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Royal Cornwall Hospitals NHS Trust

Prescribing of 3,4- Diaminopyridine (3,4-DAP) In Lambert-Eaton Myastheinic Syndrome (Lems) Clinical Guideline

V2.0

June 2020

1. Aim/Purpose of this Guideline

1.1. The purpose of this guideline is to set out the criteria for diagnosing Lambert Eaton Myasthenic Syndrome (LEMS) for which 3,4-diaminopyridine (3,4-DAP) may be prescribed and who may do so.

1.2. This guideline will apply to:

1.2.1. Consultant neurologists, who will be solely responsible for the diagnosis and potential prescribing of 3,4-DAP in LEMS.

1.2.2. Pharmacists and pharmacy staff, who will ensure that 3,4-DAP is prescribed in line with this guidance and not ordered and supplied outside of it.

1.2.3. Other hospital doctors, who will only be allowed to prescribe 3,4-DAP within the in-patient setting provided:

1.2.3.1. The patient has a confirmed diagnosis of LEMS by a consultant neurologist.

1.2.3.2. The dose and frequency is the same as what the patient was admitted on, in a previously diagnosed case.

1.2.4. Hospital nursing staff, who shall ensure that admitted patients has a confirmed LEMS diagnosis before ordering and administering 3,4-DAP.

1.2.5. General Practitioners (GPs), who will not be allowed to prescribe 3,4-DAP for LEMS unless there is an agreed shared care arrangement in place.

1.3. This version supersedes any previous versions of this document.

1.4. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can't rely on Opt out, it must be Opt in.

DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

For more information about your obligations under the DPA18 please see the 'information use framework policy', or contact the Information Governance Team rch-tr.infogov@nhs.net

2. The Guidance

2.1. LEMS is a neuromuscular autoimmune disease where it is recognised that the first choice symptomatic treatment is 3,4-DAP.

2.2. 3, 4-DAP is an unlicensed treatment in the United Kingdom. A licensed version of 3, 4-DAP (as the phosphate salt) is available in the United Kingdom called Amifampridine (Firdapse®) however this is not commissioned for prescribing within the NHS whereas 3,4-DAP is. This means that clinicians suitably trained in the diagnosis of LEMS are to prescribe 3, 4-DAP over Amifampridine unless an individual funding request by NHS England has been approved.

2.3. Where 3,4-DAP has been determined to be unsuitable for the patient e.g. allergies, adverse effects alternative symptomatic treatment may be appropriate but is beyond the scope of this guidance.

2.4. Until such time that Amifampridine is commissioned for routine prescribing for LEMS, prescribers will prescribe 3,4 –DAP over Amifampridine as per NHS England guidance.

2.5. Prescribers who feel that there are clinical reasons for Amifampridine to be used over 3,4 –DAP will make an individual funding request application. It must be advised that Amifampridine will only be supplied within the trust on a positive outcome of this application.

2.6. Below sets out the guidance for which 3,4-DAP may be commenced and prescribed for LEMS.

2.6.1. LEMS is a neuromuscular autoimmune condition that must only be diagnosed by a consultant neurologist due to the experience and skill set required.

2.6.2. 3,4 –DAP will only be dispensed by either the trust's in-patient pharmacy department or the trust's outpatient pharmacy department against an electronic generated prescription approved for use within the trust.

2.7. For 3,4 –DAP to be approved for supply to the patient with LEMS the consultant neurologist must be able to show that they have satisfied the standard diagnostic criteria (Lancet Neurology Vol 10, No 12, 1098-1107 Dec 2011).

2.8. In the out-patient setting the consultant neurologist will prescribe 3,4-DAP on the trust approved electronic O/P prescription (not FP10) to be sent to the trust's O/P pharmacy department for processing.

2.9. Due to its unlicensed status it can take time to procure the medication (of which the time frame may be outside of the control of the trust). To attempt to reduce the likeliness of treatment delay the prescription should be sent for processing at least 7 days before the

treatment is required.

2.10. In the in-patient setting 3,4-DAP will be prescribed by the patient's in-patient medical team on the patient's in-patient drug chart and ordered through the usual pharmacy requisition procedures. The pharmacy department will only order and supply should evidence that 3,4-DAP has been recommended by a consultant neurologist for the management of LEMS be available and in line with this guidance.

2.11. Dose of 3,4-DAP is typically titrated to 20mg three times a day.

2.12. Patients started on 3,4-DAP for LEMS will require:

2.12.1. Clinical review 2 months after initiation to determine clinical effectiveness, then at 12 months and then annually thereafter.

2.12.2. The clinical review will include a neurological assessment and an ECG will be undertaken.

3. Monitoring compliance and effectiveness

Element to be monitored	To monitor that 3,4-DAP is only supplied in line with guidance
Lead	Clinical Lead for Neurology and Pharmacist for Neurology
Tool	Regular clinical review for as long as the patient continues the treatment. The Neurology Department will maintain a register of all patients treated with 3,4 DAP, and will confirm that patients have been appropriately investigated and monitored on a Word or Excel template.
Frequency	Annual audit
Reporting arrangements	Report to audit committee
Acting on recommendations and Lead(s)	Neurology Clinical Lead will ensure compliance
Change in practice and lessons to be shared	Neurology Clinical Lead will ensure review at local Departmental Meeting

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the 'Equality, Inclusion & Human Rights Policy' or the Equality and Diversity website.

