

**Roles and responsibilities in primary and secondary care around how to manage patients of childbearing potential on valproate medication – Commencing Valproate**

Patient presents to Specialist Team for review (e.g. via ED, GP)

Specialist tries first line treatment options and considers starting Valproate following failure/contraindications from alternative treatments, discussing risks and taking into account capacity and patient support as appropriate

Yes

Patient is > 55 years

No

One specialist can commence treatment. PPP does not apply. Enter patient onto valproate register. Specialist must prescribe minimum of 3 months' supply of valproate as per [SCP](#) before transfer of care to GP once patient stable.

Patient is Female

Patient is Male or Transgender-woman & can father children

Two specialists\* must independently consider and document that there is no other effective or tolerated treatment.

Two specialists\* must independently consider and document on the [RAF](#) that there is no other effective or tolerated treatment or the risk of infertility or potential risk of testicular toxicity do not apply. PPP does not apply. Risks should be discussed and where appropriate the need for contraception as per [guidance](#). Enter patient onto valproate register. Monitor and review in line with [SCP](#). **Copy of the completed & signed RAF and clinic letter to be shared with GP within timely manner.**

Females prior to menarche

Permanent absent risk of pregnancy (e.g., post-menopausal, hysterectomy)

Females post menarche and potential to get pregnant

Females prior to menarche do not need to be on PPP but they and their responsible person must be aware of risks for the future. Specialist to complete step 1 of the Annual Risk Acknowledgment Form ([ARAF](#)). Enter patient onto valproate register. Provide a copy of the [Patient Guide](#). Remind the responsible person to contact their GP once they experience menarche. GP to refer patient back to the specialist prescriber. Monitor and review in line with [SCP](#). **Copy of the completed & signed ARAF and clinic letter to be shared with GP within timely manner.** Transfer of care to GP once patient stable and Specialist must prescribe minimum of 3 months' supply of valproate as per [SCP](#).

The requirements of PPP are not necessary because there are compelling reasons to indicate no risk of pregnancy. Complete step 1 of the Annual Risk Acknowledgement Form ([ARAF](#)). Enter patient onto valproate register. Monitor and review in line with [SCP](#). **Copy of the completed & signed ARAF and clinic letter to be shared with GP within timely manner.** Transfer of care to GP once patient stable and Specialist must prescribe minimum of 3 months' supply of valproate as per [SCP](#).

PPP applies to this patient – she is of childbearing potential and at risk of pregnancy. See [Valproate HCP Guide](#)

Complete Annual Risk Acknowledgement Form ([ARAF](#)). Enter patient on to valproate register. Provide a copy of the [Patient Guide](#). Only commence valproate following a negative pregnancy test. Monitor and review in line with [SCP](#). **Copy of the completed & signed ARAF, clinic letter and shared care agreement to be shared with GP within timely manner.** Transfer of care to GP once patient stable and Specialist must prescribe minimum of 3 months' supply of valproate as per [SCP](#).

GP arrange to see female patients after Specialist review. **GP practice to ensure patient is on effective contraception\*\*** whilst on valproate and record on GP prescribing system (unless absence of risk suggests none required as assessed by specialist team). Add relevant SNOMED code to EMIS. **Prescribe in line with [SCP](#) and refer back to Specialist URGENTLY if patient planning a family or possibly pregnant.** Report any adverse reactions via [Yellow Card Scheme](#) and refer back to Specialist for advice. GP to add patients to practice valproate register. Remind all female patients that they will need to see their specialist prescriber annually. Notify Specialist of any significant change in patient circumstance that may affect the PPP.

## Roles and responsibilities in primary and secondary care around how to manage patients of childbearing potential on valproate medication – Existing Female Valproate Patients

Primary Care to run their EMIS/Ardens searches (ideally monthly) to identify females of childbearing potential on valproate medication to ensure they have an up-to-date annual valproate ARAF, annual specialist review, effective contraception (as appropriate).

Has the existing valproate patient had their annual review with Specialist?

Yes

No

- Existing female valproate patients called in for annual Specialist review.
- Females of childbearing potential** should be reviewed using the [ARAF](#), which will include the need for a **second Specialist signature\*** if the patient is to continue with valproate. Subsequent annual reviews with **one Specialist** unless the patient's situation changes.
- Specialist should consider whether another treatment would be appropriate, and risk/benefits of valproate reassessed at annual review.
- Copy of signed ARAF and clinic letter shared with GP practice in timely manner.**
- Specialist valproate register updated/review documented/next appointment booked.
- If review taken place but practice haven't received signed ARAF, practice to contact specialist team for a copy of form.

