Regional Pathway for the management of patients prescribed Sodium Valproate

Final
June 2025

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1.0 Version Control

Version number	Purpose / Changes	Author	Date
1.0	• Initial Draft	[redacted]	12-03-2024
1.1	• Links to MHRA website added to Appendices • Content amended based on feedback from members of Valproate Task + Finish Group		03-04-2024
1.2	• Content amended based on feedback from members of Valproate Task + Finish Group		12-04-2024
1.3	• Pathway format restructured		07-05-2024
1.4	• Trust Sexual and Reproductive Health (SRH) services, as at May 2024 added.		20-05-2024
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1.6	• Pathway 3 aligned with MHRA guidance for Health Professionals • Glossary of terms included • Appendices 1, 2 and 3 added • Contact details for Support/information added		08-08-2024
1.7	• Grammatical amendments made • SRH details updated for WHSCT		03-09-2024
1.8	• Content amended to include transgender community • Appendices amended • Pathway 1 amended		11-09-2024
1.9	• Section on prescribing valproate to males updated under section 6.3		14-11-2024
2.0	• New Appendices added for GMC guidance and FSRH statement		19-02-2025

	• Paragraph added on women using highly effective contraception Page 16 Updated NICE guidance Page 20		
2.1	• New Appendices added for Risk Minimisation measures required for Valproate prescribing patient 55 and over • Risk Minimisation measures required for Valproate prescribing female 55 and under • Risk Minimisation measures required for Valproate prescribing for male 55 and under	[redacted]	15/03/25

2.0 Glossary of Terms

Abbreviation	Meaning
ARAF	Annual Risk Assessment form
BMI	Body Mass Index
CHM	Commission on Human Medicines
COC	Combined Oral Contraception
CS	Countersigning Specialist
FSH	Follicle Stimulating Hormone
GFR	Glomerular Filtration Rate
GP	General Practitioner
HCG	human chorionic gonadotropin
HSC	Health and Social Care
IUD	Intrauterine Device
LARC	Long Acting Reversible Contraception
MDT	Multi-Disciplinary Team
MHRA	Medicines + Healthcare Products Regulatory Agency
POP	Progesterone Only Pill
PPP	Pregnancy Prevention Programme
SP	Specialist Prescriber
SRH	Sexual + Reproductive Health
SUDEP	Sudden Death in Epilepsy

3.0 Introduction

This pathway sets out details for care providers on the care of patients prescribed valproate (as sodium valproate, valproate semi sodium, or valproic acid) in the management of any indication (including off-label use).

The care of patients prescribed valproate is shared between a wide range of services, which include, but are not exclusive to:

- Neurology
- Mental Health
- Learning Disability
- Pharmacy
- Sexual and Reproductive Health
- Paediatrics
- Obstetrics and Gynaecology
- GP's

It is expected that these services will work in partnership and collaboration to ensure patients have the correct advice and ease of access to the services they need.

This pathway refers to "men" and "women/females". These words refer to the sex assigned at birth, which we acknowledge may not be the same as the gender with which a person identifies. The rules for women/females apply to someone assigned

female at birth who is under 55. The rules for men apply to someone assigned male at birth. The rules might not apply if the person is unable to produce sperm or get pregnant, for example, if the person has had their womb, ovaries or testicles removed.

4.0 Context

Valproate (as sodium valproate, valproate semi sodium, or valproic acid; brand names Epilim®, Depakote®, Convulex®, Episenta®, Epival®, Syonell®, Belvo® and Dyzantil®) is approved in the UK to treat epilepsy and bipolar disorder. It is also sometimes used outside of the licence ('off label') to treat other conditions. Valproate can cause serious harm to an unborn baby if it is taken during pregnancy. In utero exposure to valproate is associated with serious adverse effects for the developing child, including:

- Congenital malformations. Affecting approximately 10% of cases, these include; neural tube defects (spina bifida, anencephaly), facial dysmorphia and cardiac malformations.

- Developmental disorders. Affecting approximately 30-40% of cases, these can include an increased risk of autistic spectrum disorder (approximately three-fold increase in risk), childhood autism (approximately five-fold increase in risk) and delays in early development. There is evidence that children exposed to valproate in utero may go on to have a lower IQ than children exposed to other antiepileptic drugs.

