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
Tel: 01- 8647100

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

2nd August 2023

PQ: 33545/23

**To ask the Minister for Health given the long wait times that patients experience for medicines subject to managed access protocols, if he can provide further details, in tabular form, on the timelines, from EMA approval to reimbursement, for all medicines subject to managed access protocols for the period May 2021 to April 2023; and if he will make a statement on the matter.-Colm Burke**

Dear Deputy Burke,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 33545/23), 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

Under Section 20 of the 2013 Act, the HSE may attach conditions to the supply or reimbursement. Under Section 20, subsection 2, such conditions may include one or more of the following:

(a) protocols for the supply of the listed items;
(b) the quantity of listed items which may be supplied or reimbursed, or both, during a specified period, in respect of a patient or a class of patients, or both, or in respect of patients in general;
(c) the period during which listed items may be supplied or reimbursed, or both;
(d) restrictions on the purposes for which listed items may be supplied;
(e) restrictions on the classes of prescribers who may prescribe the listed items;
(f) restrictions on the classes of patients who may be supplied with, or reimbursed under that section for, the listed items.

The HSE Drugs Group is the national committee that 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. The totality of clinical and economic evidence for a new medicine is comprehensively and extensively reviewed by HSE Drugs Group and a recommendation is then made. In cases where there is a high drug cost or a high potential budget impact, or where the marketing authorisation holder has only submitted a subset of the licensed population in their formal application for pricing and reimbursement, HSE Drugs Group may recommend reimbursement subject to the establishment of a HSE Medicines Management Programme (MMP) led managed access protocol in line with Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.

The decision making authority in the HSE is the HSE Executive Management Team (EMT). The HSE EMT 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 HSE EMT makes the final reimbursement decision.

Where a MMP led managed access protocol is recommended following the assessment process outlined above, the HSE MMP will develop and operate an individual patient approval system for the medicine.

The criteria used to inform a managed access protocol are based on the HSE EMT decision and HSE Drugs Group considerations, to ensure the managed access protocol is in line with the HSE reimbursement approval. The development of a managed access protocol includes consideration of the scientific data from the pivotal clinical trials that provide the clinical

evidence for the efficacy and safety of the medicines. It also takes into account any assessment carried out by the NCPE, including a Health Technology Assessment (HTA). This will ensure reimbursement is supported for patients who meet the pre-defined criteria, as per the HSE MMP managed access protocol.

Managed access protocols are published on the HSE website at https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/managed-access-protocols/. Reimbursement criteria for each medicine are individual and the HSE MMP engage with the relevant clinical programme in advance of the operationalisation and publication of the managed access protocol.

The table below summarises the medicines where a managed access protocol has been required (i.e. in line with the HSE EMT decision to support reimbursement) for decisions over the requested period of May 2021 to April 2023;

| INN | Brand | Date (month/year) of Market Authorisation (MA) | Pricing and Reimbursement Application Received (month/year) | Reimbursed from (month /year) |
|---|---|---|---|---|
| Dupilumab (atopic dermatitis adults) | Dupixent® | Sep-17 | Nov-17 | May-21 |
| Dupilumab (atopic dermatitis 12+ years) | Dupixent® | Aug-19 | Dec-19 | May-21 |
| Erenumab | Aimovig® | Jul-18 | Aug-18 | Sep-21 |
| Lanadelumab | Takhzyro® | Nov-18 | Mar-19 | Sep-21 |
| Patisiran | Onpattro® | Aug-18 | Dec-18 | Sep-21 |
| Fremanezumab | Ajovy® | Mar-19 | Apr-19 | Oct-21 |
| Onasemnogene abeparvovec | Zolgensma® | May-20 | Jun-20 | Oct-21 |
| Tafamidis | Vyndaqel® | Nov-11 | Mar-20 | Mar-22 |
| Dupilumab (atopic dermatitis 6+ years) | Dupixent® | Nov-20 | Aug-21 | May-22 |
| Upadacitinib (atopic dermatitis adults and 12+ years) | Rinvoq® | Aug-21 | Jun-21 | Feb-22 |
| Galcanezumab | Emgality® | Nov-18 | Dec-20 | Mar-22 |
| Tralokinumab | Adtralza® | Jun-21 | Jun-21 | Mar-22 |
| Abrocitinib | Cibinqo® | Dec-21 | Jan-22 | Jul-22 |
| Inotersen | Tegsedi® | Jul-18 | Aug-19 | Aug-22 |
| Obeticholic acid | Ocaliva® | Dec-16 | Jan-17 | Oct-22 |
| Rivaroxaban | Xarelto® | Aug-18 | Sep-18 | Oct-22 |
| Liraglutide | Saxenda® | Mar-15 | Sep-19 | Jan-23 |
| Larotrectinib | Vitrakvi® | Sep-19 | Nov-19 | May-23 |
| Eptinezumab | Vyepti® | Jan-22 | Jul-22 | Jun-23 |
| Voretigene neparvovec | Luxturna® | Nov-18 | Sep-19 | Ongoing |
| Dupilumab (asthma 12+ years) | Dupixent® | May-19 | Dec-21 | Ongoing |
| Delta-9-tetrahydrocannabinol/Cannabidiol | Sativex® | Jun-10 | Feb-18 | Ongoing |
| Risdiplam | Evrysdi® | Mar-21 | Apr-21 | Ongoing |

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service