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Jennifer Whitmore, T.D.
Dáil Éireann,
Leinster House,
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20th March 2023

PQ: 10867/23

To ask the Minister for Health if the HSE has calculated the additional cost burden on the healthcare system due to an increase in hyperemesis gravidarum patients presenting at emergency services to get an initial cariban prescription from an obstetrician consultant instead of their GP, so that they can claim back the cost of cariban under the new reimbursement scheme; and if he will make a statement on the matter. -Jennifer Whitmore

Dear Deputy Whitmore,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 10867/23), which you submitted to the Minister for Health for response.

As part of Budget 2023, the Minister announced €32.2 million in funding for Women's Health Initiatives in 2023, to include dedicated funding for Cariban® (doxylamine/pyridoxine). Cariban® is an Exempt Medicinal Product i.e. not licensed with the Health Products Regulatory Authority (HPRA) in Ireland.

An exceptional arrangement was put in place effective 1st January 2023 to support the reimbursement of the Exempt Medicinal Product (EMP), Cariban® (doxylamine/pyridoxine), under the Community Drug Schemes for the treatment of nausea and vomiting of pregnancy (NVP).

There are three combination products containing doxylamine succinate 10 mg/pyridoxine hydrochloride 10 mg licensed in Ireland:

- Xonvea® gastro-resistant tablets
- Navalem® modified-release hard capsules
- Exeltis® gastro-resistant tablets.

The Health Products Regulatory Authority (HPRA) granted Marketing Authorisations (MAs) to Xonvea®, Navalem® and Exeltis® in April 2019, May 2020 and December 2021, respectively.

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 National Centre for Pharmacoeconomics (NCPE) completed a rapid review for Xonvea® on 15th August 2019. The NCPE noted that doxylamine/pyridoxine is associated with a greater benefit than placebo but the size of the effect is small and the quality of the evidence is low. The NCPE outlined that there is no evidence presented for an increased clinical benefit for doxylamine/pyridoxine compared to other therapeutic options such as promethazine or cyclizine. The NCPE recommended that Xonvea® not be considered for reimbursement at the submitted price. To date the MA Holder of Xonvea® has not progressed the pricing and reimbursement application further with the HSE. The MA Holders for Exeltis® and Navalem® have not submitted pricing and reimbursement applications to the HSE to date.

The HSE therefore encourages clinicians, along with the Institute of Obstetricians and Gynaecologists and the National Clinical Programme for Obstetrics and Gynaecology, and other healthcare professionals to encourage the MA Holders of the licensed medicinal products (Xonvea®, Exeltis® and Navalem®) to progress with the formal pricing and reimbursement process in Ireland.

In the interim, due to the lack of a licensed and reimbursed alternative, the HSE has progressed with an exceptional arrangement to make the EMP Cariban® (doxylamine/pyridoxine) available to individuals, when initiated by a consultant following an assessment of their NVP.

Across all Community Drug Schemes and reimbursement arrangements, EMPs are expected to be consultant initiated (Ref: PCRS circulars 009/10, 039/16 and 012/23). However, whilst the original prescriber is expected to be a Consultant and specialist in the relevant field, the HSE will accept a GP prescription further to the initial hospital prescription for approved patients. This recommendation was made with the understanding that the HSE has no agreement in place with the manufacturers of EMPs, in terms of pricing and supply under the Health (Pricing and Supply of Medical Goods) Act 2013. Manufacturers can cease supply and increase the price of these medicines without consultation and notification to the HSE. Due to the uncertainty around the cost of EMPs, the HSE retains discretion as to the continued reimbursement support for any EMP. If a licensed product was subsequently approved for reimbursement this arrangement could then be reviewed/revised.

PCRS provide reimbursement support for Cariban® for approved patients under Community Drug Schemes in line with the processes above. PCRS have no role in hospital related costs such as those presenting at emergency services.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service