Due to these risks, it has been advised for some time that valproate should only be used in female children or in any woman able to have children (women of childbearing potential, that is 10-55 years) if other treatments do not work (ineffective) or are not tolerated.

If valproate is used in women of childbearing potential then the conditions of the Pregnancy Prevention Programme need to be followed. The Pregnancy Prevention Programme is designed to make sure patients are fully aware of the risks of valproate and agree to take steps to avoid becoming pregnant while taking this medicine.

The MHRA issued a patient safety alert on the risks associated with valproate for the under 55s in November 2023 (https://www.gov.uk/government/collections/valproate-safety-measures).

New regulatory measures in January 2024 for oral valproate mean that:

1. Valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply. For the majority of patients, other effective treatment options are available.

2. At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for 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.

Note: A similar system for male patients currently taking valproate is expected later in 2024.

5.0 Pregnancy Prevention Programme (PPP)

All women and girls of childbearing potential being treated with valproate medicines must be supported on a Pregnancy Prevention Programme. These conditions are also applicable to female patients who are not sexually active unless the prescriber considers that there are compelling reasons to indicate that there is no risk of pregnancy.

The Pregnancy Prevention Programme is a system of ensuring all female patients taking valproate medicines:

- have been told and understand the risks of use in pregnancy and have signed a Risk Acknowledgement Form
- are on highly effective contraception if necessary
- see their specialist at least every year

Full details of "Prevent – the valproate pregnancy prevention programme" and the accompanying risk management materials are available from the MHRA website:

Valproate Pregnancy Prevention Programme: actions required now from GPs, specialists, and dispensers - GOV.UK (www.gov.uk)

The Valproate Pregnancy Prevention Programme is supported by the following resources:

- **Patient Guide** (Patient guide): to be provided to girls (of any age) and women of childbearing potential (or their carers) who are started on or are continuing to use valproate medicines

- **Guide for Healthcare Professionals (**Medicines and Healthcare products Regulatory Agency (filecamp.com): for guidance to all prescribers, pharmacists, and other healthcare providers involved in the care of women and girls of childbearing potential using valproate medicines.

- **Risk Acknowledgement Form (**Medicines and Healthcare products Regulatory Agency (filecamp.com)**:** for the specialist and patient (or carer) to sign at initiation and at treatment reviews at least every year. The patient should receive a copy of the form; one copy should be filed in the specialist notes, and one copy sent to the patient's GP.

- **Risk Acknowledgement Form for Male patients starting valproate (**Medicines and Healthcare products Regulatory Agency (filecamp.com))

- **Patient Card (**Medicines and Healthcare products Regulatory Agency (filecamp.com)**:** to be given by pharmacists to all female patients who are dispensed valproate medicines to inform them of the risks.

- **Stickers with warning symbols (**Medicines and Healthcare products Regulatory Agency (filecamp.com)**:** for pharmacists to add to the packaging of valproate medicines where the manufacturer's packaging does not contain a visual warning symbol and warning text about the pregnancy risks and information about the new measures.

The **only exception** to PREVENT is when:

1. The specialist prescriber considers that there are reasons to indicate that there is no risk of pregnancy:

- The absence of risk of pregnancy is permanent (e.g., post-menopausal patients or those after hysterectomy).

- The absence of risk may change (e.g., the patient is pre-menarche). Although prevent does not apply to these patients, their treatment with valproate must be reviewed regularly and at least annually

2. Other treatments are ineffective or not tolerated, as judged by an experienced specialist.

Female children receiving valproate who have not yet reached menarche **DO NOT** need to fulfil the conditions of prevent, but they and their responsible person (parent/caregivers) need to be aware of the importance of the risks relating to exposure to valproate during pregnancy. Once menarche has been reached, the conditions of prevent should be discussed at the next annual review.

For circumstances in which a pregnancy prevention programme (PPP) is not appropriate, records must be kept of which decisions are taken, their justifications, and who was involved in decision-making. **Completion of a risk acknowledgment form is still required.**

The patient (or parent/caregiver/responsible person) must understand the risks and consent to treatment and agree to regular pregnancy testing as appropriate. All patients should be reviewed by their specialist annually and, where it is deemed appropriate for the individual patient, valproate should be withdrawn if alternative and safer treatments are suitable.

