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Potential Clinical Uses and Trials for LDN:

ALS (Lou Gehrig's Disease)

Addiction

Addison's Disease

Alopecia Areata

Alzheimer's Disease

Amyotrophic Lateral Sclerosis

Ankylosing Spondylitis

Anxiety

Atopic Allergy

Atopic Dermatitis

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Because LDN is an opioid receptor blocker, caution should be taken when prescribing LDN to patients who are taking opioid-type pain medications such as Morphine, Oxycodone, Hydrocodone and Fentanyl.

Exploring the Uses of Low-Dose Naltrexone (LDN)

Naltrexone, an opiate receptor antagonist, is not a new drug, but when used off label at very low doses, is a drug shown in many trials to be of therapeutic benefit. The 50mg dose of Naltrexone was approved by the FDA for opioid and alcohol addiction in 1984.

In 1985, Bernard Bihari, MD, a physician with a clinical practice in New York City, discovered the effects of a much smaller dose of Naltrexone. When reduced to doses ranging from 0.5mg to 9.0mg daily, it can modulate the immune system and may provide relief to those suffering from autoimmune diseases, chronic pain, mental health challenges and inflammation. Over the past 10 years, there has been a growing body of evidence that the body's endorphins (naturally occurring opioids) have a critical role in regulating the immune system and providing pain relief. LDN's blockade of opioid receptors has been shown to upregulate endorphin production. LDN's blockade of Toll Like Receptors is believed to contribute to the anti-inflammatory and immune dampening effects. These mechanisms help us understand why LDN can be beneficial for so many patients. LDN continues to provide life changing outcomes for many patients. It is available only by prescription and custom made at a compounding pharmacy.

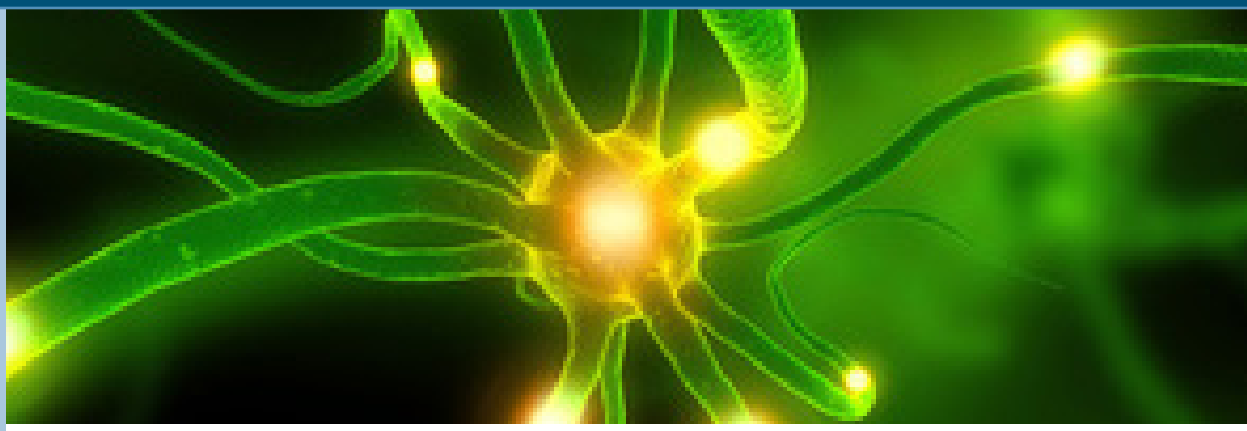
...it is critical to work with a provider or a compounding pharmacy knowledgeable in strategies that can help ensure success with LDN.

The key to success in using LDN is an understanding that optimal dosing is ultimately patient specific and is not dependent on a set protocol. Dosing strategies can vary tremendously. Some patients find success very quickly, while others need to try a variety of dosing strategies, which may take up to several months to achieve success. Therefore, it is critical to work with a provider or a compounding pharmacy knowledgeable in strategies that can help ensure success with LDN.

Since we began specializing in LDN at Town & Country, we have seen a wide variety of successes. It is these successes that motivate us to continue to try to help other patients.

