Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas,
Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

Mairead Farrell, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

6th October 2025

PQ: 49580/25

To ask the Minister for Health the plans in Budget 2026 to provide for Belimumab for those with lupus who are in urgent need; and if she will make a statement on the matter. -Mairéad Farrell

Dear Deputy Farrell,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 49580/25), 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 applications for pricing and reimbursement of belimumab (Benlysta®):

Systemic lupus erythematosus (SLE)

The HSE received an application for pricing and reimbursement on the 21st April 2023 from GSK (the applicant) for belimumab (Benlysta®) indicated 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. The NCPE advised the HSE that a full Health Technology Assessment (HTA) was recommended to assess the clinical effectiveness and cost effectiveness of belimumab 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 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 CPU met with GSK regarding their application for belimumab (Benlysta®).

- 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 considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team. The totality of clinical and economic evidence for belimumab (Benlysta®) indicated as add-on therapy in patients aged 5 years and older with active, autoantibody-positive SLE with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy along with the outputs of commercial negotiations was comprehensively and extensively reviewed by the Drugs Group at the January 2024 meeting. The Group unanimously recommended against hospital pricing approval / reimbursement under High Tech arrangements of belimumab (Benlysta®) indicated as add-on therapy in patients aged 5 years and older with active,

autoantibody-positive SLE with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-january-2024.pdf .

- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership 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 Senior Leadership Team supported the Drugs Group recommendation not to reimburse belimumab (Benlysta®) indicated as add-on therapy in patients aged 5 years and older with active, autoantibody-positive SLE with a high degree of disease activity (e.g., positive anti-dsDNA and low complement) despite standard therapy.

Lupus nephritis:

The HSE received an application for pricing and reimbursement on the 21st April 2023 from GSK (the applicant) for belimumab (Benlysta®) indicated in combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis.

- 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 16th May 2023. The NCPE advised the HSE that a full HTA was recommended to assess the clinical effectiveness and cost effectiveness of belimumab 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-lupus-nephritis-hta-id-23021/)

- The HSE commissioned a full 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 CPU met with GSK regarding their application for belimumab (Benlysta®).

- 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 considers all of the evidence and makes a recommendation to the HSE Senior Leadership Team. The totality of clinical and economic evidence for belimumab (Benlysta®) in combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis along with the outputs of commercial negotiations was comprehensively and extensively reviewed by the Drugs Group at the January 2024 meeting. The Group by majority recommended against hospital pricing approval / reimbursement under High Tech arrangements of belimumab (Benlysta®) in combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis

https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/hse-drugs-group-minutes-january-2024.pdf .

- The decision making authority in the HSE is the HSE Senior Leadership Team. The HSE Senior Leadership 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 Senior Leadership Team supported the Drugs Group recommendation not to reimburse belimumab (Benlysta®) in combination with background immunosuppressive therapies for the treatment of adult patients with active lupus nephritis.

In line with the Health (Pricing and Supply of Medical Goods) Act 2013, the HSE has provided formal written notice to the applicant of the HSE Senior Leadership Team's proposed decisions not to reimburse belimumab (Benlysta®) for the above outlined SLE and lupus nephritis indications. The applicant has been afforded the opportunity to make representations to the HSE on these proposed decisions. The HSE cannot comment on potential outcomes pending the notice of proposal and representation process.

Yours sincerely,

Suzanne Doyle
Primary Care 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