Any review should present the risks of withdrawing valproate or switching to alternative treatments, including the use of visual or other explanatory aids to support patients to understand their personalised risk. The risks of any loss of seizure control, a potential increased risk of sudden death in epilepsy (SUDEP), and deterioration of mental health on withdrawal of valproate should also be discussed. When deprescribing valproate, this should be tapered down gradually under the supervision of a specialist.

The conditions of "Prevent – the valproate pregnancy prevention programme" need to be maintained throughout the period of use of valproate medicines until discontinued. This includes patients who are switching to a therapy other than valproate medicines – the conditions of "Prevent – the valproate pregnancy prevention programme" should be continued until valproate has been discontinued.

6.0 Prescribing Valproate

Licenced Indications

- Epilepsy
- Bipolar disorder

Licensed indications vary by product and manufacturer.

Off-label use: restrictions and responsibilities still apply

Valproate is not licensed for treatment of conditions other than epilepsy or bipolar disorder in the UK. However, these medicines are sometimes used off-label (for example, in migraine prophylaxis). All women and girls of childbearing potential should meet the conditions of a Pregnancy Prevention Programme, irrespective of indication. All prescribers should be aware of their responsibilities when prescribing off-label.

Prescribers, and specialists making recommendations for treatment, must always carefully balance the benefits of valproate treatment against the risks. Valproate should only be used when other treatment options have been ineffective or have not been tolerated, as judged by an experienced specialist and confirmed by a second specialist. The ABN Guidelines for Valproate prescribing in Adult (16 and over) Neurology (Appendix 1) list those who require second signatory.

To align with the new regulatory measures in January 2024 for oral valproate, 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 (Consultant or Specialty Doctor) with special interest in epilepsy
- Epilepsy Nurse Consultant
- Specialist Nurses in relevant disciplines
- Specialist Pharmacist*.

**although not directly identified in MHRA guidance a pharmacist can be considered as a second signatory provided they have appropriate level of increased clinical oversight of valproate prescribing and meet the requirements of not being in direct line management of signatory. Where used this should be specified in local policy.*

The second signatory for initiation of valproate treatment and the decision to continue or switch valproate treatment **should not** be in direct line management of

the primary signatory. Multidisciplinary Teams (MDTs) could be used to discuss and agree a prescribing decision, with the second signatory being a representative of the MDT who meets the criteria for a specialist signatory.

6.1 Specialist Prescriber Responsibilities

1. Assess the patient and provide diagnosis.

2. Consider all other suitable therapeutic options before prescribing valproate. *(Valproate should only be initiated in patients for whom no other therapeutic options are suitable).*

3. Provide a copy of the Prevent Patient guide.

4. Fulfil Specialist Prescriber responsibilities under 'Prevent – the valproate pregnancy prevention programme'

5. Ensure female patients and/or their carer understand the risks relating to pregnancy exposure to valproate.

6. Use a shared decision-making approach; discuss the benefits and risks of the treatment with the patient and/or their carer and provide the appropriate counselling to enable the patient to reach an informed decision. Counselling should include the need for highly effective contraception. Use safety and educational materials during these discussions to support shared decision making.

7. Obtain and document patient consent.

8. Seek a second specialist (countersigning specialist) to independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks or potential risk of testicular toxicity are not applicable.

9.Perform baseline investigations & initial monitoring and ensure to complete the Annual Risk Acknowledgement Form.

10. Liaise with Trust sexual health service to arrange for appropriate contraception (IUD and LARC). Refer to section 7.0 of this document for contact details and referral pathways into these services.

If the patient has not been reviewed by secondary care in the last 12 months, the GP should arrange for referral to the specialist as well as sexual health services for review, and advise that this woman is on valproate in the referral letter.

11. Initiate and optimise treatment with valproate. Prescribe the maintenance treatment for at least 4 weeks and until optimised.

12. Notify the patient's GP that valproate has been initiated – detailing the diagnosis, current and ongoing dose, any relevant test results and when the next monitoring is required. Include a copy of the completed Risk Acknowledgement Form, and provide contact information for the specialist team.

13. Prescribe sufficient medication to enable transfer of prescribing to primary care and inform patient/carer of the arrangements for further prescriptions. Ongoing review of epilepsy will be carried out by secondary care. All patients will remain under the ongoing care of a named consultant/specialist.

