experienced a hypoglycaemic episode requiring assistance 3. Type 1 Diabetic adult patients who require third parties to carry out monitoring and where conventional blood testing is not possible Patients will be required to agree to a patient contract for use of the device to maximise potential benefit and undertake training on how to use the device. Results will be shared for audits of effectiveness.
PBR STATUS	Inclusive of tariff
COMMISSIONING IMPLICATIONS	It is yet to be established whether this treatment represents a cost-effective treatment option for the NHS, and data gathered from this limited cohort should be used to inform national data assessments.
RELEVANT CLINICAL DELIVERY GROUP	N/A
PATIENT PATHWAY IMPLICATIONS	There is a formulary for blood glucose testing strips for patients with Type 2 diabetes that has been expanded and updated. Patients with Type 1 diabetes are not restricted to this Formulary. For patients identified as meeting the criteria for use of Freestyle Libre in Dorset, the specialist service will need to arrange training, patient contract and appropriate follow up to establish that the product has shown benefit. Prescribing responsibility during this period remains with the specialists.
SUMMARY OF EVIDENCE TO SUPPORT FORMULARY STATUS	There is limited data to confirm that use of FreeStyle Libre® will result in better controlled diabetes, an improvement in patient oriented outcomes such as a reduction in complications due to poorly controlled diabetes, hospitalisation rates or ambulance/GP call out rates, improvement in overall long-term diabetes control or quality of

	life. More data is also required to confirm effectiveness of this technology in less well controlled diabetes. This limited cohort initiation will allow more data to be gathered to support use of the device. There is limited data to support the routine use in children and young people.
ASSESSMENT OF COST IMPLICATIONS	Current prevalence data suggests that 432 patients per 100,000 population have type 1 diabetes. If all eligible patients were switched to FreeStyle Libre® from current standard practice, the additional investment required is likely to be between £126k and £376k per 100,000 population (based on current retail price), excluding first year set up costs. In Dorset, this could amount to up to £2.86 million. For the cohort identified for initial use in Dorset it is estimated that there would be approximately 200 patients in total, spread across all sites and this should cost up to £200k.
REFERENCES	https://www.nice.org.uk/advice/mib110 https://westessexccg.nhs.uk/your-health/medicines-optimisation/clinical-prescribing-guidance/6-endocrine-system/3450-freestyle-libre-glucose-monitoring-system/file http://www.healthcareimprovementscotland.org/our_work/technologies_and_medicines/shtg_advice_statements/advicestatement_009-18.aspx
DATE	August 2018
REVIEW DATE	March 2019 or before, in light of new information, evidence or statutory guidance from NICE or other NHS bodies.

*this guidance is for use in Adults. An application for use in children is in process.