South East London Integrated Medicines Optimisation Committee
Formulary recommendation

Reference:	**131**
Intervention:	**Doxylamine succinate 10mg/pyridoxine hydrochloride 10mg (Xonvea®) gastro-resistant tablets for treatment of nausea and vomiting in first pregnancy** (Doxylamine is a first-generation selective antihistamine; pyridoxine (vitamin B6) is a water-soluble vitamin)
Date of Decision:	**February 2022, updated August 2025 following report on outcome data, time limit to the approval removed and re-categorised from Amber 2 to Green**
Date of Issue:	**March 2022, re-issued October 2025**
Recommendation:	**Green – can be prescribed within agreed criteria for use in primary or secondary care**
Further Information	• Doxylamine succinate 10mg/pyridoxine hydrochloride 10mg (Xonvea®)* gastro-resistant tablets are accepted for use in South East London (SEL) as one of the **first line options** for the treatment of nausea and vomiting in pregnancy, in people experiencing their first pregnancy. • This recommendation does not cover the pre-emptive use of Xonvea® for the management of **hyperemesis gravidarum.** See below for further details. • Xonvea® is recommended as a first line option alongside the existing treatment options of cyclizine** and prochlorperazine**. The patient should be reassessed after 24 – 72 hours. Refer to the SEL adult Joint Medicines Formulary (SEL JMF) for further details. • In line with advice from the National Institute for Health and Care Excellence's (NICE) Clinical Knowledge Summaries guidance if first line treatment is ineffective, a second-line antiemetic can be trialled, such as oral metoclopramide** or ondansetron**. The patient should be reassessed after 24 hours. • Further guidance regarding the pharmacological management of nausea and vomiting in pregnancy is available via the following national resources: - NICE CKS guidance - nausea and vomiting in pregnancy - Royal College of Obstetricians and Gynaecologists guidance - management of nausea and vomiting of pregnancy and hyperemesis gravidarum • The continual need for Xonvea® should be regularly reassessed by the prescribing/responsible clinician and should include: - Response to treatment and - When to gradually stop treatment (the use of Xonvea® is generally for short term use). • Patients must be counselled on the appropriate administration and gradual tapering of Xonvea®, as described in the product information. • Xonvea® can be gradually tapered when nausea and vomiting in pregnancy has resolved. • nature of treatment with Xonvea™, it is recommended that prescriptions in primary care should be noted under the "acute" prescription list and not under the repeat prescription list on GP electronic patient record systems. • In addition to this recommendation, Xonvea® is also accepted for use in SEL for the pre-emptive treatment of **hyperemesis gravidarum** (severe nausea and vomiting) in subsequent pregnancies as Amber 1 (initiation in primary care following a recommendation to prescribe from an obstetric specialist). The initiation of Xonvea® for the pre-emptive treatment of hyperemesis gravidarum in primary care may be based on a recommendation from an obstetric specialist from a previous pregnancy and does not require a new specialist recommendation from an obstetric specialist. • Pre-emptive treatment is an **off-label** use of Xonvea®. Other approved treatments (off-label use) as Amber 1 are: cyclizine, prochlorperazine, metoclopramide and ondansetron. Refer to the SEL adult JMF for further details. • **August 2025:** In February 2022 the committee approved the formulary inclusion of Xonvea® in this setting for a time limited period to enable experience of use. A report summarising outcomes with the use of Xonvea® in this setting was presented to the Committee in August 2025 and found a beneficial response in almost two-thirds of