14. Conduct the scheduled annual reviews and monitoring. This includes:
    - Review of the clinical condition;
    - Review treatment with valproate – were possible, existing patients should be switched to another treatment. Continue only if there is no other effective or tolerated treatment;
    - Completion of the Annual Risk Acknowledgement Form;
    - Referral to Sexual Health services who will discuss contraception, including a prompt to check when long-acting reversible contraceptives (e.g. implants, IUDs) must be renewed.

15. Discussions between clinicians and patients already on valproate must include counselling on alternative treatment options and the benefits and risks associated with any change for patients with epilepsy; this should include a discussion of the risks of sudden unexplained death in epilepsy (SUDEP).

16. After each review, advise primary care whether treatment should be continued, confirm the ongoing dose, and whether the ongoing monitoring outlined remains appropriate. Provide a copy of the updated Annual Risk Acknowledgement Form to primary care.

17. If a patient is planning pregnancy, they should urgently be referred into secondary care and advised to continue taking both their valproate medication and contraception until a review under secondary care has been conducted.

18. If a woman thinks they are pregnant, they should urgently be referred to secondary care and advised not to stop taking their valproate medication.

6.2 Follow up and Specialist review

1. Valproate must be reviewed by the patient's specialist at least once a year.

2. At each review the specialist should discuss the risks of valproate in pregnancy and complete and sign the Risk Acknowledgement Form with the patient or their carer.

3. At each review, prescribers must ensure that the benefits of valproate continue to outweigh the risks.

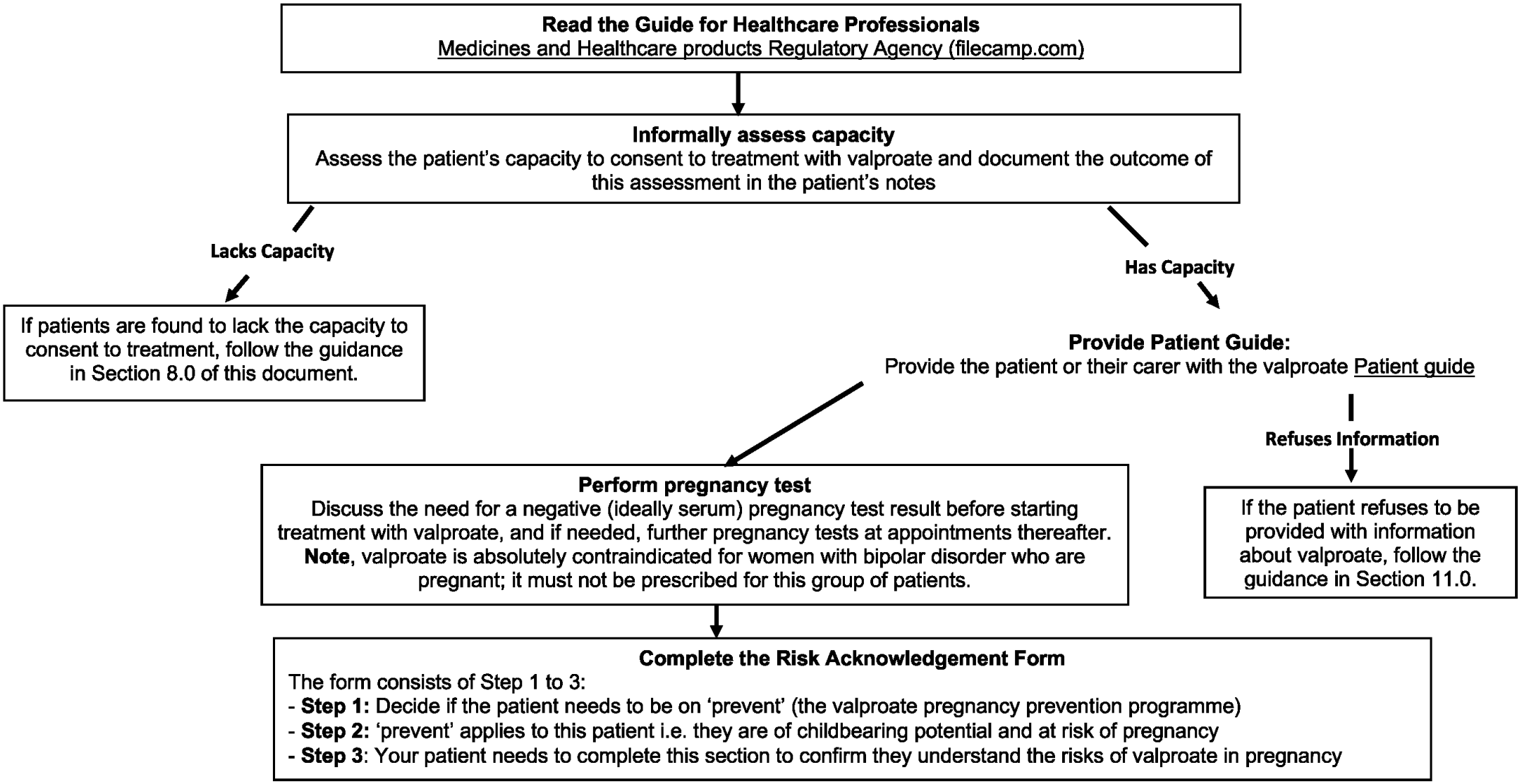
4. If a patient is prescribed valproate for the first time as an inpatient, a Risk Acknowledgement Form must be completed as an inpatient and MHRA regulations followed. The risks should be reemphasised to the patient when they are discharged.

