



Bríd Smith, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

27th September 2022

PQ: 46973/22

To ask the Minister for Health if there are plans to make the drug evusheld available in Ireland given that it has been approved by the European Medicines Agency and is currently in use in Europe and America; the stage that these plans are at; when those who are immunosuppressed are likely have access to the drug; and if he will make a statement on the matter. -Bríd Smith

Dear Deputy Smith,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 46973/22), 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

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.

In terms of the specific details of tixagevimab / cilgavimab (Evusheld®):

The HSE requested the submission a rapid review dossier from AstraZeneca on the 22nd February 2022.

The HSE commissioned the rapid review process on the 9th March 2022. 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 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.

Yours sincerely,

A handwritten signature in black ink that reads "Suzanne Doyle". The signature is written in a cursive style with a horizontal line underneath the name.

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service