

## April 2024 Update

### Primary Care actions for valproate reviews

In compliance with the MHRA [NPSA alert](#), North East London system valproate safety group has developed an action plan for all prescribers to support the implementation of these new legislative safety measures. The purpose is to strengthen the governance around the safe use of valproate in both women and men within North East London.

#### From 31 January 2024, the 2 new legislation changes are:

A	All initiations, in women and men, under 55 years must be agreed by two independent specialists with documented evidence that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply.
B	At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Annual Risk Acknowledgement Form (ARAF), to include a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

#### Action for practices:

Our advice to GPs has been to **not stop** the medication, unless otherwise advised to stop prescribing by a specialist. They have also been requested to reassure the patient and ensure that where appropriate, the patient is on a highly effective contraceptive. General patient-friendly information on contraception methods can be found on the NHS England [epilepsy](#) or [bipolar-disorder](#) decision tools and NICE has also produced professional guidance on highly effective contraception <https://bnf.nice.org.uk/treatment-summaries/contraceptives-hormonal/>

#### Additionally:

- To minimise additional pressure for appointments on secondary care, please **do not** initiate new referrals for all your existing patients who are known to Consultant Lead Clinics in secondary care.
- All secondary, community and mental health care providers within NEL ICS trusts have stated that they will review patients at their **next scheduled annual specialist reviews** as recommended by the alert. Patients that remain under the care of a specialist will be invited for this review as a scheduled appointment.
- For patients **who are not recorded as under the care** of a local specialist, should be referred to the appropriate specialist using the existing referral pathways
- Please encourage your patients to attend any offered appointments to discuss their treatment plan and to talk to a healthcare professional if they are concerned.
- In terms of the MHRA NPSA alert, men do not need to be referred to secondary care. Annual reviews are anticipated to expand to include men later in the year.
- Prescribe appropriate quantities so that pharmacists can dispense a manufacturer's original full pack which will include all the necessary safety information for the patient.
  - Where it is not in a patient's best interests to prescribe a full original pack, please document the reason in the patient record.
- Further information and educational materials to support the implementation of the new measures for valproate is available from MHRA's collection of valproate safety measures <https://www.gov.uk/government/collections/valproate-safety-measures>