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Peter Burke, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

4th October 2023

PQ: 40028/23

To ask the Minister for Health if he will review extending the access to a new treatment (deails supplied); and if he will make a statement on the matter.-Peter Burke

Details: Risdiplam (Evrysdi®) Last week the HSE announced that Risdiplam (Evrysdi®) was added to the High Tech Arrangement on 1st September 2023. A Managed Access Protocol (MAP) is in place for Risdiplam. This outlines the criteria that must be satisfied in order for a patient to be recommended for reimbursement of Risdiplam under the High Tech Arrangement. I understand that under this arrangement Risdiplam will be available to patients diagnosed with SMA type I, II & III between two months and 18 years. Patients over 18 who are already receiving Spinraza will be eligible to switch to Risdiplam. Patients already receiving Risdiplam under the Early Access Program will continue to receive the treatment for the foreseeable future. According to SMA Ireland there is roughly around 16 adults over the age of 18 who have been left behind and cannot apply for Risdiplam under this arrangement.

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 40028/23), which you submitted to the Minister for Health for response.

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.
https://www.hse.ie/eng/about/who/cspd/medicines-management/managed-access-protocols/risdiplam-evrysdi/risdiplam-evrysdi-managed-access-protocol.pdf

In terms of the specific details of an application for pricing and reimbursement of Risdiplam (Evrysdi®) for adult patients (>18 years):

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.

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 Eligibility & Reimbursement Service