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PQ: 42645/19

To ask the Minister for Health the weighting percentages to be used as part of the upcoming HSE FreeStyle Libre review decision making process that will be given to criteria (details supplied); and if he will make a statement on the matter. -Louise O'Reilly.

Short term cost savings, quality of life improvements, improved glycaemic control and the impact of flash glucose monitoring in improved health outcomes which will delay the development of medium and long term complications.

Dear Deputy O'Reilly,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 42645/19), which you submitted to the Minister for Health for response.

In line with the recommendations of the HSE Health Technology Assessment Group (HTAG), the Freestyle Libre product was made available on an individualised basis to children and young adults (4-21 years) from 1st April 2018.
The Health Technology Assessment Expert Group had arrived at the following conclusions:

- The evidence suggests that, compared with Self-Monitoring of Blood Glucose (SMBG) alone, using the Freestyle Libre may facilitate better glycaemic control, in terms of hypoglycaemia, among certain sub-groups. Expert opinion considers the reduction in hypoglycaemia, observed in the IMPACT and REPLACE trials, are of clinical importance.

- There is limited data to support the routine use in people who are less well managed or in children and young people.

- The evidence suggests that using FreeStyle Libre may reduce the average number of SMBG tests needed and may facilitate an increase in the frequency of self-monitoring blood glucose. Use of the Freestyle Libre is likely to reduce the need for finger prick testing in patients in the order of 1-2000 times per year.

- There is insufficient evidence to demonstrate that use of the Freestyle Libre will lead to reduced ambulance call outs, Accident and Emergency usage or hospital admissions related to poor glucose control or will result in long-term improvements in patient outcomes.

- There are currently no high-quality, peer-reviewed studies that compare the Freestyle Libre system with Continuous Glucose Monitoring (CGM).

- There is insufficient evidence to suggest that the system is safe to use in the younger population and during pregnancy. Although, expert opinion sought by the HTA Expert Group suggests that there is no evidence of harm to patients.

- Based on the data presented, there is insufficient evidence to support the claim that the FreeStyle Libre could yield savings for the HSE.

The Health Technology Assessment Expert Group had also made the following recommendations:

1. The Freestyle Libre represents an innovative way of managing Diabetes requiring Multiple Daily Injections, and as such represents an advance in diabetes care.

2. Reimbursement for the device should be considered, but it is important that the conditions favourable to the best case scenario presented above are maintained.

    a. HSE reimbursing a maximum of 26 sensors per year, and
    b. All replacement units being provided by Abbott and
    c. HSE realising the benefit of a 90% reduction in SMBG monitoring, and
    d. The cost of blood glucose monitoring and ketone strips suitable for use with the FSL reader staying at current cost or lower.

3. This decision should be evaluated after one year, in the light of cost analysis and any additional evidence for effectiveness of the device (in particular in relation to longer term patient outcomes).

4. Risk sharing by way of limiting reimbursement to 26 sensors per year by the HSE, with the risk from faulty or unsatisfactory device life being borne by the company should be considered as part of any agreement.

5. Careful patient selection should be part of the agreement, with hospital consultant initiation, and preference for children and young adults in the first instance so that numbers being treated do not exceed that expected.

6. The cost of blood glucose and urine Ketone strips suitable for use with the device should be agreed as part of the overall agreement.

7. After a period of one year data on costs incurred by patients using the device in the PCRS system should be reviewed to ensure that costs are in line with expectations, and to help inform the continuation or otherwise of reimbursement.

Current Position: As per recommendations above, it was agreed that after twelve months, the situation including historical reimbursement data would be reviewed to inform next steps. PCERS now have 12 months data available and have collated it in recent months.
The reimbursement cost of FreeStyle Libre sensors for the 12 month period from 1st April 2018 was in the region of €1.8 million. The number of persons granted access under GMS and Community Drug Schemes during this time was 2,798 and includes 266 exceptional arrangements.
The HSE must be satisfied that the expected 'offset' reductions in glucose monitoring ancillaries materialise. Initial review indicates that some persons with diabetes continue to access comparable (if not more) levels of ancillaries in their pharmacy. Analysis of this data is ongoing.
It was considered that the availability of clinical data in the Irish setting would also be useful to inform next steps as that has a bearing on overall cost effectiveness.

In recent months the PCERS has taken the following steps to gather the relevant data for review by the HTAG.

1. Liaison with the National Clinical Programme for Diabetes to ask for their assistance to gather whatever research data is available in the Irish setting. Some (unpublished) has been provided by the Clinical Programme in recent weeks and has been shared with HTAG.

2. Collated the reimbursement data on strip usage for persons approved for Freestyle. Reductions in strip usage can be accurately measured through the reimbursement records held in PCERS on a patient specific basis as notified to the HSE through individual pharmacy claims on a monthly basis.

3. Collated the reasons for exceptional approvals

4. Provided the quantitative data to HTAG for their review. It will take some weeks for this to be conducted

5. Provided to HTAG the Diabetes Ireland Survey on the use of this product. The HTA process envisaged in the coming months does allow for patient experience and societal aspects of benefit to be considered.

PCERS have also recently written to a sample of patients asking for their assistance to understand why they appear to continue to use two systems of glucose monitoring i.e. strips and sensors. Initial review indicates that some persons with diabetes continue to access comparable (if not more) levels of ancillaries in their pharmacy. As it was anticipated that off set efficiencies would materialise to improve affordability, this is a very important aspect in our consideration whether further extensions are possible within the current financial constraints.

Additional Information
HTAG advice:
https://www.hse.ie/eng/about/who/healthwellbeing/htag/publications/htag-advice-note-freestyle-libre.pdf

Yours sincerely,

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Primary Care Eligibility & Reimbursement Service