Potential Clinical Uses and Trials for LDN:

- Autism Spectrum Disorders
- Behcet's Disease
- Benign Prostatic Hypertrophy (BPH)
- Brain Fog
- COPD
- CREST Syndrome
- Celiac Disease
- Chronic Fatigue Syndrome
- Complex Regional Pain Syndrome
- Crohn's Disease
- Depression
- Dermatomyositis
- Diabetes Mellitus Type I
- Eczema
- Ehlers-Danlos Syndrome
- Endometriosis
- Fibromyalgia
- General anxiety Disorder
- Granulomatosis
- Graves Disease
- HIV/AIDS
- Hailey-Hailey Disease
- Hashimoto's Disease



Low-Dose Naltrexone (LDN) ...for Multiple Sclerosis

Cree et al: Naltrexone and QOL in MS *Annals of Neurology*. February 2010(1)1-18 | **UC-San Francisco Medical School**

Objective: To evaluate the efficacy of 4.5mg nightly naltrexone on the quality of life of patients with multiple sclerosis.

Population: 80 patients with multiple sclerosis between the ages of 18 and 75 with clinically definite multiple sclerosis (International Panel criteria).

Intervention: This study was conducted as a double-masked, placebo-controlled, crossover study self-reported quality of life, to evaluate the efficacy of 8 weeks of treatment with 4.5mg nightly naltrexone (low-dose naltrexone).

Results: LDN was associated with significant improvement on the 3.3-point Mental Component Summary score General Health Survey ($p<0.01$).

Conclusion: Multiple Sclerosis patients receiving 4.5mg of naltrexone (LDN) at night showed significantly improved mental health quality of life indices when compared to placebo.

...for Depression

Mischoulon et al: For Patients with Breakthrough Depression of Major Depressive Disorder (MDD) on Antidepressants. Journal of Affective Disorders 208 (2017) 6-14 | **Harvard Medical School**

Objective: To examine the efficacy of LDN as an additional therapy for depression in patients currently taking anti-depressant medication.

Population: 12 adult patients ranging in age from 25-64 with recurrent major-depressive disorder currently on antidepressant medication.

Intervention: Patients were randomized to double blind treatment with placebo or Naltrexone 1.0mg twice daily, in addition to their current therapy.

Results: A variety of depression rating scales were used to evaluate LDN's effectiveness. The MADRS-10 and the MADRS-15 demonstrated a significant advantage of LDN over placebo.

Conclusion: LDN may have beneficial effects and good tolerability as an additional agent for patients with MDD who continue to experience depression challenges on their current medication therapy.

...for Fibromyalgia

Younger et al: Fibromyalgia Symptoms are Reduced by Low-Dose Naltrexone: A Pilot Study. *Pain Medicine* 2009(10):663-72 | **Stanford Medical School**

Objective: Pilot clinical trial, to test the effectiveness of LDN in treating the symptoms of fibromyalgia.

Population: Ten women meeting criteria for moderate to severe fibromyalgia and not taking an opioid medication.

Intervention: This study was conducted as a placebo-controlled, single-blind, crossover to evaluate the efficacy of 8 weeks of treatment with 4.5mg of naltrexone (LDN) on daily, self-reported fibromyalgia symptom severity. Each patient acted as their own control and received a placebo for two weeks before treatment.

Results: During placebo, symptoms were reduced by 2.3% in the entire cohort from baseline. In the drug condition, symptoms were reduced by 32.5%. Six out of ten patients treated with LDN were considered responders (30% or greater reduction of symptoms over placebo).

Conclusion: LDN shows promise as being a well-tolerated and effective treatment for fibromyalgia in women.

...for Crohn's Disease

Smith et al: Low-Dose Naltrexone Therapy Improves Active Crohn's Disease Pilot Study. *Am J Gastroenterol* 2007; 102:820-828 | **Penn State Medical School**

Objective: Prospective pilot study for the safety and efficacy of using LDN in patients with active Crohn's disease.

Population: 17 patients with histologically and endoscopically confirmed active Crohn's Disease.

Intervention: Patients with Crohn's disease activity index (CDAI) score of 220-450 were enrolled and treated with 4.5mg naltrexone daily. Infliximab was not allowed for a minimum of 8 wk prior to study initiation. Other therapy for Crohn's disease that was at a stable dose for 4 wk prior to enrollment was continued at the same doses.

