Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Colm Burke, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

10th May 2022

PQ: 21327/22

To ask the Minister for Health the way that his Department is addressing inequalities in the uptake of continuous glucose monitoring sensors between the under 21 and over 21 years age groups; and if he will make a statement on the matter. - Colm Burke

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 21327/22), 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).

The report submitted relating to an annual saving of €4.2 million appears to be a synopsis of the recent figures for online applications and reimbursement issued by PCRS in relation to Parliamentary Questions and does not provide a comprehensive pharmacoeconomic evaluation of the product. It also does not appear to take into account the cost of traditional blood glucose testing ancillaries that are dispensed to person in receipt of FreeStyle Libre. It was anticipated that efficiencies in the use of blood glucose testing strips would be off-set against the cost of FreeStyle Libre sensors. However, internal analysis does not indicate that the projected savings envisaged in reduction of strip usage is materialising.

The FreeStyle Libre device which is currently marketed in Ireland is a Flash Glucose Monitoring (FGM) device. It is not a Continuous Glucose Monitoring (CGM) device. Whilst FGM shares a lot of common features with CGM there are definite differences between both. For example; CGM devices can connect to pumps and have built in alarms to alert for hypo's, FGM devices do not have these features. The report is extrapolating in an unscientific way that is without rigor in its assumptions.

CGM devices go through the HSE National Insulin Pump tender process and are provided locally via Aids and Appliances. There is a separate approval process for CGM devices at local level that includes the associated equipment such as a transmitter and/or a receiver and the application for approval must come from the diabetic team in the hospital setting. The ancillaries/ consumable products (sensors) associated with CGMs are available through the GMS Reimbursement List and are applied for by the company through the non-drug reimbursement application process to PCRS. In order to have a CGM added to the HSE National Tender, an application for the ancillary products also needs to be made concurrently to PCRS - it is a two-step process.

The FGM device of which there is only one marketed in Ireland at present, is provided free of charge by the company in the same manner as Blood Glucose Meters. FGM is a replacement for the use Blood Glucose Meters and does not have insulin pump connectivity or a transmitter. The only ancillary associated with FGM is the sensors. Therefore, the process for reimbursement is not through the HSE National Insulin Pump tender. Applications for addition to the GMS Reimbursement List are in line with the Health (Pricing and Supply of Medical Goods) Act 2013. Due to the budget impact associated with this product and that no additional funding has been provided for new technologies, PCRS introduced a reimbursement application system for FGM sensors.

In order to conduct a value assessment of rigor, 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,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service