4.2. *Equality Impact Assessment*

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Document Title	Prescribing of 3,4- Diaminopyridine (3,4-Dap) in Lambert-Eaton Myastheinic Syndrome (Lems) Clinical Guideline V2.0		
Date Issued/Approved:	1 June 2020		
Date Valid From:	June 2020		
Date Valid To:	June 2023		
Directorate / Department responsible (author/owner):	Dr. Jonathan Stewart, Consultant Neurologist Stephen Chan, Lead Pharmacist for Eldercare, Stroke and Neurology		
Contact details:	Dr. Jonathan Stewart – 01872 253195 Stephen Chan – 01872 252598		
Brief summary of contents	To provide advice on the use of 3,4-DAP and thereby meeting the requirement of NHS E to have a local guideline for its use		
Suggested Keywords:	Neurology, Prescribing		
Target Audience	RCHT	CFT	KCCG
	✓		
Executive Director responsible for Policy:	Medical Director		
Date revised:	April 2020		
This document replaces (exact title of previous version):	Local clinical guideline for the prescribing of 3,4-diaminopyridine (3,4-DAP0 in Lambert-Eaton myasthenic syndrome (LEMS) V1.0		
Approval route (names of committees)/consultation:	Medication Practice Committee Neurology Governance Meeting		
Care Group General Manager confirming approval processes	Sharon Matson		
Name and Post Title of additional signatories	Not required		
Name and Signature of Care Group/Directorate Governance Lead confirming approval by specialty and care group management meetings	{Original Copy Signed}		
	Becky Osborne		

Signature of Executive Director giving approval	{Original Copy Signed}			
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet & Intranet	✓	Intranet Only	
Document Library Folder/Sub Folder	Clinical/Neurology & Pharmacy			
Links to key external standards	None			
Related Documents:	None			
Training Need Identified?	No			

Version Control Table

Date	Version No	Summary of Changes	Changes Made by *(Name and Job Title)*
April 2017	V1.0	New document	Dr. Jonathan Stewart, Consultant Neurologist
April 2020	V2.0	Updated pharmacist details on governance information sheet and documents library folder/subfolder location. Updated appendix 2 and changing policy from “new” to “existing”	Stephen Chan, Lead Pharmacist for Eldercare, Stroke and Neurology

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document

This document has been created following the Royal Cornwall Hospitals NHS Trust Policy for the Development and Management of Knowledge, Procedural and Web Documents (The Policy on Policies). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Initial Equality Impact Assessment Form

<table>
<tr><th colspan="6">Section 1: Equality Impact Assessment Form</th></tr>
<tr><td colspan="6">Name of the strategy / policy /proposal / service function to be assessed
Prescribing of 3,4-diaminopyridine (3,4-DAP) in Lambert-Eaton Myasthenic Syndrome (LEMS) Clinical Guideline V2.0</td></tr>
<tr><td colspan="3">Directorate and service area:
Neurology</td><td colspan="3">Is this a new or existing Policy?
Existing</td></tr>
<tr><td colspan="3">Name of individual/group completing EIA
Stephen Chan</td><td colspan="3">Contact details:
01872 252598</td></tr>
<tr><td>1. Policy Aim
Who is the strategy / policy / proposal / service function aimed at?</td><td colspan="5">To provide advice on the use of 3,4-DAP and thereby meeting the requirement of NHS E to have a local guideline for its use.</td></tr>
<tr><td>2. Policy Objectives</td><td colspan="5">To ensure appropriate prescribing / supply of 3,4-DAP</td></tr>
<tr><td>3. Policy Intended Outcomes</td><td colspan="5">Activities related to use of 3,4-DAP comply with this guideline</td></tr>
<tr><td>4. How will you measure the outcome?</td><td colspan="5">Annual review</td></tr>
<tr><td>5. Who is intended to benefit from the policy?</td><td colspan="5">Patients receiving the medicine. Prescribers, pharmacy team</td></tr>
<tr><td rowspan="3">6a). Who did you consult with?

b). Please list any groups who have been consulted about this procedure.</td><td>Workforce</td><td>Patients</td><td>Local groups</td><td>External organisations</td><td>Other</td></tr>
<tr><td>X</td><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="5">Please record specific names of groups:
Medication Practice Committee
Neurology Governance Meeting</td></tr>
<tr><td>c). What was the outcome of the consultation?</td><td colspan="5">Approved</td></tr>
</table>

7. The Impact
Please complete the following table. If you are unsure/don't know if there is a negative impact you need to repeat the consultation step.

Are there concerns that the policy **could** have a positive/negative impact on:

Protected Characteristic	Yes	No	Unsure	Rationale for Assessment / Existing Evidence
Age		**X**		
Sex (male, female non-binary, asexual etc)		**X**		
Gender reassignment		**X**		
Race/ethnic communities /groups		**X**		
Disability (learning disability, physical disability, sensory impairment, mental health problems and some long term health conditions)		**X**		
Religion/ other beliefs		**X**		
Marriage and civil partnership		**X**		
Pregnancy and maternity		**X**		
Sexual orientation (bisexual, gay, heterosexual, lesbian)		**X**		

If all characteristics are ticked 'no', and this is not a major working or service change, you can end the assessment here as long as you have a robust rationale in place.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment:	Stephen Chan

If you have ticked 'yes' to any characteristic above OR this is a major working or service change, you will need to complete section 2 of the EIA form available here:
Section 2. Full Equality Analysis

For guidance please refer to the Equality Impact Assessments Policy (available from the document library) or contact the Human Rights, Equality and Inclusion Lead debby.lewis@nhs.net