N.B. **Currently men < 55 years prescribed valproate do not need an annual review but new regulations for this group will be published in due course.** Male patients taking valproate should be made aware of the potential increased risk of neurodevelopmental disorders in children fathered by men on valproate in the 3 months prior to conception. Male patients on valproate who are planning a family in the next year should talk to their healthcare professional about their treatment.

GP practice to send an electronic referral as per **local referral pathway** to Specialist Team to request an ARAF form and review to be completed. Update EMIS with appropriate SNOMED code. If patient DNAs appointments, primary and secondary care to discuss and decide on appropriate next steps ensuring patient safety.

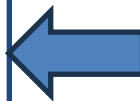
Once signed ARAF and specialist clinic letter received by GP practice, code in clinical system/EMIS using appropriate SNOMED code.



Primary Care to use the [Ardens template](#) where available to do annual review in line with valproate [guide for healthcare professionals](#). Discuss PPP where appropriate, ensuring effective contraception\*\* is used and the patient understands the need to comply with contraception throughout valproate treatment. Ensure [Patient Guide](#) given and check patient has a specialist review annually to discuss risks. Issue/generate a FP10 prescription for valproate (electronic or paper) as per Valproate [SCP](#).

Pharmacy to dispense valproate medicine in manufacturer's **original full pack as per new regulations**.

If there are **exceptional circumstances** why original full pack does not have to be supplied (e.g. requires monitored dosage system, mental health reasons) a [BNSSG Valproate Risk Assessment Form](#) (or similar such as risk assessment documented on pharmacy PMR system) needs to be completed.



Pharmacy to ensure:

- [Patient Card](#) is provided, and patient has received [Patient Guide](#) or knows they can access it online using the QR code on the package leaflet.
- Female patients have been made aware of the **risks in pregnancy**.
- Female patients have been made aware **to always use effective contraception\*\*** and to see their GP to be urgently referred to their specialist, should they be planning a pregnancy.
- Female patients have been made aware **NOT TO STOP valproate** and to immediately contact their GP for an **urgent** referral to their specialist (e.g., neurologist, psychiatrist and/or maternal medicine consultant) in case of suspected pregnancy.
- To dispense valproate in the **original package except if** exceptional circumstances, where a patient needs to receive their medication in different packaging, **ALWAYS** provide a copy of the package leaflet, the patient card and add a valproate warning sticker to the outer box.
- If a female patient reports that they are not continuously taking an effective method of contraception, they are not aware of the need for contraception or they have not been seen by their specialist in the past year, dispense their medicine and refer them to their GP (contact the GP if necessary).

\*The CHM advised that the second specialist signatory could include the following: • Consultant adult or paediatric neurologists • Consultant psychiatrists • Speciality and associate specialist doctors in psychiatry and neurology • Speciality doctors in psychiatry • Paediatrician with special interest in epilepsy • Paediatrician who regularly manages complex epilepsy or bipolar disorder • Epilepsy Nurse Consultant • Specialist Nurses in relevant disciplines.

\*\* MHRA Guidance on Pregnancy testing and contraception for pregnancy prevention during treatment with medicines of teratogenic potential, March 2019 <https://www.gov.uk/drug-safety-update/medicines-with-teratogenic-potential-what-is-effective-contraception-and-how-often-is-pregnancy-testing-needed>

## Glossary:

- ARAF – Annual Risk Acknowledgment Form (for females)
- PPP – Pregnancy Prevention Programme
- SCP – Shared Care Protocol
- MHRA – Medicines and Healthcare Products Regulatory Agency
- RAF – Risk Acknowledgment Form (for males)
- CHM – Commission on Human Medicines
- Transgender – woman: A term used to describe someone who is assigned male at birth but identifies and lives as a woman. This may be shortened to trans woman, or MTF, an abbreviation for male-to-female.<sup>1</sup>
- Transgender -man: A term used to describe someone who is assigned female at birth but identifies and lives as a man. This may be shortened to trans man, or FTM, an abbreviation for female-to-male.<sup>1</sup>

## Appendices:

- NHS Digital GP Practice SNOMED codes
- Valproate Original Pack dispensing risk assessment form
- Valproate Referral Pathways and Contact details for specialist teams
- Valproate resources
- BNSSG Valproate Shared care Protocol

## References:

1. Royal Pharmaceutical Society. *LGBTQIA+ related Microaggressions* [Online]. Available from: <https://www.rpharms.com/recognition/inclusion-diversity/microaggressions/lgbtqia> [Accessed 8th October 2024]