



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Rannan na nOspideil Ghearmhíochaine
Aonad 4A – Áras Dargan
An Ceantar Theas
An Bothar Mileata
Cill Mhaighneann
BÁC 8

Acute Operations
Health Service Executive
Unit 4A - The Dargan Building
Heuston South Quarter
Military Road
Kilmainham
Dublin 8.

4th June 2020

Deputy Cian O'Callaghan TD
Dáil Éireann
Leinster House
Dublin 2

PQ 5205/20 **To ask the Minister for Health the steps he is taking to make kuvan available through Temple Street Children's University Hospital and the Mater Hospital for phenylketonuria patients; if his attention has been drawn to the distress caused to such patients and their families over a lack of testing in public hospitals providing children's and adult metabolic services to establish if they may respond to kuvan and the need to travel abroad to avail of testing; and if he will make a statement on the matter. -Cian O'Callaghan*

Dear Deputy O'Callaghan

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

My response to you dated 27th May also refers.

The National Centre for Inherited Metabolic Disorders (NCIMD) is located in Children's Health Ireland (CHI) at Temple Street. I am advised by CHI that, since August 2019, any newborns diagnosed with PKU have been tested in CHI at Temple Street and treated, when responsive, with Kuvan. In addition, a number of other known responsive patients have been treated.

Working within current staffing levels (medical, nursing and dietetics) in CHI at Temple Street, Kuvan has been available and trialled on all newly diagnosed infants with the condition Phenylketonuria since August 2019. A number of patients (known patients established on diet) have been highlighted by the team based on need and these children have also been trialled on the medication.

Since March 2020, in line with COVID-19 pandemic and national guidance, all elective admissions for trial of Kuvan have been on hold, for both newly diagnosed infants and established patients. However, the Metabolic team have continued to prepare patients for trialling of the medication. As CHI at Temple Street phased up its non-COVID-19 services, they will re-establish these admissions. Nursing management and Patient Flow have been working with the metabolic team to establish a suitable pathway for elective/essential admissions

taking into account the need to ensure physical distancing and other Infection Prevention and Control guidance.

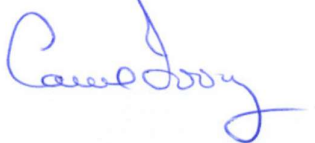
I am advised by the Mater Misericordiae University Hospital (MMUH) that there are currently three PKU adult patients followed at MMUH who are prescribed Kuvan for over 5 years.

I am also advised that for the majority of new drug approvals there is minimal or no non-drug costs associated with the treatment. However, for some rare diseases – primarily in paediatrics – some new drugs, like Kuvan, have significant assessment, monitoring and supervision requirements for treatment. In this case, additional key resources required are dietetic, nursing, laboratory and medical to especially assist at the pre-testing, testing and early treatment phases of Kuvan treatments.

I am advised that both CHI and MMUH will prepare submissions for additional resources for consideration within the 2021 estimates process to provide for these services.

I trust this is of assistance.

Yours sincerely,



Carol Ivory
General Manager, Acute Operations