



BY EMAIL ONLY

Deputy Róisín Shortall
Dáil Éireann
Leinster House
Kildare Street
Dublin 2

27th July 2022

PQ 39455/22- Deputy Róisín Shortall-To ask the Minister for Health the estimated cost of treating a patient with a product (details supplied)

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.

As of the 22nd June 2022 the HSE has not agreed a price for tixagevimab / cilgavimab (Evusheld®) under the National Application, Assessment & Decision Process for new medicines which is set out in framework agreements with the pharmaceutical industry and underpinned by Primary Legislation (Health (Pricing and Supply of Medical Goods) Act 2013).

I hope this provides you with assistance.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sharon Hayden', written over a thin horizontal line.

Sharon Hayden
General Manager
Office of the CCO