Seirbhís Aisíoca Príomhchúraim
Bealach amach 5 an M50, Án Bóthar Thuaidh, Fionnghlas, Baile Átha Cliath 11, D11 XKF3
Guthán: 01 8647100

Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: 01- 8647100

Martin Browne, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

27th February 2023

PQ: 6529/23

To ask the Minister for Health if he will provide in full the instructions given to consultants and midwives on the prescription of Cariban. -Martin Browne

Dear Deputy Browne,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 6529/23), which you submitted to the Minister for Health for response.

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.

Prior to finalising this exceptional arrangement, the HSE engaged with the National Women and Infants Health Programme and the Programme was in agreement that the burden of the application process was tolerable and that the peer clinical community would welcome any opportunity to progress this matter for women in their care.

As of 24th February, there are 567 applications from a number of maternity settings nationally, that have been received, processed and approved by the PCRS. Applications are being turned around in a short timeframe.

Yours sincerely,

Suzanne Doyle
Primary Care Eligibility & Reimbursement Service