

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	6 th September 2016
Appraisal & Details	The Northern (NHS) Treatment Advisory Group considered an appraisal of FreeStyle Libre Flash (Abbott) Glucose Monitoring System .
Recommendation	<p>The Northern (NHS) Treatment Advisory Group recommends the use of FreeStyle Libre Flash Glucose Monitoring System as an option for continuous glucose monitoring (CGM) only and for patients who fulfil the NICE criteria for CGM and as per the North East and Cumbria CGM guidelines. However to note it does not include an alarm to indicate when hypoglycaemia or hyperglycaemia occurs.</p> <p>The FreeStyle Libre system consists of sensor worn on the upper arm that measures interstitial glucose every minute and a reader device that is scanned over the sensor to get a result. The FreeStyle Libre system is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with diabetes mellitus. The group noted that the product is classified as a device and received European CE mark certification in August 2014</p>
Clinical evidence summary	The majority of the trial data assessing the use of the Freestyle Libre device is only available in conference abstracts. A Medline and Embase search only found one trial that had been fully published. The only published study available to support the use of the Freestyle Libre was by Bailey et al. This study recruited 72 patients with type 1 or type 2 diabetes, at four sites all in the USA. The purpose of the study was to evaluate the performance and usability of the FreeStyle Libre device compared with capillary blood glucose results. The investigators concluded that interstitial glucose measurements via the FreeStyle Libre system were accurate compared with capillary blood glucose reference values, and this accuracy was maintained over 14 days lifespan of the Freestyle Libre sensor.
Safety	There is limited safety data available on the use of the Freestyle Libre device. The only published study carried out by Bailey et al study reported there were no unexpected adverse device effects reported during the clinical study. Finger prick capillary blood glucose monitoring is still advised during periods of rapidly changing levels of interstitial glucose when interstitial glucose levels may not accurately reflect blood glucose levels, if hypoglycaemia or impending hypoglycaemia is reported, or the patient's symptoms do not match the system readings.
Patient Perspective	The device may offer some advantages in terms of patient acceptability and quality of life and patients will be pleased at the option to use freestyle libre if suitable.
Cost analysis summary	The products are available to buy online (incl. VAT): FreeStyle Libre Reader + 2 x Sensors: £159.95; FreeStyle Libre Reader: £57.95 (has a 3 year lifespan before requiring a service); FreeStyle Libre Single sensor: £57.95 (each sensor as a life-span of 14 days). In comparison the cost of continuous glucose



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	monitoring varies according to which system is used. Starter kits which include the transmitter and the receiver cost approximately £1000. Sensors last for between 3 days and 7 days depending on which system is used and cost approximately £40-£60 each.
Financial impact PbR: In-tariff	The FreeStyle Libre readers and sensors are not currently prescribable on FP10. There is no robust, published information on how many patients would be eligible for continuous glucose monitoring in the NTAG region. However FreeStyle Libre is cheaper than other CGM systems.