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Emerging Risk: Ketamine & Mental Healthcare

Hannah Smith • November 21, 2022

Beazley, an expert insurer of miscellaneous medical facilities and medical providers, provides analysis on ketamine as a treatment for depression – an emerging risk in the US and around the world.

Historically, ketamine has been used as an anesthetic in surgical settings and is widely known for its illegal abuse as a psychedelic drug. However, it is now gaining prominence as a treatment for mental health disorders that patients can obtain at their doctor's office. With growth in demand for mental health treatment and new medications, some providers are introducing ketamine into their clinics as a treatment against medication resistant forms of depression, suicidality, and PTSD.

How does ketamine work to treat depression?
Per Psychology Today, "Ketamine works by causing physical growth in the prefrontal cortex and other areas of the brain associated with emotion regulation and mental health disorders. It also establishes new connections among neurons while repairing damaged cells. It builds new pathways in the brain that improve function in the areas of mood, function, sleep, and others."

Is ketamine approved and safe?
Ketamine has been studied as an off-label treatment for mental health disorders, including suicidality, depression, and PTSD for over 20 years. It is known to be particularly effective for those people diagnosed with a treatment-resistant mental health disorder, where other medications and treatments have failed them in the past.

As of 2022, there is now one FDA-approved ketamine-derived medication for mental health treatment: an instant effect intranasal spray, also known as "S ketamine" or "esketamine". FDA approval of the drug brings added protection concerns to both patients and providers- increasing standards and regulation in production of the drugs, and setting dosage, use, and supervision guidelines for providers.

Another form of ketamine medication, sometimes prescribed off-label and currently studied in clinical trial is a prescription Injectable/ Intravenous infusion, known as “R ketamine”. While only esketamine is currently FDA-approved for the treatment of depression/ PTSD disorders, physicians may choose to provide the IV/ R ketamine treatment off-label.

While the FDA approves drugs for certain health conditions, physicians in the US have the ability to prescribe off-label use of those very same medications. R Ketamine is FDA approved as an anesthetic, which opens it up for off-label physician prescribing. Some criteria and reasons for off-label use may include: (1) it meets acceptable standards of efficacy, safety, and quality (2) prescribing is in the patient’s best interest (3) the FDA approves the drug (even for another condition) (4) there are no FDA approved drugs for the condition (5) the person cannot take the FDA-approved drug due to adverse effects. Off label prescribing is incredibly widespread; in fact, it is estimated that more that 20% of prescriptions in the US today are off-label. Analysts report early studies show promise for the R ketamine/ IV treatments, but await formal FDA approval and guidance.

An underwriter’s perspective on some of the risks of ketamine treatments and how medical providers can maintain patient safety and mitigate risk

- **Increased blood pressure-** providers evaluate patient medical history, including history of high blood pressure, aneurysm risk, arteriovenous malformations, and fainting history prior to prescribing. Medical history forms should be reviewed and on file when qualifying patients.
- **Dissociation-** patients may experience distortion in perception and a detached sensation from their body- so proper patient supervision is key, ideally with multiple providers present.
- **Drowsiness/ double vision**- FDA approved esketamine is only available in a healthcare setting. Providers should monitor patients after treatment for at least 2 hours after each dose, according to the FDA. Patients should not be allowed to operate vehicles or heavy machinery. Providers should look to confirm transportation method with patients in advance, or they risk liability if unsafe methods are used and someone is hurt as a result- patient or otherwise.
- **Misuse/overdose**- this medication could be hoarded and misused by patients or staff with access. A best practice for providers is to maintain a locked medication storage protocol with possibly video monitoring, limited access to cabinet, audits of the medication cabinet, and maintain multiple staff member checks/supervision. Additionally, to prevent patient hoarding or misuse, dosage should be monitored and applied under physician supervision on site, with any additional medication being removed and properly disposed of and locked immediately.
  As a lead insurer of miscellaneous medical facilities and providers, we noted an uptick in prescribing ketamine/ketamine derived medications from insureds, primarily coming from outpatient behavioral health clinics and psychiatric practices. We have maintained flexibility and expertise in underwriting to both FDA-

approved medications, as well as acceptable off-label prescribing. This offers insureds affirmative coverage and protection, while allowing insured physicians to focus on what it is they do best: providing expert patient care.

As the physician community and FDA continue to develop, test, and explore the use of medication to treat depression and other mental health disorders, Beazley is committed to remaining industry experts, on the cutting edge, and continuing to support those experts they insure.

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