	patients treated. Approximately a fifth a patients had no response to treatment and a number of these patients switched to alternative treatment. No safety issues or adverse effects reported by patients treated with Xonvea® in this setting. * Xonvea® is licensed for the treatment of nausea and vomiting of pregnancy in women who do not respond to conservative management. ** Whilst established for use in nausea and vomiting in pregnancy, the use of cyclizine, prochlorperazine, ondansetron and metoclopramide is off-label in this setting.
Shared Care/ Transfer of care required:	N/A.
Cost Impact for agreed patient group	• Local experts estimate there will be approximately 460 patients per year initiated on Xonvea™, of which ~50 -100% (260 patients) will be from SEL. • For SEL, this equates to ~£75,000 per year (~ £4,000 per 100,000 population). • This costing is based on an average dose observed in trials of 3.6 tablets per day (the maximum dose is 4 tablets per day). • **August 2025:** It is anticipated the move from third line treatment to first line treatment for the use of Xonvea® in this setting may increase the number of patients eligible for treatment with Xonvea® by an additional 113 patients per annum. If Xonvea® is used instead of cyclizine, 6 weeks of Xonvea® costs £209.93 per patient (6-week course of cyclizine is £5.53). For the additional 113 patients per annum who may be prescribed Xonvea® as first line treatment in this setting, this equates to £23,722 per annum (£1,190 per SEL 100,000 population). This cost impact includes pre-emptive use and is estimated to be ~50% of patients treated.
Usage Monitoring & Impact Assessment	**Acute Trusts:** • Monitor and audit usage against this recommendation and report back to SEL IMOC when requested.
	SEL Borough Medicines Optimisation Teams: • Monitor primary care prescribing data • Exception reports from GPs if inappropriate prescribing requests are made to primary care
Evidence reviewed	**References (from evidence evaluation)** 1. Scottishmedicines.org.uk. 2019. Doxylamine succinate 10mg and pyridoxine hydrochloride 10mg gastro-resistant tablets (Xonvea®). [online] Available here [Accessed 14 December 2021]. 2. Awmsg.nhs.wales. 2019. AWMSG Secretariat Assessment Report Doxylamine succinate/pyridoxine hydrochloride (Xonvea®) 10 mg/10 mg gastro-resistant tablets. [online] Available here [Accessed 14 December 2021]. 3. Nice.org.uk. 2019. Evidence review Doxylamine/pyridoxine (Xonvea) for treating nausea and vomiting of pregnancy. [online] Available here [Accessed 14 December 2021]. 4. Cks.nice.org.uk. 2021. Scenario: Management | Management | Nausea/vomiting in pregnancy | CKS | NICE. [online] Available here [Accessed 14 December 2021]. 5. Rcog.org.uk. 2016. The Management of Nausea and Vomiting of Pregnancy and Hyperemesis Gravidarum. [online] Available here [Accessed 14 December 2021]. 6. http://tww-wafr/WAFR-FAD/Applications/ClinicalGuidance/DocumentViewer.aspx?d=5593 7. Koren, G., Clark, S., Hankins, G., Caritis, S., Miodovnik, M., Umans, J. and Mattison, D., 2010. Effectiveness of delayed-release doxylamine and pyridoxine for nausea and vomiting of pregnancy: a randomized placebo controlled trial. American Journal of Obstetrics and Gynecology, [online] 203(6), pp.571.e1-571.e7. Available at here [Accessed 14 December 2021]. 8. Zhang, R. and Persaud, N., 2017. 8-Way Randomized Controlled Trial of Doxylamine, Pyridoxine and Dicyclomine for Nausea and Vomiting during Pregnancy: Restoration of Unpublished Information. PLOS ONE, [online] 12(1), p.e0167609. Available here [Accessed 14 December 2021]. 9. Pope, E., Maltepe, C. and Koren, G., 2015. Comparing pyridoxine and doxylamine succinate-pyridoxine HCl for nausea and vomiting of pregnancy: A matched, controlled cohort study. The Journal of Clinical Pharmacology, [online] 55(7), pp.809-814. Available here [Accessed 14 December 2021]. 10. Boskovic, R., Einarson, A., Maltepe, C., Wolpin, J. and Koren, G., 2003. Diclectin Therapy for Nausea and Vomiting of Pregnancy: Effects of Optimal Dosing. Journal of Obstetrics and Gynaecology Canada, [online] 25(10), pp.830-833. Available here [Accessed 14 December 2021]. 11. Oliver L, Capp S, You W et al. Ondansetron compared with doxylamine and pyridoxine for treatment of nausea in pregnancy: a randomized controlled trial. Obstet Gynecol. 2014 Oct;124(4):735-742. 12. Matthews A, Haas D, Mathuna D et al. Interventions for nausea and vomiting in early pregnancy. Cochrane Database of Systematic Review 2015. 13. Medicines.org.uk. 2020. Xonvea 10 mg/10 mg gastro-resistant tablets - Summary of Product Characteristics (SmPC) - (emc). [online] Available here [Accessed 14 December 2021]. 14. Antenatal care NG201, August 2021. National Institute for Health and Care Excellence. Available here [Accessed 8 February 2022]

NOTES:

a) SEL IMOC recommendations and minutes are available publicly via the website.

b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.

c) Not to be used for commercial or marketing purposes. Strictly for use within the NHS.