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Primary Care Reimbursement Service
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Bernard Ryan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

8th October, 2019

PQ: 38591/19

To ask the Minister for Health the status of the rolling out of plenadren as an alternative hydrocortisone therapy here under the HSE drugs schemes in view of the fact it has been approved in the UK, Spain and the United States of America; and if he will make a statement on the matter. -Brendan Ryan

Dear Deputy Ryan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 38591/19), 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 using the resources available (provided) to it. In doing so, the HSE robustly assesses applications to ensure available resources can be stretched as far as possible and to deliver the best value in relation to each medicine and ultimately more medicines to Irish citizens and patients.

Were the HSE not to do so, the Irish taxpayer would be faced with funding demands of hundreds of millions in excess of current demands i.e. the assessment and decision making processes continue to deliver significantly improved offerings to the Irish State enabling the State to provide patient access to medicines. There are formal processes which govern the pricing and reimbursement of medicines and the application process for new medicines to be funded and / or reimbursed.

The HSE considers a pricing application for indicated uses in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act

2013. The HSE considers the following criteria prior to making any decision on funding / reimbursement:

(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 application for pricing and reimbursement of Modified-release Hydrocortisone (Plenadren®):

The HSE received an application for pricing / reimbursement in May 2016 for the treatment of adrenal insufficiency in adults.

Pursuant to Section 18 of the 2013 Act, the HSE has determined that the application in respect of Modified-release Hydrocortisone (Plenadren®)is refused (9th April 2019).

The HSE has not received a new application for reimbursement of Modified-release Hydrocortisone (Plenadren®) to date. The HSE remains open to receiving and considering a new application for reimbursement.

Yours sincerely,

Kieran Healy
Primary Care Eligibility & Reimbursement Service