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Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
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William Aird, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

16th May 2025

PQ: 21933/25
To ask the Minister for Health if her Department will engage with a company (details supplied) that has completed a HTA, for the provision of treatment for adults with spinal muscular atrophy; and if she will make a statement on the matter. -William Aird

Details Supplied:
Roche

Dear Deputy Aird,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 21933/25), 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 risdiplam (Evrysdi®):

Reimbursement approval is in place for risdiplam (Evrysdi®) for the treatment of 5q spinal muscular atrophy (SMA) under the High Tech arrangements from the 1st September 2023. Reimbursement support is for a subgroup of the licensed indication. As a condition of reimbursement, an individual patient approval system has been put in place by the HSE, to enable reimbursement for patients who meet the pre-defined criteria as per a HSE devised managed access protocol. Managed Access Protocol – Risdiplam (Evrysdi®) for the treatment of 5q Spinal Muscular Atrophy

If the manufacturer of risdiplam (Roche) submits a de novo application for adult patients with a clinical diagnosis of SMA Type 1, Type 2 or Type 3, that application will be duly progressed through the formal processes governing the pricing and reimbursement of medicines.

Yours sincerely,

Suzanne Doyle
Primary Care Reimbursement Service

The Health Service Executive operates the General Medical Services Scheme, which includes Medical Cards and GP Visit Cards, under the Health Act 1970, as amended. It has established a dedicated contact service for members of the Oireachtas specifically for queries relating to the status of Medical Cards and GP Visit Cards applications, which the Deputy / Senator may wish to use for an earlier response. Tel: 01-8647180 / email: Oireachtas.pcrs@hse.ie