



Réada Cronin, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

6th May 2022

PQ: 20886/22

To ask the Minister for Health if he will investigate the apparent impasse affecting the undertaking of a health technology assessment for FreeStyle Libre; if his Department will offer an alternative process for such assessment; and if he will make a statement on the matter. -Réada Cronin

Dear Deputy Cronin,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 20886/22), which you submitted to the Minister for Health for response.

FreeStyle Libre Flash Glucose Monitoring (FGM) sensors were made available on an administrative basis to people with Type 1 Diabetes in line with a recommendation accepted by the HSE from the Health Technology Advisory Group from 1st April 2018. Consultant Endocrinologists may apply to the HSE, on behalf of specific patients, for reimbursement support of FreeStyle Libre Flash Glucose Monitoring (FGM) sensors. The application process is undertaken by means of a dedicated online portal, which has been operational since 3rd April 2018. In line with the recommendations outlined of the Health Technology Assessment Group, access to this product was made available to children and young adults (4 -21 years).

In order to conduct a value assessment, the HSE requested that the National Centre for Pharmacoeconomics (NCPE) carry out a full Health Technology Assessment (HTA) on Freestyle Libre. The company Abbott were formally notified of this on April 13th 2021. Abbott had a scoping meeting with the NCPE in July 2021 and committed to submitting their HTA Dossier for end of October 2021. However, Abbott informed the PCRS that they would not be submitting the HTA dossier on 15th November 2021 because they did not have the level of Randomized Controlled Trials (RCT) evidence that they stated was required for a full HTA process. Despite the HSE emphasising the importance of engaging with the HTA to progress, the company will not be progressing with the HTA.

In the preparation of the National Service Plan, the HSE considered all of the service priorities to be delivered against all of the resources made available to it. Additional funding for extension of Freestyle Libre to other cohorts was not provided in the National Service Plan 2022. In the absence of a full value assessment of the product, the HSE is not in a position to remove the age restriction. However, the online application process does cater for the Consultant to make an application in very exceptional circumstances for a type 1 diabetic patient who is over 21 years of age.

The HSE Chief Clinical Officer has written to HIQA to ask them if they can consider a system wide HTA across diabetes care and await the outcome of this request. In the absence of a full value assessment, it is not possible to progress matters further at the moment.

It remains open to Abbott to re-engage with the NCPE as they indicated they would in July 2021.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Suzanne Doyle', written over a thin horizontal line.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service