North Central London
Joint Formulary Committee

Shared Care Guideline
Rufinamide
Adjunctive treatment of seizures associated with Lennox- Gastaut syndrome in patients aged 16 years and over

Dear Primary Care Prescriber,

The information in this shared care guideline has been developed in consultation with Primary Care, with agreement that shared care is appropriate.

Sharing of care assumes communication between the specialist, primary care prescriber and patient. The intention to share care should be explained to the patient by the specialist clinician when treatment is initiated. It is important that patients are consulted about treatment and are in agreement with it.

Further information on shared care, including out of area referrals, can be found in the North Central London (NCL) Interface Prescribing Guidance.

Shared Care Guideline

Indication	As per local formulary agreement, rufinamide (Inovelon®) is a third-line treatment option in patients with Lennox-Gastaut Syndrome (LGS) who have failed treatment with or are intolerant to alternative agents. This is a licensed use of rufinamide. Rufinamide is restricted to Consultant Epileptologists who will consider contraindications (link: BNF & SmPC) and cautions (link: BNF & SmPC) for use. LGS is a rare epilepsy syndrome of paediatric origin. It is characterised by a triad of slow spike-and-wave pattern on the Electroencephalogram (EEG), multiple types of seizures (tonic, atypical absence, drop attacks) occurring at a high daily frequency, and impaired mental development.
Shared Care criteria	Once a patient has been stabilised on treatment for three months, a shared care arrangement with you will be requested.

<table>
<tr>
<td>Dose</td>
<td>
Rufinamide is indicated as adjunctive therapy in the treatment of seizures associated with LGS in patients (licensed for ages over 1 years old) and is approved as a third line treatment option for patients with LGS within NCL.

First-line treatment options on the NCL Joint Formulary for LGS include sodium valproate, lamotrigine, clobazam, topiramate and cannabidiol (third-line treatment option). However other anti-seizure medication may be used.

Dosing for use in adults, adolescents and children 4 years of age or older of 30 kg or over:

• Rufinamide should be taken orally twice a day with food.
• Rufinamide may be administered with or without sodium valproate and this can alter the dose of rufinamide prescribed for a patient.

Patients weighing > 30kg and receiving sodium valproate:

Treatment should be initiated at a dose of 400mg daily (administered as 200mg twice daily). This can be increased depending on clinical response and tolerability in 400mg/day increments as frequently as every other day up to a maximum recommended dose as indicated in the table below:

<table>
<tr><th>Patient weight range</th><th>Maximum daily dose</th></tr>
<tr><td>30.0 - 50.0 kg</td><td>1200mg/day</td></tr>
<tr><td>50.1 – 70.0 kg</td><td>1600mg/day</td></tr>
<tr><td>≥ 70.1 kg</td><td>2200mg/day</td></tr>
</table>

Patients weighing > 30kg and NOT receiving sodium valproate:

Treatment should be initiated at a daily dose of 400 mg (administered as 200mg twice daily). According to clinical response and tolerability, the dose may be increased by 400 mg/day increments, as frequently as every other day, up to a maximum recommended dose as indicated in the table below

<table>
<tr><th>Patient weight range</th><th>Maximum daily dose</th></tr>
<tr><td>30.0 - 50.0 kg</td><td>1800mg/day</td></tr>
<tr><td>50.1 – 70.0 kg</td><td>2400mg/day</td></tr>
<tr><td>≥ 70.1 kg</td><td>3200mg/day</td></tr>
</table>

If the recommended calculated dose of rufinamide is not achievable, the dose should be rounded to the nearest whole 100mg tablet.

Conditions requiring dose adjustment

<u>Renal and hepatic impairment</u>

No dose adjustments are required for patients with severe renal impairment.

