Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
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Bernard J Durkan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

5th January 2023

PQ: 63112/22

To ask the Minister for Health the drugs that are currently available and approved by the HSE for the treatment of cystic fibrosis and other similar conditions, the medication which is awaiting approval in this country or in the European Union; when it is expected that those drugs still waiting for approval are likely to become available to patients likely to require the treatment; and if he will make a statement on the matter. -Bernard J. Durkan

Dear Deputy Durkan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 63112/22), 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 Long Term Illness (LTI) Scheme is a non-means tested, condition specific, prescription charge exempt primary care scheme overseen by the Primary Care Reimbursement Service (PCRS) within the HSE. The scheme commenced in 1970 through the Health Act (1970) and was last amended in 1975. To qualify, a patient must have one (or more) of sixteen eligible conditions. Cystic Fibrosis is one such specified eligible condition.

Drugs and non-drug items reimbursable under the Long Term Illness (LTI) Scheme are intended for the treatment of the primary condition. Core Lists were developed following detailed consultation with Medical Officers, HSE Pharmacists and HSE Medicines Management Programme. The HSE is satisfied that all medicines that should be necessary for the treatment of each primary LTI condition are provided on these Core Lists. The Core Lists are published on the HSE website at https://www2.hse.ie/services/schemes-allowances/lti/approved-medications/.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service