5. Suspected side effects to valproate should be reported via the Yellow Card reporting scheme:
Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

Pathway 1 below summarises the actions that must be completed by anyone who initiates valproate, or who makes a recommendation for valproate to be prescribed, for a female patient under 55 years of age and of child bearing potential.

Pathway 2 summarises the actions for clinicians responsible for initiating the prescription of valproate in female patients under 18 years of age, however, it is recognised that the age at which females transition to adult services is managed at a local level and may vary between HSC Trusts/Services.

Pathway 1: Actions that must be completed by Specialist prescriber who initiates valproate, or who makes a recommendation for valproate to be prescribed, for a female patient under the age of 55 years with childbearing potential.



Pathway 2: Pathway for Specialist prescriber initiating the prescription of valproate in female patients under 18 years of age.

Female patient <18 years old possibly requiring treatment with sodium valproate

- Sodium valproate should be initiated by a Consultant with specialist training / expertise in epilepsy only.
- Patients must be reviewed by a specialist prescriber at least annually
- The Annual Risk Acknowledgment form (ARAF) completed, given to the parent/guardian, stored in medical notes and sent to the patient's GP

There is a permanent reason that there is no risk of pregnancy

- ARAF completed by specialist prescriber (SP). Countersigning Specialist (CS) not required.
- Complete Step 1 of the ARAF. Select "The absence of pregnancy risk is considered to be permanent" and give the reason (e.g. severe intellectual disability)
- PPP/ Step 2-4 do not need to be completed. Give parents the Patient Information Guide. Parents do not need to sign the form.

The patient has not yet reached menarche

- ARAF completed by specialist prescriber (SP), with countersigning specialist (CS) independently considering and documenting that there is no other "effective or tolerated" treatment.
- SP completes Step 1: "The patient has not yet reached menarche at the time of this appointment"
- SP completes Step 2 with all categories that apply e.g. "The patient's condition does not respond to other treatments or other treatments are not tolerated"
- CS reviews patient and independently completes step 2
- SP gives the parent/guardian the patient guide and a copy of the completed ARAF. SP tells parent/guardian to contact their epilepsy nurse/consultant if patient reaches menarche before the next appointment. Step 3 and Step 4 are not required until the patient reaches menarche.
- Renew the ARAF form annually until the patient reaches menarche. When the patient reaches menarche, follow the treatment pathway "**Patient has reached menarche AND NO permanent absence of pregnancy risk"**. CS signature is not required for subsequent reviews until the patient reaches menarche (or there is another significant change in circumstances).

