



# KEEPING UP WITH CLINICAL RISK MANAGEMENT

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## Risk Controls to Consider Before Offering Ketamine-Assisted Psychotherapy Services

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Ketamine is a phencyclidine analog that has been used as an anesthetic agent for children and adults for more than 30 years. However, it was not until the 2000s that medical professionals noticed its therapeutic benefits in reducing depression and suicidality. Now, ketamine-assisted psychotherapy (KAP) has been gaining significant popularity. KAP is a unique psychotherapy that shows promising results for individuals diagnosed with various mental health disorders, including treatment-resistant depression, resistant mood disorders, post-traumatic stress disorder, chronic pain, and anxiety.

There are a few available routes for ketamine administration:

**Infusions** – The most common forms of therapy for chronic pain and diagnoses such as fibromyalgia, migraines, and complex regional pain syndrome.

**Nasal spray** – The most common form of administration for a diagnosis of treatment-resistant depression (TRD).

**Oral** – The least expensive and most convenient way to administer ketamine and indicated for the treatment of TRD.

It is worth noting that, although ketamine is an FDA-approved medication, the only approved indication is as an anesthetic agent for diagnostic and surgical procedures. All other uses of ketamine for non-approved indications are considered “off-label use.” In 2019, the FDA approved the use of Spravato (esketamine) nasal spray in conjunction with an oral depressant for the treatment of TRD. Because of the risk of serious adverse outcomes resulting from sedation and dissociation, and the potential for abuse and misuse of the drug, the FDA has created a somewhat cumbersome process by restricting the distribution of Spravato under a risk evaluation and mitigation strategy (REMS).

With KAP being a newer form of therapy with a lack of long-standing claims loss history, obtaining professional liability insurance can become challenging

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when offering this treatment. To best prepare your organization when going to market for insurance coverage for either new or existing KAP services, the following are some recommendations for risk controls that carriers may require to be in place:

**Strong Patient Selection Criteria:** The clinical team should collaborate to evaluate which patients are appropriate for KAP, considering the patient's diagnosis, any pre-existing conditions, and required monitoring. Patients with unstable or poorly controlled hypertension or pre-existing aneurysmal vascular disorders may be at increased risk for adverse cardiovascular or cerebrovascular effects.

**Specific Consent Form:** A specific consent form should be developed that reinforces the provider's conversation with the patient regarding the risks, benefits, and alternatives to KAP. The most common side effects experienced by patients treated with ketamine were disassociation, dizziness, nausea, sedation, vertigo, decreased feeling or sensitivity (hypoesthesia), anxiety, lethargy, increased blood pressure, vomiting, and feeling drunk. The consent should also contain information regarding ketamine's off-label use/non-FDA approval for KAP treatment.

**Treatment Location:** KAP may be delivered in inpatient, office-based, and some home settings, as long as the location has the appropriate equipment and personnel to safely administer and monitor patients undergoing KAP.

**Patient Monitoring:** Because of the risk of sedation and dissociation associated with ketamine, patients receiving it should be monitored for at least two hours and have staff on emergency response in case of an adverse event. Equipment should be sized appropriately to the population you serve and

may include oxygen, bag-valve masks, non-rebreather face masks, and defibrillators. The REMS requires that both the prescriber and the patient sign a patient enrollment form clearly stating that the patient understands they should make arrangements to safely leave the healthcare setting to get home and should not drive or use heavy machinery for the rest of the day on which they received the drug. Additionally, Spravato must be dispensed with a patient medication guide outlining the drug's uses and risks.

**Supervising Agreements Between Clinicians:** Some medical malpractice insurance carriers do not allow a prescriber and therapist who work for the same practice to provide this type of split treatment. Facilities should be aware of the scope of practice limitations and supervisory requirements set forth for nurse practitioners or other advanced practice providers in the state in which they are licensed. Carriers may also question whether the state in which the practitioner practices considers KAP to be part of the "practice of the profession" in that state.

**Telehealth:** If portions of KAP are delivered via telehealth, the facility should have a written telehealth policy/guidelines. Some malpractice carriers will want to ensure that communication between patients and healthcare providers remains private, is provided on a HIPAA-compliant platform, and is properly documented.

**Quality Improvement:** Carriers will want to ensure that facilities have quality improvement policies/procedures that track provider ketamine prescribing practices, review quality and safety incidents surrounding care, reduce potential liability, and seek to continually improve the care provided to patients.

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Your current or future professional liability carrier may have specific questions and concerns that need to be addressed before you can add KAP services to your policy. For example, carriers will want to better understand the percentage of overall KAP-related services that are being offered (by revenue or patient encounters) compared to other service lines. An insurance broker can be an important partner in helping a KAP provider or practice navigate the appropriate risk controls and build an ideal insurance program for your KAP practice and patients.



*Danielle Donovan is Parker, Smith & Feek's Clinical Risk Manager, dedicated to helping improve our healthcare clients' operations and mitigate risks. She publishes regular articles to support this effort and provide unbiased advice on issues facing all types of healthcare organizations. Stay tuned for her next installment, and contact Parker, Smith & Feek's [Healthcare Practice Group](#) if you would like to learn more.*

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