Caution and careful dose titration is recommended when treating patients with mild to moderate hepatic impairment and use in severe hepatic impairment is not recommended. Liver impairment is graded by how high liver functions tests (LFTs) are over the upper limit of normal (ULN):

• Severe hepatic impairment: 5x or more ULN of LFT markers
</td>
</tr>
</table>

	• Moderate hepatic impairment: ≥3x to <5x ULN of LFT markers • Mild hepatic impairment: ≥ULN to <3x the upper limit of normal of LFT markers Liver function to be assessed by the GP if there are factors or conditions that suggest deterioration. Further information about prescribing in elderly, children, pregnant women and patients with hepatic or renal impairment can be found here (link: BNF & SmPC) **Missed doses** In the case of one or more missed doses, individualised clinical judgement is necessary. The specialist team should be contacted for advice when required. **Preparations available** Tablets for oral administration: 100mg, 200mg and 400mg film-coated tablets. For patients that have difficulty swallowing, tablets can be crushed and administered in half a glass of water. Alternatively, use the score line to break the tablet into two equal halves for administration. Oral suspension: 40mg/1ml (460ml total volume) The manufacturer advises that rufinamide (Inovelon®) oral suspension and rufinamide (Inovelon®) film- coated tablets may be interchanged at equal doses. Care should be taken when switching between formulations and the patient should be monitored during the switch over period. The specialist team should be contacted for advice when required.
Duration of treatment	Lifelong if effective and tolerated.
Stopping criteria and treatment discontinuation	When treatment is to be discontinued, it should be withdrawn gradually, and this should be guided by the consultant. In clinical trials, rufinamide discontinuation was achieved by reducing the dose by approximately 25% every two days.
Baseline monitoring (by specialist)	Baseline monitoring: The manufacturer of Inovelon® tablets and liquid does not specify that routine clinical monitoring is required in patients treated with rufinamide. However, if the consultant deems any tests to be performed, the consultant must state what the recommended tests are, why they are needed and the location in which these tests will be carried out. **Continued monitoring by specialist** At each review, the patient should be monitored for signs of suicidal ideation and behaviour (possibility of an increased risk with rufinamide), and appropriate treatment considered. At each review the consultant will access the patients seizure control. The patient will be asked to keep a seizure diary documenting their seizures (type and frequency) as well as any adverse effects.
Ongoing monitoring (by primary care clinician)	The manufacturer of Inovelon® tablets and liquid does not specify that routine clinical monitoring is required in patients treated with rufinamide. If additional tests are recommended, the consultant should explain what these tests are and the rationale for doing them in addition to the location for the tests to be carried out. The consultant should detail who is to review the results and the action(s) to be taken if a result is abnormal.

<table>
<tr><td></td><td colspan="3">Patients should continue to keep a seizure diary and any possible adverse events (including suicidal ideation and behaviours), or inadequate seizure control should be reported promptly to the epilepsy CNS/Consultant neurologist.</td></tr>
<tr><td>Follow up arrangements</td><td colspan="3">Review by specialist team at least on a yearly basis.</td></tr>
<tr><td rowspan="5">Adverse effects and management

For a full list of adverse effects, please refer to the (link: BNF & SmPC)

Healthcare professionals are asked to report any suspected adverse reactions to the MHRA via the Yellow Card Scheme.</td><td>Adverse event</td><td>Frequency</td><td>Action for GP</td></tr>
<tr><td>Headache</td><td>Very common</td><td>The patient should be advised to keep hydrated with water and rest. If the headache persists, this should be discussed with the specialist.</td></tr>
<tr><td>Somnolence and fatigue</td><td>Very common</td><td>These symptoms should subside; however, if symptoms persist this should be discussed with the specialist</td></tr>
<tr><td>Dizziness</td><td>Very common</td><td>The patient should be advised to exercise caution with activities. If this does not subside, this should be discussed with the specialist.</td></tr>
<tr><td>Nausea and vomiting</td><td>Very common</td><td>Manage symptomatically, if this persists it should be discussed with the specialist.</td></tr>
<tr><td>Advice to patients and carers</td><td colspan="3">Patients (and caregivers of patients) should be advised to seek medical advice should signs of suicidal ideation or behaviour emerge.

