



SpecialCare Hospital
Management Corporation

“FDA Approves Lofexidine HCL for Opioid Withdrawal”

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FDA Approves Lofexidine HCL for Opioid Withdrawal Symptoms

In May of 2018, the Federal Drug Administration approved Lofexidine (Lucemyra) as the first non-opioid treatment for management of opioid withdrawal symptoms.

Lofexidine is not a treatment currently recommended for opioid use disorders; however, it can be used as a transitional treatment medication and aide in treatment of the acute symptoms of withdrawal. The medication is currently recommended for treatment up to 14 days.

The safety and effectiveness of the medication is supported by 2 randomized, double-blind controlled trials of 866 patients who met health criteria and were deemed physically dependent on opioids and experiencing acute opioid withdrawals.

The medication, which acts much like the medication Clonidine, displayed promising results when compared to management of opioid withdrawal in a 3-day rapid withdrawal process utilizing Clonidine. Patients treated with Lofexidine displayed fewer symptoms of withdrawals compared to patients treated with Clonidine.

Lofexidine is an oral, selective alpha 2-adrenergic receptor agonist that decreases the levels of norepinephrine released during withdrawal. The actions of norepinephrine in the autonomic nervous

system are believed to play a role in many of the symptoms of opioid withdrawal (FDA, 2018). “The most common side effects from treatment with Lucemyra include hypotension (low blood pressure), bradycardia (slow heart rate), somnolence (sleepiness), sedation and dizziness. Lucemyra was also associated with a few cases of syncope (fainting). Lucemyra effect the heart’s electrical activity, which can increase the risk of abnormal heart rhythms. When Lucemyra is stopped, patients can experience a marked increase in blood pressure. The safety and efficacy of Lucemyra have not been established in children or adolescents less than 17 years of age. After a period of not using opioid drugs, patients may be more sensitive to the effects of lower amounts of opioids if relapse does occur and taking opioids in amounts that were used before withdrawing from opioids can lead to overdose and death” (FDA, 2018).

Results are promising and therefore, New Vison™ will look to add the medication to our recommended protocols once there is more research to support use in a 3-day withdrawal process.

New Vision™ Celebrates 26 Years of Service

This year, SpecialCare Hospital Management Corporation celebrates 26 years of providing services to the community! Since 1992, SHMC has offered the New Vision™ Service in hospitals across the country and treated over 400,000 clients seeking to break the cycle of addiction.



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1. FDA, 2018. <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm607884.htm>
2. HHS, 2018. <https://www.hhs.gov/opioids/about-the-epidemic/index.html>

SpecialCare Hospital Management Corporation administers this service for the hospital and has a financial interest in this service. The diagnosis of need for inpatient admission can only be made by a licensed physician.

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Opioid Epidemic in the United States

In the 90's drug companies reassured the medical community that clients have minimal risk of addiction to opioid pain medications and therefore prescribers began utilizing them at greater rates.

In 2017, the Department of Health and Human Services declared a public health emergency and announced strategies to reduce the fatal outcomes associated with opioid use, abuse, and overdose.

The devastating crisis which is now spoken of daily by multiple news outlets has grown and continues to result in an increased need for client support and awareness.



Photo: www.pointsadsblog.com

“Opioid overdoses accounted for more than 42,000 deaths in 2016, more than any previous year on record” (HHS, 2018) and an estimated 500,000 deaths between the years 2000 and 2015

(IRP, 2018). Currently, it is estimated that an average of 116 people dies daily from opioid overdoses (HRSA, 2018).

A publication in 2018 by the Institute for Research on Poverty (IRP) suggests that opioid overdose is the leading cause of accidental death in the United States. Initially, prescription painkillers were thought to drive the opioid epidemic; however, over time the crisis has grown to include other illicit drugs such as heroin and synthetic opioids.

The IRP cited data from the Center for Disease Control (CDC) that estimates a baby is born addicted to opioids every 25 minutes. The number of babies born with symptoms of Neonatal Abstinence Syndrome (NAS) was mostly due to maternal opioid use during pregnancy, which is also significantly increasing. 65% of newborns with NAS in 2012 were to mothers in the lowest two median income quartiles compared to 33% in the highest median quartiles

(IRP, 2018). These numbers reflect that the gaps in socioeconomics are widening to include more individuals in the middle-class populations compared to previous years.

The primary culprit to lower socioeconomic status relating to higher rates of substance abuse is attributed to low education and limited labor market opportunities.

In the following excerpt from the article titled *The opioid epidemic and socioeconomic disadvantage*, it is noted that the costs of these overdoses are also significantly increasing.

“The White House Council of Economic Advisers (CEA) recently estimated that opioid epidemic-related spending on health care, substance abuse treatment, criminal justice, and lost productivity was \$72.3 billion in 2015, and the cost of opioid fatalities was \$431.7 billion.”

These figures do not reflect the costs associated with foster care placements which is also noted to have considerable costs on state levels.

Prevention and access to treatment for opioid dependency and addiction as well as access to medications which reverse the effects of overdose are just some of the measures being instituted and evaluated by agencies such as the Health and Human Services Department.

A call to action is needed to decrease the upward trend in opioid related fatalities and provide a much-needed community service. One such service is New Vision™.

New Vision™ is partnered with individual hospitals across the country to provide inpatient medical stabilization and connect patients with an after-care plan.

Interested in learning more about New Vision™?

Contact Matthew Walters, Director of Clinical Services to schedule an introductory call.

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