The Patient has reached menarche AND there is current or future pregnancy risk

- ARAF completed by specialist prescriber (SP), with countersigning specialist (CS) independently considering and documenting that there is no other "effective or tolerated" treatment.
- SP completes Step 2 with all categories that apply e.g. "The patient's condition does not respond to other treatments or other treatments are not tolerated"
- CS reviews patient and independently completes step 2
- The SP completes Step 3, explicitly discussing each point with the parent/ guardian.
- The parent/guardian completes Step 4 putting their initial at each point, signing and printing their name. SP give the parent/guardian the Patient Guide and copy of the completed ARAF.
- Renew the ARAF form annually. CS signature is not required for subsequent reviews unless there is a significant change in circumstances

6.3 Prescribing Valproate in Males

1. inform male patients (of any age) who may father children of the possible risk at initiation of valproate or at their next regular treatment review – this counselling should be given irrespective of the indication for valproate and also after intravenous use of valproate
2. as a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate
3. at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options
4. if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling
5. advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate report any suspected adverse drug reactions associated with valproate on a Yellow Card

Information for healthcare professionals to provide to patients:

1. if you father a child while you are taking valproate or in the 3 months after stopping valproate, there is a potential small increased risk of the child being diagnosed with a mental or movement related developmental disorder (neurodevelopmental disorder).
2. it is recommended that you and your female sexual partner should both use effective birth control (condoms and another form of female contraception) as a precaution while you are taking valproate and for at least 3 months after stopping valproate.
3. allow at least 3 months to pass after stopping valproate before trying to father a child.
4. you should not donate sperm whilst taking valproate and for 3 months after stopping. Do not stop taking valproate unless you are advised to do so by a healthcare professional, report any suspected adverse drug reactions associated with valproate on a Yellow Card.

7.0 Contraception

Patients under the age of 55 who are prescribed valproate must use 'highly effective' contraception if they are able to become pregnant and pregnancy should be excluded before initiation on valproate medicines with a negative plasma pregnancy test, confirmed by a healthcare professional.

Highly effective contraception is considered for regulatory purposes to be those user independent methods such as:

- The long acting reversible contraceptives (LARC)
- Copper intrauterine device (Cu-IUD)
- Levonorgestrel intrauterine system (LNG-IUS)
- Progestogen only implant (IMP)
- Female sterilisation

These methods of contraception all have a failure rate of less than 1% with typical use. If highly effective contraception is not used, two complementary forms of contraception including a barrier method should be used and regular pregnancy testing considered.

Individual circumstances should be, in each case, evaluated when choosing the contraception method, involving the patient in the discussion to guarantee their engagement and compliance with the chosen measures.

Contraception methods which are not considered to be highly effective include the progestogen-only injectable, oral hormonal contraception, barrier methods (condoms, cap, diaphragm) and fertility awareness-based methods. These methods are not considered highly effective due to the higher failure rate with typical use, as outlined in Appendix 2. It is recognised that the use of COC and POP are the most popular methods of hormonal contraception. Women using progestogen-only implants must not take any interacting drugs that could reduce contraceptive effectiveness.

Additional contraceptive precautions (eg condoms or a second effective contraceptive method) are not required if a Cu-IUD, LNG-IUS, LARC, IMP or male or female sterilisation is being used. However, a woman may choose to use condoms in addition to reduce the risk of unintended pregnancy even further and for protection against sexually transmitted disease.

If any health professional is removing or ceasing a highly effective method of contraception on a female of child bearing potential who is currently prescribed valproate, they must:

- Refer back to specialist for review and;
- **Recommend alternative forms of contraception;**
- Confirm that they have been made aware about the risks of using valproate during pregnancy and ensure they have a copy of the Patient guide;
- Ensure that a prescription of high dose folic acid (5mg) for women who are planning pregnancy has been issued and advise them to commence treatment immediately.

Diagram 1 below lists the Trust Sexual and Reproductive Health (SRH) services, as at May 2024.

