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 Róisín Shortall
Dáil Éireann
Leinster House
Kildare Street
Dublin 2

27th July 2022

PQ 39454/22- Deputy Róisín Shortall- To ask the Minister for Health the status of a product (details supplied); when he expects the full technology assessment to be completed; and if he will make a statement on the matter.

Dear Deputy Shortall,

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.

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®):

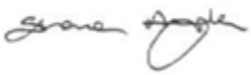
The HSE requested the submission a rapid review dossier from AstraZeneca on the 22nd February 2022.

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 formal pharmacoeconomic assessment (i.e. HTA) is completed by the NCPE in 90 days. As of the 22nd June 2022 a HTA dossier has not been submitted by the company, which is required for the NCPE to commence the assessment of the clinical benefits and the associated costs of this medicine.

I hope this provides you with assistance.

Yours sincerely



Sharon Hayden
General Manager
Office of the CCO