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

19th October 2022

PQ: 48136/22

To ask the Minister for Health if he will include respreeza under the general medical scheme and or the drug payment scheme; and if he will make a statement on the matter. - Patricia 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 48136/22), 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.

The HSE carefully considered the pricing and reimbursement of human alpha1-proteinase inhibitor (Respreeza®) for maintenance treatment, to slow the progression of emphysema in adults with documented severe alpha1-proteinase inhibitor deficiency (e.g. genotypes PiZZ, PiZ(null), Pi (null,null), PiSZ) through its decision making processes, which were aligned with the statutory criteria set out in the Health (Pricing and Supply of Medical Goods) Act 2013.

Human alpha1-proteinase inhibitor (Respreeza®) was formally reviewed by the HSE Drugs Group and the HSE Leadership team / HSE Directorate.

In August 2017, the HSE decided that it would not support reimbursement of human alpha-1 proteinase inhibitor (Respreeza®).

The HSE can confirm it has not received any further pricing and reimbursement application for Human alpha1-proteinase inhibitor (Respreeza®) to date.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service