South Sefton
Clinical Commissioning Group

Our Ref: FOI ID 47064

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Re: Freedom of Information Request

Please find below the response to your recent Freedom of Information request regarding FreeStyle Libre system services within NHS South Sefton CCG.

Request/Response:

- How many people have been successful in getting the FreeStyle Libre system prescribed since it was included on the NHS Drug Tariff in November 2017?

  NHS South Sefton CCG does not hold this information. You may wish to redirect your query to NHS England in regards to GP Practices and also the following providers:-

  NHS England.
  england.contactus@nhs.net

  Mersey Care NHS Trust
  freedomofinformation@merseycare.nhs.uk

  Aintree University Hospitals NHS Foundation Trust:
  FOIrequests@aintree.nhs.uk.

- What are the criteria on which decisions about prescribing the FreeStyle Libre system are made?

  NHS South Sefton CCG are part of the Pan Mersey Area Prescribing Committee. The criteria on which the decisions are being made are based on the NHS England Regional Medicines Optimisation Committee Position Statement, please see below.

  The Regional Medicines Optimisation Committee (North) reviewed the use of the flash glucose monitoring system, Freestyle Libre®, at its meeting on 26 October 2017.

The advice of this group to Area Prescribing Committees is as follows:

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.

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 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.

We 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 be discontinued and an alternative method of monitoring used.

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. Accessed 17/10/2017 via https://www.diabetes.org.uk/Documents/Position%20statements/DiabetesUK_Facts_Stats_Oct16. pdf

- What was the decision-making process for establishing the prescribing criteria for the FreeStyle Libre system?

NHS South Sefton CCG following the Pan Mersey Area Prescribing Committee process. Please see the link below.

http://www.panmerseyapc.nhs.uk/recommendations/documents/PS212.pdf