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John Lahart, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

17th July 2024

PQ: 30114/24

To ask the Minister for Health if there are plans to update the reimbursement criteria for heart failure patients with reduced ejection fraction to align with European cardiology guidelines (details supplied); if he is aware that this update could potentially save 2,000 to 4,000 outpatient appointments annually, cut outpatient appointment costs and ultimately reduce mortality and hospitalisation risks for patients;; and if he will make a statement on the matter. -John Lahart

Dear Deputy Lahart,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 30114/24), which you submitted to the Minister for Health for response.

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

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 pharmacoeconomic report will be reviewed by the HSE Drugs Group along with the outputs of any commercial negotiations, and any patient group submission(s) received. The HSE Drugs Group considers all of the evidence and makes 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.

Entresto® (sacubitril+valsartan) became available for reimbursement on 1st December 2017. Due to the relatively high cost associated with this treatment (as compared with many other treatments for heart failure) approval was granted on condition of the establishment of a managed access process for a subset of the licensed population (i.e. those with a left ventricular ejection fraction of ≤ 35% and who already are receiving optimal medical therapy for heart failure).

An online reimbursement application system was established to manage this process for the HSE. Clinicians are required to apply for reimbursement approval on an individual patient basis for Entresto®.

Further information on this process is available at the following link: https://www.hse.ie/eng/about/who/cspd/medicines-management/managed-access-protocols/sacubitril-and-valsartan-entresto/.

Amendments to the approved HSE reimbursement criteria for a particular managed access process (e.g. different subgroup(s)/patient populations/place in therapy) may be considered if the Marketing Authorisation Holder (MAH) submits additional clinical evidence to the HSE. In such cases, the HSE can consider the updated clinical evidence, along with information relating to cost-effectiveness and the potential budget impact of the proposal to facilitate an informed decision.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service