Príomhoifigeach Cliniciúil
Oifig an Phríomhoifigigh Cliniciúil
Ospidéal Dr Steevens, Lána Steevens
Baile Átha Cliath 8 , D08 W2A8

Chief Clinical Officer
Office of the Chief Clinical Officer
Dr Steevens Hospital, Steevens Lane
Dublin 8, D08 W2A8

www.hse.ie
@hselive
t 01 635 2000
e cco@hse.ie

BY EMAIL ONLY

Deputy Bernard J Durkan
Dáil Éireann
Leinster House
Kildare Street
Dublin 2

16th December 2022

58186/22- Deputy Bernard J Durkan- To ask the Minister for Health the grounds upon which Evusheld which is used to prevent Covid-19 was not considered for emergency authorisation; and if he will make a statement on the matter.

Dear Deputy Durkan,

Thank you for your representation.

The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, from the resources available (provided) to it.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds.

The pricing and reimbursement of COVID-19 anti-viral agents is now incorporated into the well-established HSE medicines reimbursement process. The principles underpinning the assessment of new medicines are outlined in the framework agreement on the supply and pricing of medicines (IPHA Agreement 1/10/2021). The legislative basis underpinning the process includes the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE robustly assesses applications for pricing and reimbursement to make sure that it can stretch available resources as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

Following scientific assessment by the European Medicines Agency (EMA), tixagevimab / cilgavimab (Evusheld®) received marketing authorisation for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg from the European Commission on the 25th March 2022.

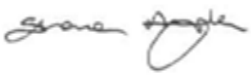
The HSE commissioned the rapid review process on the 9th March 2022 for the pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg. Following receipt of a rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) advised the HSE (11th April 2022) that a full Health Technology Assessment (HTA) was required. The HSE commissioned a full HTA on the 29th April 2022. A full HTA was submitted by the applicant company on the 16th of August 2022. On the 28th October 2022 the NCPE sent a

preliminary review to the applicant company. Following receipt of further information, on the 28th November 2022 the HTA re-commenced.

The NCPE website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Further details are available at https://www.ncpe.ie/drugs/tixagevimab-cilgavimab-evusheld-hta-id-22015/.

I hope this provides you with assistance.

Yours sincerely



Sharon Hayden
General Manager
Office of the CCO