Diagram 1: Trust Sexual and Reproductive Health (SRH) services, as at May 2024

Trust	Details
South Eastern Health and Social Care Trust [redacted]	Central phone line (028) 90 413796, phone lines are open every Monday, Tuesday, Thursday and Friday from 09:00-12:30. Email: FamilyPlanning@setrust.hscni.net **Valproate** - Trust have a priority pathway for patients on valproate, referral via email above.
Western Health and Social Care Trust [redacted]	SRH clinic locations (clinics operate different days and times) Brae Clinic, Waterside Health Centre, 127-147 Spencer road BT47 6AH. Tel: 028 71 321758 Monday to Friday from 9am-1pm & 2:00pm-5:00pm Omagh Hospital and Primary Care Complex. Tel: 028 82 835536 Monday & Thursday from 9am- 1pm & 2:00pm-5:00pm Erne Campus South West College. Tel: 028 66 382 693 / 07920154737 South West Acute Hospital, Enniskillen. Tel: 028 66 382693 Wednesday from 9am-12.00 & 12.30-3.30pm **Valproate - Referral from healthcare professional –** complete attached referral and submit to email below for priority appointments. Service lead is attending trust valproate group. Referral Form Brae Clinic.docx Email: SRH@westerntrust.hscni.net
Northern Health and Social Care Trust [redacted]	CASH (Contraception and Sexual Health) Service - clinics operate on an appointment system. Central booking service / emergency contraception Tel: 028 28 266163 Email: SRH@northerntrust.hscni.net **Valproate** - Referrals from healthcare professionals to email above. No priority appointments related to valproate however trust has short waiting lists for LARC. Clinical lead is part of the trust valproate group. The Sexual Reproductive central booking line is open from 9:00am-5pm, Monday - Friday.

	Clinic locations: Causeway Hospital Mid Ulster Hospital Braid Valley Hospital Glengormley Community Clinics
Belfast Health and Social Care Trust [redacted]-***SRH Sister*** ***Admin lead -*** [redacted] ***Clinical lead -*** [redacted]	Central Hub-16 College Street Belfast BT1 6BT Some LARC clinics in Beech Hall, Carlisle & Holywood Arches Health & Wellbeing Centres **No walk-in contraceptive service-Phone first** **Telemedicine clinics (028 95 045500)** • **Monday to Thursday from 9am to 11:30am and 1.30pm to 3.30pm** • **Friday from 9am to 11.30am** **Medical & surgical abortion up to 12 weeks in the Rose Clinic-BPAS referral** **Valproate –** service have had meetings with Valproate Implementation Group and have developed a contraception referral form for other hospital specialities to refer directly to us as well as patients self-referring. This should go live very soon.
Southern Health and Social Care Trust [redacted] *Lead Nurse, CASH* [redacted]	CASH (Contraception and Sexual Health) Service - clinics operate on an appointment system. Tel: 028 37 562200 Email: contraception@southerntrust.hscni.net **Valproate -** Trust have a priority pathway for patients on valproate. Referral is via email above. Clinic locations: Portadown Health Centre John Mitchel Place, Newry South Tyrone Hospital, Dungannon Brownlow Health Centre, Legahory Centre, Craigavon Patients can use the following QR code to self-refer into the Contraception Service: 

8.0 Patients who lack capacity

All patients should be reviewed by their specialist, who is responsible for assessing their capacity relating to decisions regarding choice of medication. Where appropriate the specialist should enter discussion with the appropriate services as per local level arrangements regarding the patient's capacity and decisions relating to contraception and childbearing. If the patient lacks capacity, then the specialist is responsible for having these discussions with the patient's responsible person.

9.0 Patients where there is permanently no possible risk of pregnancy

In cases where there is permanently no possible risk of pregnancy, 'Step 1' of the risk acknowledgment form must still be completed and in such cases the risk does not need to be discussed in the next annual review and the requirements of 'prevent' (valproate pregnancy prevention programme) do not apply i.e. steps 2 and 3 of the risk acknowledgement form do not need to be completed.

10.0 Complex Patients – For whom the Pregnancy Prevention Programme cannot be fully met

Specialists must review patients who are currently prescribed valproate-containing medicines at least once a year. This review must include detailed consideration of the alternatives to valproate preparations, and their replacement whenever possible.

In exceptional circumstances, where it is deemed clinically necessary to prescribe Valproate for a patient who cannot meet the requirements of the PPP, then the responsible Consultant must discuss the case of the individual patient with another specialist for approval before prescribing.

It may also be appropriate to consider additional resources such as consultation with the multidisciplinary team to facilitate decision making. Each patient should be fully involved in the choices they make about their health and fertility.
All discussions, including those with the patient must be fully documented and the annual risk acknowledgement form must be completed and filed correctly. The consultant must have **compelling reasons** to indicate there is no risk of pregnancy and must document these on the annual risk acknowledgement form.

