

NHS Shropshire Clinical Commissioning Group and NHSTelford and Wrekin Clinical Commissioning Group Joint Commissioning Policy:

Low-dose naltrexone for the treatment of multiple sclerosis

Policy statement:

NHS Shropshire CCG and NHS Telford and Wrekin CCG do NOT consider low dose naltrexone, for the treatment of multiple sclerosis, suitable for routine prescribing within Shropshire or Telford and Wrekin due to limitations in existing clinical trial data and lack of evidence that low dose naltrexone represents value for money in terms of use of NHS resources.

The funding of low dose naltrexone for the treatment of multiple sclerosis will only be considered in exceptional circumstances through the <u>Individual Funding Request (IFR)</u> route.

Background

Naltrexone is licensed in the UK as an adjunctive prophylactic treatment in the maintenance of detoxified, formerly opioid dependent patients. Its use is usually initiated in specialist clinics with a typical dose being 50mg orally daily.

When used to treat multiple sclerosis (MS), typically doses of 3 to 4.5mg daily are taken; hence the term low-dose naltrexone $(LDN)^1$.

There are no commercially available LDN products and therefore the formulations (e.g. capsules or a liquid preparation) have to be specially prepared (i.e. they are "specials"). LDN therapy is therefore an unlicensed treatment in the UK²

Summary of the evidence

In autumn 2011 Multiple Sclerosis UK carried out a review of the evidence for LDN as a potential treatment for MS¹. So far there have been three trials in MS, and their report concluded that:

- These trials were not long enough to fully assess the benefits of LDN for people with MS.
- There was no evidence that LDN could reduce levels of disability or slow progression of MS.
- There is no evidence to indicate what dose of LDN might be most beneficial for people with MS.
- The effects of LDN on MS were unclear: one study reported no benefit to people with MS while the other reported some quality of life benefits.
- They stated that there needs to be more research that fully evaluates the potential benefits of LDN for people with MS.

This policy is based on the best available information at the time of writing.

¹ UK Multiple Sclerosis Society. Low-dose naltrexone (LDN) – a review of the clinical trial evidence. December 2011. Date accessed 27/09/18 <u>https://www.mssociety.org.uk/research/explore-our-research/emerging-research-and-treatments/low-dose-naltrexone-ldn</u> ² Specialist Pharmacy Service What is the evidence for low dose naltrexone for the treatment of multiple sclerosis? <u>https://www.sps.nhs.uk/articles/what-is-the-evidence-for-low-dose-naltrexone-for-treatment-of-multiple-sclerosis-2/</u> Accessed 27/09/18