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| **SHARED CARE Guideline – Amber Traffic Light Classification** |
| **Name of medicine** | Sodium Valproate |
| **Indication** **(including whether for adults and/or children)** | Epilepsy – treatment in females of childbearing potential |
| **PCN policy statement reference** **(if applicable)** | PCN 380-2018  |
| **Author(s):** Alison Marshall, Lead Pharmacist, Quality & Governance**Organisation(s):** Surrey & Borders Partnership NHS Foundation Trust |
| **Version:V3** | **PCN recommendation date: 12/2018** | **Review date: December 2021** |

The Shared Care Guideline (SCG) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface.

This **AMBER** shared care sets out the patient pathway relating to this medicine and any information not available in the British National Formulary and manufacturer’s Summary of Product Characteristics. Prescribing must be carried out with reference to those publications.

The SCG must be used in conjunction with the PCN agreed core roles and responsibilities stated in annex A.

An agreement notification form is included in annex B for communication of request for shared care from provider and agreement to taken on prescribing by primary care.

**Roles and Responsibilities**

Listed below are specific medicine/indication related responsibilities that are additional to those core roles and responsibilities that apply to all SCGs listed in annex A.

Prescribers must be familiar with the materials published on the MHRA website regarding the pregnancy prevention programme ([www.gov.uk/guidance/valproate-use-by-women-and-girls](http://www.gov.uk/guidance/valproate-use-by-women-and-girls))

**Consultant**

***Pretreatment checks***

* To discuss the risks with the patient or parent/caregiver/responsible person
* To exclude pregnancy by serum pregnancy test in women of childbearing potential before the first prescription is issued
* To complete the annual risk acknowledgement form with the patient or parent/caregiver/responsible person, give them a copy and send a copy to the GP.
* To ensure that highly effective contraception\* is being used, and to refer for contraception services as needed.

*(\*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) and progestogen only implant (IMP) and female sterilisation, all of which have a failure rate of less than 1% with typical use. At least one highly effective method of contraception (preferably a user independent form such as an intrauterine device or implant) or two complementary forms of contraception including a barrier method should be used. Individual circumstances should be evaluated in each case, when choosing the contraception method involving the patient in the discussion, to guarantee her engagement and compliance with the chosen measures. Even if she has amenorrhoea she must follow all the advice on highly effective contraception.)*

To undertake baseline tests as per the monitoring section below.

To initiate prescribing of sodium valproate for a minimum of 1 month until patient is stable only if other treatments are ineffective or not tolerated and pregnancy is excluded by means of a negative serum pregnancy test.

***Patient education***

* To ensure the patient or parent/caregiver/responsible person has been given a copy of the Valproate Patient Guide. (This may be requested from the pharmacy department, or issued by the consultant.)
* To ensure the patient or parent/caregiver/responsible person understands the “*prevent*” programme, and the risks to the unborn child of using sodium valproate during pregnancy.
* Ensure she understands the need to comply with contraception throughout treatment and undergo pregnancy testing when required – e.g. if there is any reason to suggest lack of compliance or effectiveness of contraception

***Subsequently***

* To review the patient annually and to complete the annual risk acknowledgement form at a face-to-face appointment and send a copy to her GP
* To undertake pregnancy testing if indicated
* To refer for contraception services as needed