11.0 Patients who refuse information

Occasionally patients may not wish to receive information when valproate is prescribed, or they may not currently be receptive to such information.

However, if the initiation of valproate is considered to be absolutely necessary, then the prescriber must complete the following actions:

- Complete as much of the Risk Acknowledgement Form as possible at the current time, and add this to the patient's records.

- Ensure that another attempt to provide the information to the patient is made at the earliest possible opportunity.

- Make an entry in the patient's medical records stating why it was not possible to complete the full checklist, and why it was considered necessary to prescribe the medication despite this.

12.0 Further Information

12.1 Patient support networks

Any women or females of childbearing potential who are currently taking valproate should be provided with details of the following available support networks:

- Bipolar UK - 0333 323 3880
- Epilepsy Action - 0808 800 5050
- Epilepsy Society - 01494 601 400
- Mind - 0300 123 3393

Patients can also be provided with a copy of the Valproate Care pathway for patients as seen in Appendix 3 to help them understand the risks and benefits of valproate and the who the appropriate health professional is to contact is for advice/information.

12.2 Clinical resources

The following resources are available to support healthcare professionals understand their clinical responsibilities for valproate:

- NICE – Summary of guidance and safety advice
- NHS – Decision support tool: is valproate the right epilepsy treatment for me?
- Association of British Neurologists – ABN Guidelines for Valproate prescribing in Adult (16 or over) Neurology
- British Paediatric Neurology Association (BPNA) and the Royal College of Paediatrics and Child Health (RCPCH) – Joint guidance to provide recommendations about the use of valproate in female patients under 18 years of age
- BPNA, OPEN UK, RCPCH prescribing guidance document
- https://www.nice.org.uk/guidance/ng217/resources/epilepsies-in-children-young-people-and-adults-pdf-66143780239813

13.0 Dispensing Valproate

Appendix 7 summarises the actions that should be taken when dispensing Valproate to women of childbearing potential.

14.0 Actions for Gynaecologists/obstetricians, Midwives, Nurses, GPs and Family Planning Clinics

1. Provide counselling on methods of contraception and pregnancy planning in non-pregnant patients and ensure they have a copy of the Patient guide. (Refer to Section 7.0 of this pathway).

2. Confirm that they have been made aware about the risks of using valproate during pregnancy.

3. When a patient consults during pregnancy, urgently refer them to be seen (within days) by their specialist prescriber and to a specialist experienced in prenatal medicine for evaluation and counselling regarding the exposed pregnancy. Advise the woman that Valproate should be continued to be taken until review with the specialist and **NOT** stopped suddenly.

15.0 Reporting Arrangements

It is the responsibility of the HSC Trusts to report to the Valproate Implementation group on a monthly basis the progress that is being made in reviewing women in the 10-55 years age group taking sodium valproate medication. This should be produced on the Monitoring return form which can be seen in Appendix 5.

16.0 Appendices

Number	Title	Document
Appendix 1	The ABN Guidelines for Valproate prescribing in Adult (16 and over) Neurology	abn_guidelines_for _valproate.pdf
Appendix 2	How Effective is your contraception leaflet	How effective is your contraception.
Appendix 3	GMC Decision making and consent (Nov 2020)	GMC-guidance-for-doctors---Decision-r
Appendix 4	GMC Key legislation and case law relating to consent and decision making	GMCFactsheet---Key-legislation-and-ca
Appendix 5	FSRH CEU statement: Contraception for women using known teratogenic drugs or drugs with potential	FSRH of RCOG teratogenic-medicat
Appendix 6	Valproate Care Pathway for Patients	Valproate Care Pathway for Patients
Appendix 7	Checklist for Dispensing Valproate to women of childbearing potential	Checklist for Dispensing Valproa
Appendix 8	Valproate Monitoring template	Action Plan and Monitoring Templat
Appendix 9	Risk Minimisation measures required for Valproate prescribing patient 55 and over	250213_MHRA_Valproate_Infographic_5
Appendix 10	Risk Minimisation measures required for Valproate prescribing female 55 and under	250213_MHRA_Valproate_Infographic_F

Appendix 11	Risk Minimisation measures required for Valproate prescribing for male 55 and under	 250213_MHRA_Valproate_Infographic_M