Results: 17 patients with a mean CDAI score of 356 +/- 27 were enrolled. CDAI scores decreased significantly (P=0.01) with LDN, and remained lower than baseline 4 wk after completing therapy. Eighty-nine percent of patients exhibited a response to therapy and 67% achieved a remission (P<0.001). Improvement was recorded in both quality of life surveys with LDN compared with baseline. No laboratory abnormalities were noted. The most common side effect was sleep disturbances, occurring in 7 patients.

Conclusion: LDN appears to be a safe and effective treatment for patients suffering from active Crohn's disease.

Potential Clinical Uses and Trials for LDN:

- **Hypothyroidism**
- **Irritable Bowel Syndrome (IBS)**
- **Kawasaki's Disease**
- **Lupus**
- **Lyme Disease**
- **Menier's Disease**
- **Migraine Headaches**
- **Multiple Sclerosis (MS)**
- **Obsessive Compulsive Disorder (OCD)**
- **Pandas Disease**
- **Parkinson's Disease**
- **Pediatrics**
- **Pemphigoid**
- **Periodontal Disease**
- **Polycystic Ovary Syndrome (PCOS)**

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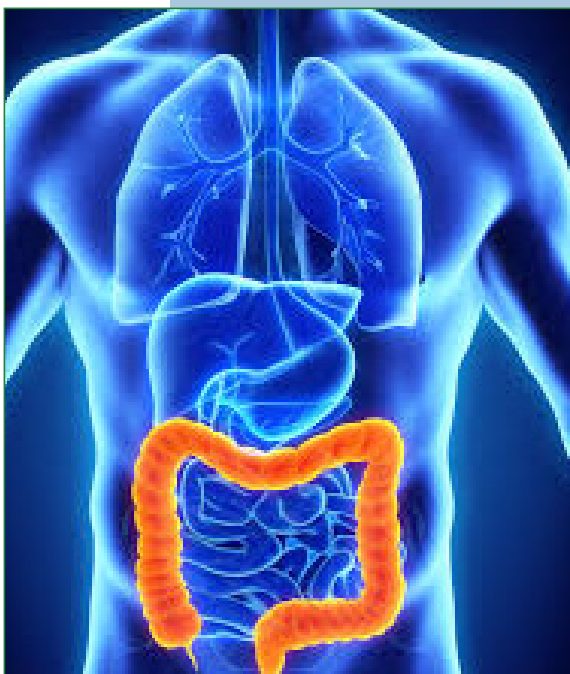

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Potential Clinical Uses and Trials for LDN:

- **Post-Traumatic Stress Disorder (PTSD)**
- **Primary Lateral Sclerosis (PLS)**
- **Psoriasis**
- **Psoriatic Arthritis**
- **Restless Leg Syndrome**
- **Rheumatoid Arthritis**
- **SIBO**
- **Sarcoidosis**
- **Scleroderma**
- **Sjogren's Syndrome**
- **Stiff Person Syndrome (SPS)**
- **Transverse Myelitis**
- **Ulcerative Colitis**
- **Wegener's**
- **Weight Loss**
- **Women's Health**
- **Vitiligo**

Refer to: LDNresearchtrust.org for more information

...for Inflammation and Pain

Younger et al: The Use of Low-Dose Naltrexone (LDN) as a Novel Anti-Inflammatory Treatment for Chronic Pain. Clinical Rheumatology (2014) 33:451-459 | **Stanford Medical School**

Objective: Review the evidence that LDN may act as a novel anti-inflammatory agent in the Central Nervous System thru its action on microglial cells.

Content: Additional information about the background, theory, mechanism of action, evidence of effectiveness, published research on pain disorders, advantages of LDN and disadvantages of LDN.

Evidence of Effectiveness:
Two proposed mechanisms of action:

1. Brief blockade of opiate receptors resulting in increased endorphin production and pain relief
2. Brief blockade of non-opiate receptors (TLR receptors) preventing activation of Microglial cells and production of inflammatory factors.

In an initial pilot study on fibromyalgia, baseline erythrocyte sedimentation rate (ESR) was a significant predictor of clinical response from LDN. (ESR is a common test that is sensitive to both chronic and acute inflammatory processes).

A variety of chronic inflammatory conditions have been shown to respond positively to LDN treatment.

Conclusion: The totality of the basic and clinical research to date suggests that LDN is a promising treatment approach for chronic pain conditions thought to involve inflammatory processes.

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