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John Paul Phelan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

19th October 2022

PQ: 50796/22

To ask the Minister for Health the amount of the 2021 and 2022 funding for approval of new medicines that was spent on non-oncology orphan medicinal products; and if he will make a statement on the matter. -John Paul Phelan

Dear Deputy Phelan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 50796/22), which you submitted to the Minister for Health for response.

'The HSE has statutory responsibility for decisions on pricing and reimbursement of medicines in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE is committed to providing access to as many medicines as possible, in as timely a fashion as possible, using the resources available (provided) to it and the HSE considers a range of proposals from Industry when assessing pricing and reimbursement applications. The 2013 Act enables the HSE to consider the terms of any framework agreement in place when it is making decisions in relation to pricing. The HSE robustly assesses applications to ensure available resources can be stretched 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 and are in line with the criteria set out under the Health (Pricing and Supply of Medical Goods) Act 2013. The HSE is required to consider the following criteria prior to making any decision on funding / reimbursement:

(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

NSP 2021 had an allocation of €50m and NSP 2022 had an allocation of €30m for new medicines, or new uses of existing medicines.

The HSE has negotiated a series of managed entry schemes or managed entry agreements (MEAs) for medicines it has approved in recent years, including medicines for rare diseases. These agreements include innovative financial or pricing measures including confidential rebates or discounts, budget caps and/or other outcomes based innovative measures such as clinical outcomes monitoring or aspects of payment by results. The preference of the HSE would be that such pricing arrangements would be clear and transparent, but suppliers and manufacturers of these medicines will generally only agree to such measures on the condition of commercial confidentiality. Notwithstanding the lack of transparency due to commercial confidentiality required by Industry these innovative measures do contribute significantly to reducing the cost of new therapies being reimbursed, thus improving both access and affordability of new medicines.

Due to conditions of commercial confidentiality placed on the HSE by pharmaceutical companies (when negotiating improved commercial terms) the HSE cannot provide details at individual medicine level of the net additional cost of the addition of medicines to the reimbursement lists.

The list on the following page details the new non-oncology medicines/new use of medicines that were approved for reimbursement in 2021-2022 YTD that maintained their orphan designation at the time of approval.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service

International Non-proprietary Name	Brand Name	HSE Reimbursement / Pricing Approval	5 Year Budget Impact (as reported in NCPE HTA Technical Summary, where publically available)
2022			
Tafamidis	Vyndaqel	Mar-22	€99,781,946
Ivacaftor, Tezacaftor, Elexacaftor (subset of 6-11 year licence)	Kaftrio	May-22	-
Pasireotide	Signifor	Jul-22	-
Inotersen	Tegsedi	Aug-22	€41,390,000
Obeticholic acid	Ocaliva	Oct-22	€21,500,000
2021			
Teduglutide	Revestive	Jan-21	€3,665,034
Tezacaftor, Ivacaftor (paediatric)	Symkevi	Jan-21	-
Letermovir	Prevymis	Feb-21	€2,800,000
Burosumab	Crysvita	May-21	€35,100,000
Ivacaftor, Tezacaftor, Elexacaftor	Kaftrio	Aug-21	-
Lanadelumab	Takhzyro	Sep-21	€11,300,000
Onasemnogene abeparvovec	Zolgensma	Oct-21	€26,200,000
Patisiran	Onpattro	Oct-21	€59,200,000
Cannabidiol (Dravet Syndrome)	Epidyolex	Dec-21	€2,600,000
Cannabidiol (Lennox-Gastaut Syndrome)	Epidyolex	Dec-21	€24,400,000
Cannabidiol (Tuberous Sclerosis Complex)	Epidyolex	Dec-21	-