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Paul Murphy, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

19th October 2022

PQ: 47935/22

To ask the Minister for Health the reason that evusheld has not been made available in Ireland given that it has been approved by the European Medicines Agency and is in wide use in Europe and America. -Paul Murphy

Dear Deputy Murphy,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 47935/22), which you submitted to the Minister for Health for response.

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.

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.

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

There are formal processes which govern applications for the pricing and reimbursement of medicines, and new uses of existing medicines, to be funded and / or reimbursed.

The HSE considers the following criteria prior to making any decision on pricing / reimbursement, in line with the Health (Pricing and Supply of Medical Goods) Act 2013:
(1) The health needs of the public,
(2) The cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,
(3) The availability and suitability of items for supply or reimbursement,

(4) The proposed costs, benefits, and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,
(5) The potential or actual budget impact of the item or listed item,
(6) The clinical need for the item or listed item,
(7) The appropriate level of clinical supervision required in relation to the item to ensure patient safety,
(8) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies) and,
(9) The resources available to the HSE.

In terms of the specific details of the pricing and reimbursement (P&R) assessment for Tixagevimab / Cilgavimab (Evusheld®):

Pre-exposure prophylaxis of COVID-19 in adults and adolescents aged 12 years and older weighing at least 40 kg:

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

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Phamacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 9th March 2022.

- The NCPE Rapid Review assessment report was received by the HSE on the 11th April 2022. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was required for this medicine.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 29th April 2022.

- The National Centre for Pharmacoeconomics (NCPE) publishes details on medicines where the HSE has commissioned a Rapid Review assessment on their website. The 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/

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. The pharmacoeconomic report will be reviewed by the HSE Drugs Group along with the outputs of any commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group will consider all of the evidence and make a recommendation to the HSE Executive Management Team.

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is

faced with (across all services) whether it can fund a new medicine, or new use of an existing medicine, from the resources that have been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

The application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

Treatment of adults and adolescents (aged 12 years and older weighing at least 40 kg) with COVID-19, who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19:

- Following scientific assessment by the European Medicines Agency (EMA), Tixagevimab / Cilgavimab (Evusheld®) received marketing authorisation for the treatment of adults and adolescents (aged 12 years and older weighing at least 40 kg) with COVID-19, who do not require supplemental oxygen and are at increased risk of progression to severe COVID-19 from the European Commission on the 16th September 2022.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier). The HSE-Corporate Pharmaceutical Unit (CPU) has not received a Rapid Review dossier from the Marketing Authorisation holder (AstraZeneca) to commence an assessment process for this indication to date.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service