**Primary Care Prescriber**

***Maintenance***

* Inform any woman who may be of childbearing potential taking sodium valproate of the known risks and ensure that she understands she must not get pregnant whilst taking sodium valproate
* Arrange to see each woman of childbearing potential after Consultant Neurologist review and ensure she is on “*prevent*”.
* Ensure she has the Patient Guide and has a copy of the Annual Risk Acknowledgment Form signed by the Consultant Neurologist, and file a copy of the form in her medical records
* Ensure she is using contraception and understands the need to comply with contraception throughout treatment and undergo pregnancy testing when required – e.g. if there is any reason to suggest lack of compliance or effectiveness of contraception
* Remind her that she will need to see her Consultant Neurologist at least every year while taking sodium valproate medicines and arrange for referral as necessary
* Tell her to contact you immediately if she suspects there has been a problem with her contraception or she may be pregnant.
* Refer her back to the Consultant Neurologist or appropriate contraceptive service immediately if her contraceptive becomes ineffective for any reason (e.g. removal, or non-compliance with scheduled appointment) and inform her not to stop contraception or sodium valproate unless advised to do so by her Consultant Neurologist.
* Refer any woman taking sodium valproate who wishes to become pregnant to the Consultant Neurologist prescriber, and inform her not to stop contraception or sodium valproate until advised to do so by her Consultant Neurologist.
* If she presents with an unplanned pregnancy inform her not to stop sodium valproate; refer her to a Consultant Neurologist and ask her to be seen urgently (within days)
* Undertake annual tests as specified in monitoring section

**Patient Relatives & Carers**

* It is your responsibility to follow these guidelines, and the stipulations set out by the “prevent” programme. The guidelines and the pregnancy prevention programme are here for your safety, health and wellbeing.
* To adhere to the requirements of the “*prevent*” programme, ie to use highly effective contraception\* and not to stop contraception whilst taking sodium valproate.
* To attend for annual review with the Consultant Neurologist prescriber including completion of an annual risk acknowledgement form. **Non-attendance of appointments may result in treatment being stopped**

**Key information on the medicine**

Please refer to the current edition of the British National Formulary (BNF), available at https://bnf.nice.org.uk/ and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

**Background to disease and use of medicine for the given indication**

NICE guidance was published in 2012, and updated in 2018 on the topic of the diagnosis and management of epilepsies (Clinical Guideline 137). The guideline covers diagnosing, treating and managing epilepsy and seizures in children, young people and adults in primary and secondary care. It offers best practice advice on managing epilepsy to improve health outcomes so that people with epilepsy can fully participate in daily life. Specific treatment recommendations are given for each individual seizure type.

**Indication**

Sodium valproate is licensed for the treatment of all forms of epilepsy.

**Contraindications**

Sodium valproate containing medicines are contraindicated in women of childbearing potential unless the conditions of the pregnancy prevention programme are fulfilled. If the medicine is to be used outside of its licensed indications, then an individual agreement between the Consultant Neurologist and primary care prescriber will need to be put in place.

**Dosage and Administration**

Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk) and other specialist guidelines.

**Monitoring**

**Note - A woman of childbearing potential is defined as a pre-menopausal female who is capable of becoming pregnant.**

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| **Monitoring requirements including frequency and appropriate dose adjustments** | **Responsible clinician** |
| **Pre-treatment** - W**omen of childbearing potential*** Exclude pregnancy by means of a negative serum pregnancy test
* Assess potential for pregnancy and if necessary discuss the need for her to be on the “*prevent*” programme if she is to take valproate
* Ensure she understands the risks to the unborn child of using sodium valproate during pregnancy and provide the Patient Guide
* Complete and sign the Annual Risk Acknowledgment Form (and at every annual visit); give a copy to her and send one to her GP

**Pre-treatment** – **All people prescribed sodium valproate**LFTs, FBC (including platelet count, bleeding time and coagulation tests) and BMI/weight. TFT if new diagnosis or clinical concerns.**During stabilisation - All people prescribed sodium valproate**Periodic monitoring of LFTs during the first 6 months until patient is stabilised. The frequency may need to be determined on a patient by patient basis | *Consultant Neurologist*  |
| **At 6 months after initiation*** FBC, LFTs, Weight/ BMI
 | Consultant Neurologist |
| **Maintenance** - W**omen of childbearing potential**:* Annual review by specialist prescriber
* Continue treatment with sodium valproate only if other treatments are ineffective or not tolerated and pregnancy is excluded by means of a negative pregnancy test when indicated
* Discuss the need for her to be on the “*prevent*” programme if she is to continue taking sodium valproate
* Ensure she understands the risks to the unborn child of using sodium valproate during pregnancy and provide the Patient Guide
* Ensure she understands the need to comply with contraception throughout treatment and undergo pregnancy testing when required – e.g. if there is any reason to suggest lack of compliance or effectiveness of contraception
* Complete and sign the Annual Risk Acknowledgment Form (at initiation and every annual visit); give a copy to her and send one to her GP

