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BY EMAIL ONLY

Deputy Jennifer Whitmore
Dáil Éireann
Leinster House
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31st July 2023

PQ34188/23- Deputy Jennifer Whitmore- To ask the Minister for Health to outline the terms of reference for the HSE review of access to cariban under the drug payment scheme for sufferers of hyperemesis; who is leading the review and what stakeholders have been consulted for the purposes for the review; and if he will make a statement on the matter.

Dear Deputy Whitmore,

Thank you for your representation.

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) against the dedicated funding of €1.3m as part of Budget 2023. 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.

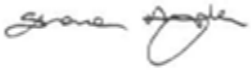
Following a review of the available evidence and in light of the exceptional circumstances of unmet clinical need for this patient cohort, the HSE considered the potential for a time-limited, quantity-dependent reimbursement arrangement for women with NVP, to access Cariban®

ULM, when prescribed by a consultant obstetrician and in line with clear clinical criteria, as set out by the HSE. This recommendation was made with the understanding that the HSE has no agreement in place with the manufacturers of Exempt Medicinal Products (EMPs) (i.e. unlicensed medicines), 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.

Since 1st January 2023, applications for this medicine are being processed by PCRs and are being turned around in a short timeframe. The HSE are undertaking a preliminary desktop review of Cariban®. However, as this medicine has been part of a reimbursement process since January this year it would be important to review the data over the course of the women's pregnancy. It is envisaged that this review will be completed this month.

I hope this provides you with some assistance.

Yours sincerely



Sharon Hayden
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