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Ruairi O'Murchu, T.D.
Dáil Éireann,
Leinster House,
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27th January, 2021

PQ: 4802/21

PQ 4802/21 - To ask the Minister for Health when the HSE, executive management team will consider the recommendations and decide on the approval for reimbursement of the drug dupilumab; and if he will make a statement on the matter. -Ruairí Ó Murchú.

Dear Deputy O'Murchu,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 4802/21), 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 funding / 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 HSE has received pricing and reimbursement applications for the following indications for Dupilumab (Dupixent®):

- Treatment of moderate-to-severe atopic dermatitis in adults who are candidates for systemic therapy
- Treatment of moderate-to-severe atopic dermatitis in adolescents 12 years and older who are candidates for systemic therapy

In terms of the specific details of the application for pricing and reimbursement of Dupilumab (Dupixent®):

- The HSE received an application for pricing / reimbursement of Dupilumab (Dupixent®) on the 10th November 2017 from Sanofi (the applicant) for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy

- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process on the 13th November 2017. Following receipt of a rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) advised the HSE on the 24th November 2017 that a full Health Technology Assessment (HTA) was required for this medicine

- The HSE commissioned a full Health Technology Assessment on the 29th November 2017 as per agreed processes

- The NCPE health technology assessment report (http://www.ncpe.ie/wp-content/uploads/2017/11/Website-Summary-Dupilumab.pdf) was received by the HSE on the 12th December 2019. The NCPE recommended that Dupilumab (Dupixent®) be considered for reimbursement if cost-effectiveness could be improved relative to existing treatments

- Subsequent to this, the HSE received an application for pricing / reimbursement of Dupilumab (Dupixent®) on the 13th December 2019 for the treatment of moderate-to-severe atopic dermatitis in adolescents 12 years and older who are candidates for systemic therapy. The HSE commissioned the rapid review process on the 17th December 2019. Following receipt of a rapid review dossier, the National Centre for Pharmacoeconomics (NCPE) advised the HSE on the 17th January 2020 that a HTA was not recommended and that Dupilumab (Dupixent®) should not be considered for reimbursement at the submitted price (http://www.ncpe.ie/drugs/dupilumab-dupixent-hta-id-19056/)

- The HSE Corporate Pharmaceutical Unit (CPU) engaged in commercial negotiations with Sanofi in February 2020 regarding the applications for both the adult and adolescent populations

- The HSE Drugs Group is the national committee which 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 final HTA report (adults), the Rapid Review (adolescents) was reviewed by the HSE Drugs Group, along with the outputs of commercial negotiations, and the patient group submission received during the HTA process. The HSE Drugs Group considered all the evidence and made a recommendation not to support reimbursement of Dupilumab (Dupixent®) for the treatment of moderate-to-severe atopic dermatitis in both adults and adolescents 12 years and older who are candidates for systemic therapy to the HSE Executive Management Team. https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-march-2020.pdf

- 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 considered this medicine and has supported the HSE Drugs Group recommendation not to support reimbursement. The decision of the HSE EMT was received by the CPU on the 14th July 2020

- Where the HSE EMT has considered a recommendation of the Drugs Group, and when circumstances arise where it is minded to accept a Drugs Group recommendation of non-reimbursement, the HSE is legally required (in line with the Health [Pricing and Supply of Medical Goods] Act 2013) to set out in detail a notice of any proposed decision to an applicant company. The HSE where such circumstances apply, is also legally required to provide at least a 28 day period (from the formal written notice of proposal) to enable an applicant company to consider any such proposal not to reimburse and to make representations to the HSE where it is so minded. The HSE is legally required to consider any such representations in advance of a formal decision

- The CPU issued a formal notification to the applicant (Sanofi) of the proposed decision not to support reimbursement of Dupilumab for the treatment of moderate-to-severe atopic dermatitis on the 21st August 2020

- Sanofi submitted representations on the 18th September 2020 in response to the formal notification of the proposed decision of the HSE not to support reimbursement of Dupilumab for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents aged 12 years or older who are candidates for systemic therapy

- The HSE Drugs Group reviewed these representations at their January 2021 meeting. The Drugs Group supported reimbursement for a defined subgroup of the full licensed indication i.e. moderate-to-severe atopic dermatitis in refractory adults and adolescents 12 years and older for whom immunosuppressant treatment has failed, or is not tolerated or is contraindicated

- The HSE EMT subsequently supported reimbursement of Dupilumab under High Tech Arrangements subject to a managed access programme being implemented and that reimbursement is restricted to a defined subgroup of the full licensed indication i.e. moderate-to-severe atopic dermatitis in refractory adults and adolescents 12 years and older for whom immunosuppressant treatment has failed, or is not tolerated or is contraindicated

- As part of the National Service Plan 2021 and budgetary process, the HSE has worked closely with the Department of Health to secure a significantly enhanced budget of €50m for new medicines in 2021. Funding of Dupilumab will be from this allocation

- As a condition of reimbursement an individual patient approval system will now be implemented by Primary Care Reimbursement Services (PCRS) to enable reimbursement for patients who meet the pre-defined criteria as per the Medicines Management Programme (MMP) devised managed access protocol that is in development

- The HSE cannot comment on the time line for the HSE approval to be formalised as the processes required to implement the managed access programme are currently ongoing.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & 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