

Formulary Council Meeting Minutes

March 16, 2022

Present: Formulary Council Chair Natalie Gustafson, RPh, PharmD; Council Members: Will McClatchey, RPh; Adam Alani, PhD; Carmen Ionescu, MD, ND; Stephanie Culver, ND, Lara Williams, MD, Bill Walter, ND & Mary-Beth Baptista, Executive Director.

Meeting started at 9:30 am

Dr. A. Alani left the meeting at 11:30 am.

Guest: Dr. Matthew Hicks, ND, MS & Dr. Angela Carter, ND

Approval of Formulary Council Minutes: The Formulary Council approved the September 15, 2021 unanimously approved. Dr. B. Walter abstained was absent from part of the September 15, 2021 meeting.

Ketamine Formulary Restrictions

Dr. Hicks gave an overview on ketamine use.

Ketamine was developed, and is widely used, as a general anesthetic, it has many other applications including the treatment of unipolar¹ and bipolar^{2,3} depression in adults and children^{4,5}, suicidality⁶, chronic pain⁷, headaches⁸, alcohol⁹ and heroin¹⁰ dependence, PTSD¹¹, and more. Ketamine may be delivered via multiple routes, including intravenous infusion, intramuscular injection, subcutaneous injection, oral, sublingual, intranasal, and rectal. Of these options, the injectable and intranasal forms of administration have been the most studied for the treatment of major depressive disorder and treatment resistant depression.

Ketamine does carry some risk, including transient increases in blood pressure, stress on the urinary system when used chronically, and abuse as a street drug, in clinical settings it has a long track record of safety. For these reasons we offer two alternative regulations for NDs to use ketamine. The first alternative would be to require additional training comparable to the current requirements to practice intravenous infusions. Approximately ten hours of didactic and experiential training would be sufficient to competently practice the administration of ketamine. The second alternative would be to regulate the dose, rather than the route of administration. We recommend a limit of 3.0 mg/kg. In most clinical applications mentioned above a range of 0.5 to 3.0 mg/kg is most common. Beyond 3.0 mg/kg patients begin to experience more general anesthesia. Limiting NDs to non-injectable forms of ketamine has several unintended consequences. The first of which is inaccurate dosing. Sublingual is the most common alternative and has a variable absorption rate ranging from 20 to 30% compared to 100% with the intravenous route or 93% for intramuscular. This causes a larger burden on metabolic pathways, but also results in unpredictability in how patients will respond to certain doses.

Formulary Discussion:

The Board wants a way to control injectable ketamine that is therapeutic. Insure no pop-up ketamine clinics. Make sure that ND's have the proper training to administer ketamine. Storage around ketamine/DEA has strict rules on storing ketamine in office. If the Formulary Council approved the use of ketamine additional education and training to administer ketamine would be in rule.

Dr. B. Walter made motion to set up a ketamine subcommittee for rule making. Dr. A. Alani seconded. Formulary Council unanimously approved.

OHA Psilocybin Advisory Board Update

Dr. Carter reported progress from the OHA Psilocybin Advisory Board. Draft rules have been created for education/training to become certified. Currently working on licensing. Rules advisory committee meeting coming up soon. Public comment open and draft rule available to view April 1-22, 2022. The goal is to begin training of psilocybin program in June/July 2022. 120 hours for facilitators anyone graduated/GED or above. Facilitators are support system only not prescriber, collect general health information before treatment. ND's can act as facilitators and own a service center. The OBNM Board/Formulary Council will put in place rules around psilocybin/medical screening prior to patient using psilocybin. Psilocybin is not FDA approved and not approved by insurance companies. The link to the OHA Psilocybin Advisory Board: <https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/Pages/Oregon-Psilocybin-Services.aspx>

Next meeting Wednesday, September 21, 2022. The reason why meetings were held on Monday was due to Dr. McNeil travel from Southern Oregon. Moving meetings to 2nd Friday in March (check spring break week) and 3rd Friday in September.

Meeting adjourned at 11:57 am