This Policy Statement establishes the State Emergency Medical Advisory Committee (SEMAC) and the Department’s criteria for including ketamine in an EMS agency’s controlled substance formulary. Please take the time to read and understand this Policy Statement. Each individual EMS agency, its controlled substances agent and the medical director are responsible for adhering to all applicable laws, regulations and policies.

**History:**
In June of 2009, the SEMAC approved ketamine to be added to the State EMS Drug Formulary. This change required the Department to review and approve the medication, the process for inventory, security and training. This updated version reflects changes allowed by the Bureau of Narcotics Enforcement (BNE) and based on SEMAC approved advanced life support protocols.

Based on the potency of ketamine and the potential for serious issues of diversion and abuse, the Department remains extremely concerned about its applications in the prehospital environment.

**Conditions for Approval:**
In order for the Department to approve the addition of ketamine to an EMS agency with a current Class 3C controlled substance license, the following conditions must be met and the Department must review and issue written approvals.

1. The Regional Medical Advisory Committee (REMAC) must develop protocols for the administration of ketamine and a semi-annual evaluation of its use on the regional level.
2. The protocols must also be approved by the SEMAC and then by the Department.
3. The service medical director must approve, in writing, ketamine for use by the EMS service.
4. Only those individuals certified at the paramedic level may administer ketamine.
5. The EMS agency must submit an amendment to their Controlled Substance Operations Plan to include, but not be limited to the following:
   < A detailed description of the procurement; inventory process and security of ketamine.
   < A program for 100% quality assurance by the service medical director for instances where ketamine has been administered.
   < A separate Semi-Annual Report (attached) for ketamine stock and administrations. This must be received by the Department by January 31st and July 31st annually.
6. The EMS agency must submit for review and approval by the Department, the training program developed to in-service personnel. The program must include, but not be limited to training on the updated controlled substance plan, inventory, security, patient administration and reporting policies and procedures. The curriculum format must follow the BEMS required curriculum addition format.

7. Each substock (the controlled substance medications carried on each vehicle) is limited to a **MAXIMUM of 1,000 mg**.

8. There are two (2) components of the reporting process:
   
   a. The EMS agency must submit a semi-annual Report form ([http://www.health.ny.gov/forms/doh-3848.pdf](http://www.health.ny.gov/forms/doh-3848.pdf)). This must be received by the Department before January 31st and July 31st annually.

   b. The EMS agency medical director is required to provide a written report of the service’s use of ketamine in the prior year no later than **January 31st of each year**. It must include, but not be limited to the following items:

      < The total number of administrations, amount or medication used and dose.
      < The amount of ketamine wasted.
      < A summary of the patient presenting problems.
      < A narrative summary highlighting the Quality Assurance reviews conducted for each ketamine administration.

9. All instances where a theft, loss or diversion, are suspected **MUST BE REPORTED TO THE DEPARTMENT IMMEDIATELY**. This report must be made to the BEMS Central Office using the Loss of Controlled Substances Report form (DOH-2094). This form is available on line at [http://www.health.ny.gov/forms/doh-2094.pdf](http://www.health.ny.gov/forms/doh-2094.pdf).

10. **Prior** to including ketamine in the EMS agency’s formulary, the medical director and the agent must receive written approval from the Department.

11. If the agency makes any changes or updates to the Controlled Substance Operations Plan, it must provide the specific changes to the Department in writing **prior** to implementation.

   The Department continues to closely monitor the EMS agencies that maintain a Class 3C controlled substance license to ensure that there is the strictest compliance with all applicable sections of Public Health Law, the Codes, Rules and Regulations – Part 800 and Section 80.136 of the Part 80 Rules and Regulations on Controlled Substances in New York State, as well as the EMS service’s approved Controlled Substance Operations Plan.
### Drug Formulary

**KETAMINE**

<table>
<thead>
<tr>
<th>Class</th>
<th>Anesthetic Induction</th>
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**Description**
Ketamine is a controlled substance medication that is a rapid-acting general anesthetic producing an anesthetic state characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, normal or slightly enhanced skeletal muscle tone, cardiovascular and respiratory stimulation, and occasionally a transient and minimal respiratory depression.