If relevant, females of childbearing age should be counselled on using effective contraception whilst taking rufinamide. The effectiveness of hormonal contraceptives (such as oral contraceptives, vaginal rings, hormonal implant and patches) may be reduced with rufinamide therefore alternative, or concomitant methods of contraception (e.g. barrier methods) should be used.

Patients will be asked to keep a seizure diary, and any possible adverse events should be reported promptly to the GP and Consultant neurologist.</td></tr>
<tr><td>Resources and key references</td><td colspan="3">Summary of Product Characteristics for Inovelon® tablets. Eisai Limited. Accessed online via: https://www.medicines.org.uk/emc/product/410/smpc on 13.11.2024 Summary of Product Characteristics for Inovelon ® oral suspension. Eisai Limited. Accessed online via: https://www.medicines.org.uk/emc/product/2354/smpc on 13.11.2024 British National Formulary 2024/25 Edition 88 . Accessed online via www.medicinescomplete.com on 13.11.2024 NCL Joint formulary. North Central London Formulary Accessed 25/03/2025 NICE guideline [NG217]. Overview | Epilepsies in children, young people and adults | Guidance | NICE. 25/02/25.</td></tr>
</table>

Contact Details

National Hospital for Neurology and Neurosurgery (NHNN)

Hospital switchboard:	020 3456 7890
Epilepsy Nurse Specialists (please be aware this is an answerphone, but messages are listened to daily) For individual consultants at NHNN, please see letterhead in clinic letters or call via Switchboard	020 3448 8627 (answerphone)
Specialist or Dept. Pharmacist: NHNN Pharmacist	020 3448 3160
Consultant details:	Please contact the relevant consultants secretary via the UCLH hospital switchboard (telephone number above)

Royal Free London (RFL) Neurology services

Hospital switchboard:	020 3758 2000
Epilepsy specialist nurses advice line and email address	020 78302864 rf.epilepsyteam@nhs.net
Specialist or Dept. Pharmacist	Pharmacy Department 020 7472 6306 Neurosciences pharmacist – bleep 2750
Consultant details:	Please contact the relevant consultants secretary via the RFL hospital switchboard (as above)

Document control

Date	Version	Amendments
12.01.2026	1.2	• Adapted to new North Central London (NCL) template for Transfer of Prescribing Documents. • Additional notes have been included to indicate when the specialist team should be contacted. • Information has been added regarding counselling for females of childbearing age. • A defined timeframe for patient stabilisation prior to share care with primary care. • Guidance on liver function testing (LFT) has been included where LFTs are appropriate.

Groups / Individuals who have overseen the development of this guidance:	Lindsey Stockford, UCLH Evelyn Frank, UCLH LMC members
Groups which were consulted and have given approval:	NCL Neurology Consultants NCL Medicine Optimisation Pharmacists NCL Shared Care Group
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Version number:	V2.2
Available on:	www.ncl-mon.nhs.uk
Disseminated to:	NCL Formulary Pharmacists and Commissioners
Equality impact assessment:	No impact identified
NCL Shared Care Group Approval date:	June 2025
Review date:	June 2028

Appendix 1: xxx transfer form: from [Trust] to GP practice

Section A: to be completed by secondary care *Send to practice*

This document is to request the shared care pathway of your patient and comprises an agreement betweer the GP and named consultant. The patient will continue to be seen by the named consultant as regular foll up.

Fix address label here (ensure NHS Number.on)	Clinic stamp *or give details below*

Department			
Clinic phone			
Consultant		Email	
Indication for prescription			
Drug prescribed			
Date	Drug started	Current dose	
Relevant conditions			
Monitoring variations			
Date next blood test		Next disease review due in	months' time.

Section B: [Accept Shared Care] to be completed by practice

*Send back **FAO referring consultant** above*

The above patient has been accepted into our monitoring service.

Practice date for next blood test		Practice stamp
Signed / Designation		
Date		

Section B: [Reject Shared Care] to be completed by practice

*Send back **FAO referring consultant** above*

The above patient has not been accepted into our monitoring service.

Reason		Practice stamp
Signed / Designation		
Date		