

To: Trust Chief Executives
(for onward cascade to
appropriate staff)

All General Practitioners and
Practice Pharmacists

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25th January 2017

Dear Colleague,

Re: Low Dose Naltrexone – not recommended for use

Naltrexone is a drug which, in its licenced form of 50mg tablets, is used for the treatment of addiction to opiate drugs. However there is increasing usage of low-dose Naltrexone (LDN) (i.e. 3mg and 4.5mg naltrexone) for the treatment of autoimmune diseases in the UK.

Currently there is not enough evidence-based information to prove LDN is an effective treatment. LDN is not in the Northern Ireland Formulary and is not recommended to be prescribed in primary care because (i) there is no robust clinical evidence available to indicate that it is beneficial in the treatment of autoimmune diseases and (ii) it is not licensed for treatment of such indications.

As with any other unlicensed and unevidenced therapy, it cannot be justified as a safe nor appropriate use of HSC funds and we are therefore requesting the following actions:

GPs:

- patients are not commenced on this treatment
- existing patients being prescribing LDN should be reviewed and treatment stopped if not beneficial to the patient

Trusts:

- patients are not commenced on this treatment unless their treatment is part of a clinical trial.

- Clinical trials should be approved by the Trust D&T in advance and include a clear exit strategy including a timeframe for feedback on the evaluation of the pilot to the Trust D&T
- clear processes should exist to advise GPs:
 - that the recommendation to prescribe LDN is part of a clinical trial
 - of the review process for patients and the outcome of the review
- clear processes should exist to advise patients:
 - that prescribing is part of a clinical trial
 - of the planned exit strategy i.e. it is being prescribed on a trial basis for a defined time period
- Trust Drugs & Therapeutic Committees (or equivalents) should ensure that there is a Trust policy around use of LDN by Trust clinicians in both the inpatient and outpatient settings. Patients being prescribing LDN on the recommendation of a Trust clinician should be reviewed and treatment stopped if not beneficial to the patient.

Please note this communication does not refer to the higher doses of naltrexone used in opioid and alcohol addiction which should continue to be prescribed as normal.

Thank you for your cooperation.

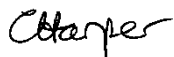
Yours sincerely



Mr Joe Brogan
Assistant Director of Integrated Care
Head of Pharmacy & Medicines
Management



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Assistant Director Integrated Care
Head of GMS Integrated Care



Dr Carolyn Harper
Medical Director/Director of Public
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Cc: All Community Pharmacists