**Onset & Duration**
- **Onset:** Rapid – IV within 30 seconds half life 10-15 min.; IM within 3-4 minutes
- **Duration:** IV 2 mg/kg lasts 5-10 minutes; IM 9 to 13 mg/kg lasts 12-25 minutes

**Indications**
1. Ketamine is indicated as the sole anesthetic induction agent for management of trauma patients in extreme pain requiring proper immobilization and/or extrication.

**Contraindications**
1. Ketamine is contraindicated in those in whom a significant elevation of blood pressure would constitute a serious hazard and in those who have shown hypersensitivity to the drug.

**Adverse Reactions**
1. Cardiovascular - blood pressure and pulse rate are frequently elevated following administration of Ketamine alone. However, hypotension and bradycardia have been observed. Arrhythmia has also occurred.
2. Respiration - Although respiration is frequently stimulated, severe depression of respiration or apnea may occur following rapid intravenous administration of high doses of Ketamine.
Laryngospasms and other forms of airway obstruction have occurred during Ketamine anesthesia.

3. Eye - Diplopia and nystagmus have been noted following Ketamine administration. It also may cause a slight elevation in intraocular pressure measurement.

4. Neurological - In some patients, enhanced skeletal muscle tone may be manifested by tonic and clonic movements sometimes resembling seizures.

5. Gastrointestinal - Anorexia, nausea and vomiting have been observed; however, this is not usually severe and allows the great majority of patients to take liquids by mouth shortly after regaining consciousness.

6. General: Anaphylaxis, local pain and exanthema at the injection site have infrequently been reported. Transient erythema and/or morbilliform rash have also been reported.

**Ketamine continued...**

**Drug Interactions**

- Prolonged recovery time may occur if barbiturates and/or narcotics are used concurrently with Ketamine.

**How Supplied**

- Injection: IM or IV 15 mg (15 mg/mL) and 30 mg (30 mg/mL)

Ketamine Hydrochloride Injection, USP is supplied as the hydrochloride in concentrations equivalent to Ketamine base.

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<thead>
<tr>
<th>Container</th>
<th>Concentration</th>
<th>Fill</th>
<th>Quantity</th>
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</thead>
<tbody>
<tr>
<td>Fliptop</td>
<td>100 mg/mL</td>
<td>5 mL</td>
<td>Box of 10</td>
</tr>
<tr>
<td>Vial</td>
<td>50 mg/mL</td>
<td>10 mL</td>
<td>Box of 10</td>
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Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if a precipitate appears.

- Store at 20 to 25°C (68 to 77°F).
- Protect from light.

**Dosing**

- Adult IV 1-4.5 mg/kg IV over 1 min.
- Adult IM 6.5-13 mg/kg IM one dose
Pediatric IV >3 months 1.5 mg/kg IV over 1 min.
Pediatric IM >3 months 4-5 mg/kg one dose

Protocol

<table>
<thead>
<tr>
<th>MA XX</th>
<th>Adult Pain Management</th>
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<tbody>
<tr>
<td>MA XX</td>
<td>Pediatric Pain Management</td>
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</table>

Special Considerations

1. Elevation of blood pressure begins shortly after injection, reaches a maximum within a few minutes and usually returns to preanesthetic values within 15 minutes after injection.
2. Because pharyngeal and laryngeal reflexes are usually active, Ketamine can not be used alone for advanced airway management such as intubation. Mechanical stimulation of the pharynx should be avoided, whenever possible, if Ketamine is used alone.
3. The incidence of emergence reactions may be reduced if verbal and tactile stimulation of the patient is minimized during the recovery period. This does not preclude the monitoring of vital signs.
4. The intravenous dose should be administered over a period of 60 seconds. More rapid administration may result in respiratory depression or apnea and enhanced pressor response.
5. Use with caution in the chronic alcoholic and the acutely alcohol-intoxicated patient.
6. This medication is a Class III controlled substance medication approved for prehospital use by the SEMAC and the Department.