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Catherine Connolly, T.D.
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Leinster House,
Kildare Street,
Dublin 2.

1st March 2022

PQ: 10212/22

To ask the Minister for Health his plans to include treatments for hyperemesis in the drugs payment scheme; and if he will make a statement on the matter. -Catherine Connolly

Dear Deputy Connolly,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 10212/22), which you submitted to the Minister for Health for response.

Cariban (doxylamine / pyridoxine) is an unlicensed product that is not reimbursable under GMS and Community Drug Schemes. Only licensed products are added to the formal GMS Reimbursement List in line with the Health (Pricing and Supply of Medical Goods) Act 2013.

The HSE has a standard assessment process in place for pricing and reimbursement approval of new medicines. This process is intended to arrive at decisions on the funding of medicines that are clinically appropriate, fair, consistent and sustainable. The reimbursement process is underpinned by statutory legislation, the 2013 Act. The HSE does not reimburse medicines or agree reimbursement terms in advance of the completion of the required processes.

Pharmaceutical companies are required to submit formal applications if they wish their medicines to be added to the list of reimbursable items / funded via hospitals. This process first involves a company making an application and submitting a clinical and economic dossier to support its pricing and reimbursement application. That dossier is reviewed by experts at the National Centre for Pharmacoeconomics (NCPE). The NCPE then provides a report to the HSE in relation to the company dossier. The NCPE process also enables the provision of a Patient Interest Group Submission. The NCPE uses a decision framework to systematically assess whether a drug is cost-effective as a health intervention. The NCPE makes recommendations on reimbursement to assist HSE decisions.

The HSE must then consider the report and the pricing & reimbursement application from the company. Frequently the HSE Corporate Pharmaceutical Unit will engage with companies to discuss and explore solutions to issues raised in NCPE reports.

The HSE has a national committee, the HSE Drugs Group, which is set up to provide advice to the HSE Executive Management Team (EMT) arising out of the information included in the NCPE report, the company response, patient interest group submission and any commercial discussions. The responsibility of the Drugs Group is to make a recommendation in relation to each individual application having considered the criteria set down by the Oireachtas in relation to pricing and reimbursement of new medicines.

The HSE must consider the following criteria prior to making any decision on funding / reimbursement:
(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

Final Decision making is reserved to the HSE Executive Management Team (EMT).

In terms of the specific details of the application for the pricing and reimbursement of doxylamine / pyridoxine (Xonvea®):

- The HSE received a pricing and reimbursement application for doxylamine / pyridoxine (Xonvea®) tablets on the 23rd July 2019 for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management.
- The first step in the process is the submission of a rapid review dossier. The HSE commissioned the rapid review process for this medicine on 23rd July 2019.
- A rapid review assessment was completed by the NCPE on 15th August 2019 in line with agreed processes. The NCPE advised that "A full Health Technology Assessment is not recommended. The NCPE recommends that doxylamine / pyridoxine (Xonvea®) not be considered for reimbursement at the submitted price".
- 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 has received and reviewed the NCPE rapid review assessment report. https://www.ncpe.ie/drugs/doxylamine-pyridoxine-xonvea/
- CPU has made contact with the company responsible for commercialization of this medicine to request an update on whether it intended to proceed with the application for pricing and reimbursement of Xonvea®. The company has recently responded to outline that they are not in a position to commercially launch Xonvea® in Ireland at this point in time.

- The HSE Corporate Pharmaceutical Unit consider that the pricing and reimbursement application for Xonvea® is now closed.

To date, a pricing and reimbursement application has not been received by the HSE for the licensed product Navalem® (Doxylamine / Pyridoxine).

To date, a pricing and reimbursement application has not been received by the HSE for the licensed product Exeltis® (Doxylamine / Pyridoxine).

It should be noted that in reviewing the Summary of Product Characteristic (SPC) for the licensed products – Xonvea®, Navalem® and Exeltis®, it states "there is limited evidence in cases of hyperemesis gravidarum for the combination doxylamine/pyridoxine. These patients should be treated by a specialist."

As the pricing and reimbursement process has now closed, the HSE has asked the Medicines Management Programme to examine the appropriateness and feasibility of a patient specific arrangement for the product.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service