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

Cormac Devlin, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

11th October, 2022

PQ: 46710/22

To ask the Minister for Health the status of the roll-out under the drug treatment scheme of the new prescription medication, inclisiran which is used to treat high cholesterol in persons with an adverse reaction to statins; and if he will make a statement on the matter. -Cormac Devlin

Dear Deputy Devlin,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 46710/22), 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 Inclisiran (Leqvio®) from Novartis (the applicant):

- The HSE commenced the assessment for pricing / reimbursement of Inclisiran (Leqvio®) on 20th November 2020, for adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet:
  - In combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
  - Alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated

- The first step in the process is the submission of a Rapid Review dossier. The HSE commissioned the Rapid Review process on the 23rd November 2020.

- The NCPE Rapid Review assessment report was received by the HSE on the 16th December 2020. The NCPE advised the HSE that a full HTA was recommended to assess the clinical effectiveness and cost effectiveness of Inclisiran (Leqvio®) compared with the current standard of care. https://www.ncpe.ie/drugs/inclisiran-leqvio-hta-id-20051/

- The HSE commissioned a full Health Technology Assessment (HTA) on the 6th January 2021 as per agreed processes.

- The NCPE Health Technology Assessment was received by the HSE on the 23rd March 2022 (https://www.ncpe.ie/wp-content/uploads/2020/12/Inclisiran-Technical-Summary-20051.pdf). The NCPE recommended that Inclisiran (Leqvio®) not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments.

- 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 role of the CPU is to manage the process around pricing and reimbursement applications for new medicines received by the HSE from industry and to lead on pricing negotiations with individual companies around specific medicines. CPU have met with Novartis regarding their application for Inclisiran (Leqvio®) and further engagement from the applicant company is now awaited.

- 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 pharmacoeconomic report will be reviewed by the HSE Drugs Group along with the outputs of commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group will consider all of the evidence and make a recommendation to the HSE Executive Management Team.

- 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 application for Inclisiran (Leqvio®) remains under consideration. The HSE cannot make any comment on possible outcomes from the ongoing process.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service