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BY EMAIL ONLY

Deputy Duncan Smith
Dáil Éireann
Leinster House
Kildare Street
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12th July 2024

PQ27349/24- Deputy Duncan Smith- To ask the Minister for Health if he is aware that Ireland has not yet implemented international guidelines recommended by a medical organisation (details supplied) when it comes to treating heart failure patients with reduced ejection fraction; when he intends to instruct the HSE to adopt the organisation's guidelines which would mean that patients can use an ARNI as a first-line therapy, reducing mortality and hospitalisations by 20%, and reducing on average the number of appointments they have to attend by four, thus helping to reduce cardiology waiting lists significantly; and if he will make a statement on the matter.

Dear Deputy Smith,

Thank you for your representation.

The HSE has statutory responsibility for decisions on pricing and reimbursement of medicines under the Community Drug Schemes, in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013.

HSE decisions on which medicines are reimbursed by the taxpayer are made on objective, scientific and economic grounds, on the advice of the National Centre for Pharmacoeconomics (NCPE). 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. These processes are individual to Ireland under the Health (Pricing and Supply of Medical Goods) Act 2013.

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 totality of clinical and economic evidence for a new medicine is comprehensively and extensively reviewed by the HSE-Drugs Group and a recommendation is then made. In cases where there is a high drug cost or a high potential budget impact or where only a subset of the licensed population has been put forward for consideration, the HSE-Drugs Group may recommend reimbursement subject to

the establishment of a HSE-Medicines Management Programme (MMP)-led managed access approach, in line with Section 20 of the Health (Pricing and Supply of Medical Goods) Act 2013.

The decision-making authority in the HSE is the HSE-Senior Leadership Teams (SLT). The HSE-SLT 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-SLT will make the final reimbursement decision.

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.

I hope this provides you with some assistance.

Yours sincerely

Sharon Hayden
General Manager
Office of the Chief Clinical Officer