**Maintenance** – **All people prescribed sodium valproate****Every 12 months subsequently*** FBC, LFTs, Weight / BMI
 | Consultant Neurologist *General Practitioner or other Health Care Professional* |

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| **Test**  | **Abnormal Result** | **Action if Abnormal Result** |
| Pregnancy | Pregnancy confirmed | * Women presenting to their GP or other HCP with an unplanned pregnancy should not immediately stop sodium valproate, but be referred to a Consultant Neurologist to be seen urgently (within days).
* Women presenting to the Consultant Neurologist with an unplanned pregnancy should have their treatment switched.
 |
| FBC, LFTs | Outside normal range | * Consider alternative explanations
* Refer to specialist
* Monitor until returned to normal)
 |
| Weight/ BMI | Significant upward trend | * Discuss lifestyle choices, weight management, diet and exercise.
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**Cautions, contraindications -** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk).

*Specific advice relating to use by women and girls, as issued by the MHRA in May 2018 is reproduced below:*

Valproate must not be used in any woman or girl able to have children unless she has a pregnancy prevention programme in place. This is designed to make sure patients are fully aware of the risks and the need to avoid becoming pregnant.

**Adverse effects -** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

*Specific advice regarding exposure during pregnancy which was issued by the MHRA in May 2018 is reproduced below:*

If sodium valproate is taken during pregnancy, up to 4 in 10 babies are at risk of developmental disorders, and approximately 1 in 10 are at risk of birth defects.

In women who take sodium valproate while pregnant, around 1 in 10 babies will have a birth defect.

Birth defects seen when mothers take sodium valproate during pregnancy include:

spina bifida (where the bones of the spine do not develop properly)

facial and skull malformations (including cleft lip and palate, where the upper lip or facial bones are split)

malformations of the limbs, heart, kidney, urinary tract and sexual organs.

In women who take sodium valproate while pregnant, about 3–4 children in every 10 may have developmental problems. The long-term effects are not known.

The effects on development can include:

being late in learning to walk and talk

lower intelligence than other children of the same age

poor speech and language skills

memory problems.

Children exposed to sodium valproate in the womb are more likely to have autism or autistic spectrum disorders. There is also some evidence children may be more likely to be at risk of developing symptoms of attention deficit hyperactivity disorder (ADHD).

**Drug interactions -** Refer to current Summary of Product Characteristics (SPC): [www.medicines.org.uk](http://www.medicines.org.uk)

**Support and Advice for the Primary Care**

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| Name | Speciality | Telephone No. | Email address |
| XXXXX | XXXXX | XXXXX | XXXXX |
|  |  |  |  |
|  |  |  |  |
| Hospital Pharmacy | XXXXX | XXXXX | XXXXX |
| Out of Hours | XXXXX | XXXXX | XXXXX |

**Annex A: PCN agreed core roles and responsibilities for the shared care of medicines**

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| **Patients** |
| **To get the most out of your treatment it’s important that you work together with your specialist. You must follow these guidelines to ensure your own safety, health and wellbeing. You should be able to decline shared care If after due consideration of the available options you decide it is not in your best interests.*** You must make sure that you understand about your treatment
* If you do not understand ask for more information from the person prescribing the medicine
* Read the Patient Information Leaflet included with your medication. It will provide you with information about your medication
* You must raise concerns about your treatment with the person prescribing the medicine
* Talk to the specialist and come to an agreement of how the treatment should be provided to you
* Give permission to have aspects of your care communicated to healthcare providers
* Ensure that you are provided with contact details for support and help if required; both in and out of hours.
* You must attend all appointments. Non-attendance of appointments may result in treatment being stopped
* You must keep a written list of all of the medicines you are taking
* You must keep lists of any additional vitamins, minerals, or other dietary supplements
* You must bring these lists with you each time you visit a healthcare provider or are admitted to a hospital
* You must carry these lists on you in case of an emergency
* You must not let anyone else take your medication.

