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Patricia Ryan, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

26th June 2024

PQ: 25738/24

To ask the Minister for Health when the 1,500 people living with lupus in Ireland can expect to be given access to belimumab and aniflolumab for the treatment of systemic lupus erythematosuswhen the 1,500 people living with lupus in Ireland can expect to be given access to belimumab and aniflolumab for the treatment of systemic lupus erythematosus; and if he will make a statement on the matter. -Patricia Ryan

Dear Deputy Ryan,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 25738/24), 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.

In terms of the specific details of the application for pricing and reimbursement of Belimumab (Benlysta®):

- The HSE received a new application for pricing and reimbursement of Belimumab (Benlysta®) on the 21st April 2023 from GSK (the applicant) as add-on therapy in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 24th April 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 29th May 2023. A full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Belimumab (Benlysta®) compared with the current standard of care, on the basis of the proposed price relative to currently available therapies. (https://www.ncpe.ie/belimumab-benlysta-for-systemic-lupus-erythematosus-hta-id-23022/)

- The HSE commissioned a full Health Technology Assessment (HTA) on the 31st May 2023 as per agreed processes.

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications.

- The 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 HSE Drugs Group consider all of the evidence and make a recommendation to the HSE Executive Management Team. The totality of clinical and economic evidence for Belimumab (Benlysta®) was comprehensively and extensively reviewed by the Drugs Group at the January 2024 meeting. The Drugs Group unanimously did not recommend in favour of reimbursement of Belimumab (Benlysta®). https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use 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 Executive Management Team supported the Drugs Group recommendation not to reimburse Belimumab (Benlysta®) as add-on therapy in patients aged 5 years and older with active, autoantibody-positive systemic lupus erythematosus (SLE) with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy.

In terms of the specific details of the application for pricing and reimbursement of Anifrolumab (Saphnelo®):

- The HSE received an application for pricing and reimbursement of Anifrolumab (Saphnelo®) on the 19th May 2023 from AstraZeneca (the applicant) indicated as an add-on therapy for the treatment of adult patients with moderate to severe, active autoantibody-positive systemic lupus erythematosus (SLE), despite standard therapy.

- The first step in the process is the submission of a Rapid Review dossier (a clinical and economic dossier) to the National Centre for Pharmacoeconomics (NCPE) for assessment. The HSE commissioned the Rapid Review process on the 19th May 2023.

- The NCPE Rapid Review assessment report was received by the HSE on the 14th June 2023. A full health technology assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of Anifrolumab (Saphnelo®) compared with the current standard of care, on the basis of the proposed price relative to currently available therapies.

- The HSE commissioned a full Health Technology Assessment (HTA) on the 5th July 2023 as per agreed processes.

- The NCPE publishes details of medicines where the HSE has commissioned a Rapid Review assessment and / or a full health technology assessment on their website. The website is updated at regular intervals and includes assessment outcomes and updates on reimbursement for each individual medicine and indication listed. Details of the assessment(s) of Anifrolumab (Saphnelo®) are available at: https://www.ncpe.ie/anifrolumab-saphnelo-hta-id-23027/

- The HSE Corporate Pharmaceutical Unit (CPU) is the interface between the HSE and the Pharmaceutical Industry in relation to medicine pricing and reimbursement applications.

- The 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 HSE Drugs Group consider all of the evidence and make a recommendation to the HSE Executive Management Team. The totality of clinical and economic evidence for Anifrolumab (Saphnelo®) was comprehensively and extensively reviewed by the Drugs Group at the January 2024 meeting. The Drugs Group concluded that a full HTA should be conducted to assess the clinical effectiveness and cost effectiveness of Anifrolumab (Saphnelo®) and that a robust deliberation could not take place in its absence. https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/

- The decision making authority in the HSE is the HSE Executive Management Team. The HSE Executive Management Team decides on the basis of all the demands it is faced with (across all services) whether it can fund a new medicine, or new use 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.

Both applications remain under consideration with the HSE. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service