

Wednesday 6<sup>th</sup> May 2020

## **Valproate Pregnancy Prevention Programme (PPP): temporary advice for management during coronavirus (COVID-19) pandemic**

The MHRA has issued the following temporary advice to ensure the PPP requirements can be met safely.

**Initiation** of valproate in girls (of any age) and women of childbearing potential requires face-to-face consultation, except where the patients are shielding due to other health conditions. Where the patient is shielding, a remote consultation should be considered based on an individual risk assessment by the clinician in charge that must be documented in the notes.

**Annual reviews** with a specialist should not be delayed due to the pandemic.

**Arrangements for annual review** - Specialist prescribers should undertake video virtual consultation (preferably) or telephone consultation (if video is not possible) with the patient in line with the following process:

1. Email or WhatsApp (if possible) the Valproate Patient Guide, and the Annual Risk Acknowledgment Form (ARAF) when booking the virtual appointment. If the patients do not have access to receive electronic files, this should be recorded in the notes and paper copies sent to the patient by post.
2. Prior to the appointment, check that the patient has received the information.
3. At the appointment, go through the ARAF together and get verbal confirmation that the patient understands the requirements of the valproate PPP. Consideration should be given to the need for a “responsible person” to support the discussion.
4. Ensure the patient has access to effective contraception. Where there are difficulties in accessing contraception, refer to [The Faculty of Sexual and Reproductive Healthcare guidance](#).
5. Document verbal confirmation that the patient understands the requirements of the PPP on the ARAF and record the reason a patient signature was not possible in the notes (remote working due to COVID-19).
6. Send a copy of the completed ARAF to the patient and their GP.
7. Ask the patient to confirm (via email/WhatsApp if possible) receipt of the ARAF, that it reflects the discussion with the prescriber and that they understand the requirements of the valproate PPP.
8. If (within 2 weeks) the patient refuses or fails to confirm in writing their receipt of the ARAF and their understanding of the requirements of the PPP, follow up with the patient to seek verbal assurance of receipt of the ARAF and understanding of the requirements and record this in the notes.

**Pregnancy testing** Where face-to-face consultation is not possible and pregnancy testing is required, home pregnancy testing could be acceptable, at the discretion of the clinician.



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**To maintain the supply chain do NOT over order any medicines**

### Vitamin B12 Update

The British Society for Haematology has updated its [guidance](#) on the replacement of hydroxocobalamin during Covid-19:

- The need for intramuscular (IM) hydroxocobalamin should be discussed with each patient individually. We recommend that screening questions for COVID-19 infection are asked before patients attend their GP surgeries. Alternatives to attending the GP surgery such as local pharmacies or home administration by district nurses should be explored.
- As an alternative, oral cyanocobalamin can be offered at a dose of 1 mg per day until regular IM hydroxocobalamin can be resumed, i.e. once GP surgeries are able to do so safely, aiming to have a shortest possible break from regular injections.

Local guidance will be amended accordingly. A licensed high strength formulation of oral cyanocobalamin is not currently available in the UK, so it will need to be prescribed as an unlicensed food supplement (either 1mg or 2 x 500microgram strengths).

### Routine vaccination schedule

With the current high profile of everything related to coronavirus, it is easy to overlook the importance of more routine interventions such as vaccination for diseases such as measles. In order to support the [RCGP](#) recommendation to continue with all routine immunisations, the NHS is running a [nationwide campaign](#) to encourage people to attend regular vaccination appointments. Vulnerable patients in high risk groups should be prioritised in line with RCGP guidance.

### Adverse effects – coronavirus tests and treatments

The MHRA has launched a new website for reporting side effects and incidents with tests, equipment and medicines that are directly employed in the diagnosis or treatment of covid-19: <https://coronavirus-yellowcard.mhra.gov.uk/>

### Inhaled beclometasone

For some parts of Hampshire, Soprobec is the beclomethasone containing inhaler of choice and where possible this continues to be prescribed. In other areas Clenil Modulite has been the main brand although there have been some difficulties with supply. To address the increased demand at this time issue additional batches of Clenil Modulite MDI 100microgram have been released into the UK supply chain, but the inhalers bear some visual differences to the ones that we are used to:



- The colours of the plastic actuator and protective cap are beige and yellow respectively (instead of brown and beige respectively)
- The beige actuator is not embossed
- There is no dose indicator

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