It is your responsibility to follow these guidelines. The guidelines are here for your safety, health and wellbeing. If you would like more information on your rights, roles and responsibilities in your healthcare please ask a NHS professional for information on the NHS constitution or visit,[www.gov.uk/government/publications/the-nhs-constitution-for-england](https://www.gov.uk/government/publications/the-nhs-constitution-for-england) |
| **Relatives and Carers**  |
| **As a carer or relative (where it is not possible for the patient to make a decision about future treatment e.g. mental capacity, where possible you should be included in discussions about shared care.*** To support the patient in fulfilling their roles and responsibilities as outlined above.
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| **Consultant/ Specialist** |
| **Good Prescribing Guidelines*** Be aware that if you recommend that a colleague, for example a junior doctor or Primary Care Prescriber, prescribes a particular medicine for a patient, you must consider their competence to do so. You must satisfy yourself that they have sufficient knowledge of the patient and the medicine, experience (especially in the case of junior doctors) and information to prescribe. You should be willing to answer their questions and otherwise assist them in caring for the patient, as required (Ref GMC).
* Be aware that if you delegate assessment of a patients’ suitability for a medicine, you must be satisfied that the person to whom you delegate has the qualifications, experience, knowledge and skills to make the assessment. You must give them enough information about the patient to carry out the assessment required.
* Be aware that you are asking the Primary Care Prescriber to take full medico-legal responsibility for the prescription they sign(Ref GMC). For this reason the shared care guidelines (SCGs) are agreed at the PCN with input from specialists and Primary Care Prescribers, and, for individual patients, the patient’s Primary Care Prescriber must agree to take over responsibility before transfer of care, before the patient is discharged from specialist care.
* Be aware of the formulary status and the traffic light classification of the medicine you are prescribing within the patient’s CCG
* Assume clinical responsibility for the guidance given in the SCG, and where there is new information needed on the SCG to liaise with your Formulary Pharmacist who will facilitate an update via the PCN

**Before initiating treatment*** Evaluate the suitability of the patient for treatment, including consideration of the patient’s current medication and any significant interactions.
* Discuss and provide the patient with information about the reason for choosing the medicine, the likelihood of both harm and benefits, consequences of treatment, and check that their treatment choice is consistent with their values and preferences
* Advise patient of unlicensed status of treatment (including off-label use) if appropriate and what this may mean for their treatment.
* Undertake baseline monitoring and assessment.

**Initiating and continuing treatment in secondary care*** Prescribe initial treatment and provide any associated training and counselling required.
* Inform the Primary Care Prescriber when initiating treatment so that the Primary Care Prescriber is aware what is being prescribed and can add to Primary Care Prescriber clinical record
* Continue to prescribe and supply treatment with appropriate monitoring until the patient’s condition is stable or predictable; the patient is demonstrably benefiting from the treatment and is free from any significant side effects.
* At any stage of treatment, advising Primary Care Prescriber of concerns regarding monitoring or potential adverse effects of treatment

**Transfer of care to Primary Care prescriber*** Liaise with the primary care prescriber to agree to share the patient’s care and provide relevant accurate, timely information and advice.
* Only advise the patient that shared care will take place, and prescribing will be transferred, once the primary care prescriber has agreed to share responsibility of the patient care, and that this has been confirmed in writing.
* If the primary care prescriber feels unable to accept clinical responsibility for prescribing then the consultant must continue to prescribe the treatment to ensure consistency and continuity of care.
* Ensure that the patient (and carer/relatives) are aware of their roles and responsibilities under the SCG
* Provide sufficient information and training for the patient to participate in the SCG

