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David Cullinane, T.D.
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Leinster House,
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Dublin 2.

24th February, 2021

PQ: 9413/21

To ask the Minister for Health the drugs approval process for luxturna; and if he will make a statement on the matter. -David Cullinane.

Dear Deputy Cullinane,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 9413/21), 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

In terms of the specific details of the application for pricing and reimbursement of Voretigene neparvovec (Luxturna®):

The HSE received an application for pricing / reimbursement of Voretigene neparvovec (Luxturna®) on the 23rd of September 2019 from Novartis for the treatment of adult and paediatric patients with vision loss due to inherited retinal dystrophy caused by confirmed biallelic *RPE65* mutations and who have sufficient viable retinal cells.

- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process on the 24th of September 2019. Following receipt of a rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) advised the HSE (23rd of October 2019) that a full Health Technology Assessment (HTA) was required for this medicine

- The HSE commissioned a full Health Technology Assessment (HTA) on the 29th of October 2019 as per agreed processes

- The NCPE Health Technology Assessment report (http://www.ncpe.ie/wp-content/uploads/2019/10/Technical-Summary-document-voretigene-neparvovec-Luxturna.pdf) was received by the HSE on the 18th of September 2020. The NCPE recommended that Voretigene neparvovec (Luxturna®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications. CPU engaged in commercial negotiations with Novartis in November 2020 regarding their application for Voretigene neparvovec (Luxturna®)

- The Drugs Group is the national committee which the HSE has in place to make recommendations on the pricing and reimbursement of medicines. The membership of the HSE Drugs Group includes public interest members. Voretigene neparvovec (Luxturna®) was considered at the February 2021 meeting of the Drugs Group. The Drugs Group have requested Patient and Clinician Engagement input via the Rare Diseases Technology Review Committee (RDTRC) to assist the group in making its recommendation to the HSE Executive Management Team regarding reimbursement of Voretigene neparvovec (Luxturna®). The Drugs Group will review the output of the RDTRC at the earliest opportunity and will consider a reimbursement recommendation at that time

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new uses of an existing medicine, from the resources that have

been provided to it in line with the Health (Pricing and Supply of Medical Goods) Act 2013

The application remains under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service