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Thank you for entrusting in the compounding services at Madison Medical Compounding Pharmacy to help meet the unique medication needs of your patients. We are excited to share our monthly newsletter with you and look forward to working with you. Please don't hesitate to let us know how we can assist you and your practice.

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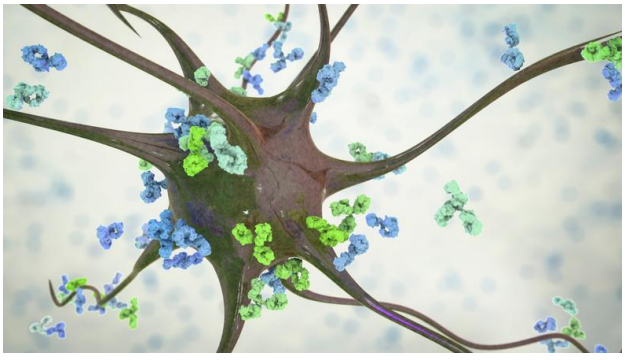
Customized Therapy for Chronic Pain and Autoimmune Diseases



Autoimmune disease happens when the body's natural defense system mistakenly attacks normal cells. There are more than 80 types of autoimmune diseases that affect over 23 million Americans, and nearly 80 percent of those affected are women. Types of autoimmune disease include lupus, rheumatoid arthritis and thyroid disease.

The cause of autoimmune disease and why more women are affected is unknown. One theory is that higher levels of hormones in women, especially during the childbearing years, could make women more susceptible to autoimmune diseases. The incidence of autoimmune disease is increasing dramatically with environmental toxins and gut microbiome playing a significant role.

Recently, LDN has been used as an off-label therapy for several chronic diseases. New studies support the benefits of using Low Dose Naltrexone (LDN) to manage autoimmune disorders such as Crohn's disease and multiple sclerosis. LDN causes different pharmacological effects than higher doses of naltrexone which is an FDA-approved medication to treat addiction.

LDN has been used to treat:

- Memory loss, mood disorders, and neurological conditions
- Post-COVID Syndrome
- Psoriasis and other chronic inflammatory skin conditions and itching associated with eczema, cholestasis, burns, etc.
- Orofacial pain

- Autoimmune diseases including multiple sclerosis and inflammatory bowel disease
- Chronic pain disorders including fibromyalgia, complex regional pain syndrome (CRPS), and diabetic neuropathy

LDN may also be helpful in treating cancer-related pain and may improve quality of life in patients unable to tolerate chemotherapy due to LDN's immune-enhancing effects. Research indicates that LDN may promote resilience and emotional well-being, as well as improvement of psychiatric problems such as anxiety and depression. However, larger studies need to confirm these potential benefits.

LDN is a viable treatment option for chronic pain disorders because LDN is an anti-inflammatory and immunomodulator. Other drugs used to treat chronic pain, such as nonsteroidal agents (NSAIDs) like ibuprofen, have adverse effects of gastrointestinal bleeding, renal injury, and increase a patient's risk of myocardial infarction or stroke. Conversely, LDN has minimal adverse side effects and is relatively inexpensive compared with other options for chronic pain. There has not been any observed toxicity or withdrawal symptoms with chronic use.

LDN is not commercially available but can be prescribed for preparation by a compounding pharmacy.

LDN and Autism

ASC (autism spectrum conditions) may result from a failure of striatal beta endorphins to diminish with maturation. Many symptoms of ASC resemble behaviors induced in animals or humans by opiate administration, including decreased socialization, diminished crying, repetitive stereotypies, insensitivity to pain and motor hyperactivity. Naltrexone, an opioid antagonist, has been used in the management of children with ASC and can produce a clinically significant reduction in the serious and life-threatening behavior of self-injury for individuals who have not been responsive to any other type of treatment and is important for this reason. A review of the literature from 2010 until 2013 revealed that 155 children participated in 10 studies. In these studies, 27 received a placebo. Of the 128 that received naltrexone, 98 (77%) showed statistically significant improvement in symptoms of irritability and hyperactivity. Side effects were mild, and the drug was generally well-tolerated. The review concluded that naltrexone may improve hyperactivity and restlessness in children with autism but there was not sufficient evidence that it had an impact on core features of autism in the majority of the participants.

J Intellect Disabil Res. 2015 Apr;59(4):293-306.

Crohn's Disease

Endogenous opioids and opioid antagonists have been shown to play a role in the healing and repair of tissues. In an open-labeled pilot prospective trial, the safety and efficacy of LDN were tested in patients with active Crohn's disease. At Pennsylvania State University College of Medicine, eligible subjects with histologically and endoscopically confirmed active Crohn's disease activity index (CDAI) score of 220-450 were enrolled in a study using 4.5mg naltrexone administered orally each evening. Infliximab was not allowed for a minimum of 8 wk prior to study initiation. Another therapy for Crohn's disease that was at a stable dose for 4 wk prior to enrollment was continued at the same doses. 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 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.

Am J Gastroenterol. 2007 Apr;102(4):820-8.

LDN and Lyme Disease

Chronic Lyme disease is a symptom complex of borrelial organisms and multiple co-infections with bacteria and other parasites. Krause et al. noted that multiple co-infections may suppress the immune system or may cause a nonspecific stimulation of the immune system, leading to inflammation, pain, and immune dysfunction.

At the 2012 Integrative Healthcare Symposium, Richard Horowitz, MD, of Hudson Valley Healing Arts Center, Hyde Park, N.Y., and President of the International Lyme and Associated Diseases Educational Foundation, noted, “Usually, the sickest patients require a combined approach using pharmaceuticals and nutraceuticals.” Dr. Horowitz notes that low-dose naltrexone (LDN) has helped patients with Crohn’s disease, multiple sclerosis, and fibromyalgia. In his open-label study of 500 patients with Lyme disease and MCIDS, approximately 75% of patients experienced less fatigue, myalgia, and arthralgia when the naltrexone dose was titrated to 4.5 mg at bedtime, using compounded LDN.

For the patient with a stimulated immune system that produces inflammatory cytokines, alpha-lipoic acid (ALA), glutathione, resveratrol, and curcumin have been found to relieve pain, fatigue, and “brain fog.” Dr. Horowitz concluded that treating the three forms of B. burgdorferi, co-infections, hormonal abnormalities, heavy metals, neurotoxins, sleep disorders, psychiatric problems, and nutritional deficiencies is the best way for patients to regain their health and to decrease pain.

“Most conventional practitioners do not believe that Lyme disease exists in chronic form, because they think the blood tests are reliable when they come up negative. But ELISA (enzyme-linked immunosorbent assay) is unreliable; you need a Western blot looking at the Lyme-specific bands from a good lab,” Dr. Horowitz said.

Pharmacy & Therapeutics. Apr 2012; 37(4): 247–249.