**Post transfer of care*** Follow up and monitor the patient at appropriate intervals.
* Advise Primary Care Prescriber if treatment dose changes or treatment is discontinued
* Inform Primary Care Prescriber if patient does not attend planned follow-up
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| **Primary Care Prescriber** |
| * Be aware of the formulary and traffic light status of the medicine you have been asked to prescribe.
* Be aware that Amber medicines have been assessed by the PCN as requiring careful transition between care settings but SCGs will be available to support safe transfer of care.
* It would be usual for Primary Care Prescribers to take on prescribing under a formal SCG. If you are uncertain about your competence to take responsibility for the patient’s continuing care, you should seek further information or advice from the clinician with whom the patient’s care is shared or from another experienced colleague. If you are still not satisfied, you should explain this to the other clinician and to the patient, and make appropriate arrangements for their continuing care.
* Be aware that if you prescribe at the recommendation of another doctor, nurse or other healthcare professional, you must satisfy yourself that the prescription is needed, appropriate for the patient and within the limits of your competence (Ref GMC).
* Be aware that if you prescribe, you will be responsible for any prescription you sign (Ref GMC).
* Keep yourself informed about all the medicines that are prescribed for the patient
* Be able to recognise serious and/ or frequently occurring adverse side effects, and what action should be taken if they occur.
* Make sure appropriate clinical monitoring arrangements are in place and that the patient and healthcare professionals involved understand them
* Keep up to date with relevant guidance on the use of the medicines and on the management of the patient’s condition.
* Respond to requests to share care of patients in a timely manner, in writing (including use of form in annex B)
* Liaise with the consultant to agree to share the patient’s care in line with the SCG in a timely manner.
* Continue prescribing medicine at the dose recommended and undertake monitoring requirements
* Undertake all relevant monitoring as outlined in the monitoring requirements section below, and take appropriate action as set out in this shared care guideline
* Monitor for adverse effects throughout treatment and check for drug interactions on initiating new treatments
* Inform the Consultant or specialist of any issues that may arise
* Ensure that if care of the patient is transferred to another prescriber, that the new prescriber is made aware of the share care guideline (e.g. ensuring the patient record is correct in the event of a patient moving practice).
 |
| **All** |
| * Where it has been identified that a SCG requires update e.g. new information needed, liaise with the SCG author and/or your organisation PCN representative who will facilitate an update via the PCN.
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**Annex B: Shared care agreement notification form for medicines and indications approved as amber on the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary.**

**For the attention of the Practice Manager**

**FAX – Confirm you have the correct Safe Haven Fax Number before sending**

**E-mail – Confirm both sender and recipient e-mail addresses are nhs.net before sending**

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| --- | --- | --- | --- |
| To: | [Recipient Name] | Fax: | [fax number] |
| From: | [Your Name] | Date: | [Click to select date] |
| Re: | [Subject] | Pages: | [number of pages] |
| cc: | [Name] |  |  |

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[Notes]

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| **Name of medicine** | Sodium Valproate |
| **Indication** | Epilepsy in females of childbearing potential |

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| Person removing form from fax machine |  |
| Relevant patients GP available to action within 5 days (if not Trust needs to be informed on day of receipt of request) | Yes/ No |
| If GP is NOT available within 5 days, please communicate to the requesting specialist the date when the GP will be available |  |

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| Hospital/ Patient information | Practice information |
| Consultant Making Request |  | GP Name: |  |
| Consultant Speciality Details: |  | Practice: |  |
| Patient Name: |  | I agree to undertake shared care: |  |
| Patient NHS Number: |  | I do not agree to undertake shared care: |  |
| Patient Hospital Number: |  | If NOT please give reasons: |  |
| Patient DOB: |  | Signed: |  |
| Drug Name/ Dose: |  | Date: |  |
| Next Prescription Due: |  | Please return form to: | Specialist safe haven fax number |
| Discharge letter written and sent: |  |  |  |
| Please refer to the Surrey PAD or Crawley, Horsham and Mid-Sussex net formulary for relevant shared care documents |

**Primary Care Prescriber should reply within 5 days of receipt of this form indicating participation (or not) in shared care of the patient**