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BY EMAIL ONLY

Deputy Róisín Shortall
Dáil Éireann
Leinster House
Kildare Street
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11th October 2022

PQ 47440/22- Deputy Róisín Shortall - To ask the Minister for Health if his attention has been drawn to the approval of Evusheld for the treatment of Covid-19 by the European Union; if he intends to fast track approval of this treatment based on this decision; 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 assess 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 tixagevimab / cilgavimab (Evusheld®):

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 requested the submission of a rapid review dossier from AstraZeneca on the 22nd February 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 and the HTA appraisal is ongoing.

The 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/.

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 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.

I hope this provides you with assistance.

Yours sincerely

Sharon Hayden
General Manager
Office of the CCO