



New York State
Department of Health
Bureau of Emergency Medical Services

POLICY STATEMENT

Supersedes/Updates:

No. 10 - 04

Date: May 24, 2010

**Re: Ketamine for
Prehospital EMS
Services**

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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. As this requires a change to the prehospital use of controlled substances formulary, the Department must review and approve the medication, the process for inventory, security and training. Once done, the Commissioner makes a final ruling. This request was reviewed by the Department's Division of Legal Affairs, the Bureau of Narcotic Enforcement (BNE), the Bureau of Emergency Medical Services (BEMS) and given final approval by the Commissioner of Health.

Based on the potency of ketamine and the potential for serious issues of diversion and abuse, the Department is 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 quarterly 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 Quarterly Report (attached) for ketamine stock and administrations. This must be received by the Department within 30 days of the end each quarter.

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. ***KETAMINE MAY ONLY BE ADMINISTERED TO A PATIENT UNDER A DIRECT ON-LINE ORDER FROM A MEDICAL CONTROL PHYSICIAN.***
9. There are two (2) components of the reporting process:
 - a. The EMS agency must submit a Ketamine Quarterly Report form (attached) within 30 days of the end of each quarter.
 - 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.
10. 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.nyhealth.gov/forms/doh-2094.pdf>
11. **Prior** to including ketamine in the EMS agency's formulary, the medical director and the agent must receive written approval from the Department.
12. 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 insure that there is the strictest compliance with all of the 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.

This report must be submitted pursuant to PHL Article 33 within 30 days of the end of each Quarter. Reports must be submitted regardless of usage. Retain a copy of this Quarterly Report for a period of 5 years from the date of filing.

Quarterly Reporting Period: _____

Agency Name	NYS-EMS ID No.	NYS-BNE License No.		
Address	City	State	Zip	Business Phone
Name of DEA Registrant	DEA License No.	Day Phone		

	KETAMINE		RESPONSE/ TRANSPORT HISTORY
Total Quantity at Start of Quarter	Stock: _____ Substock: _____ TOTAL of above: _____	Total Number of EMS Response/Transports this Quarter	
Total Quantity Received from DEA Registrant		Total Number of Patients Receiving ketamine this Quarter	
Total Quantity Administered		Number of ketamine Administrations pursuant to Direct Medical Control	
Total Quantity Wasted		Number of Quality Assurance reviews conducted by the service medical director	
Total Quantity Lost (Attach copy of DOH Form 2094)		Number of Adverse Reactions to ketamine Administration	
Total Quantity Remaining at End of Quarter		Number of EMS Personnel Authorized to Administer ketamine	Flight Nurses _____ EMT-P _____ EMT-CC _____

I certify that on _____ I conducted an actual physical inventory of the controlled substance listed above. Losses have been reported on a "Loss of Controlled Substances Report" DOH Form 2094 and have been submitted to BNE and a copy of the form has been enclosed. Overages are explained on a separate attached report.

I affirm that this is a true and accurate record of the controlled substance utilization by the above named agency.

Name of Agent (print)

Signature of Agent

Date

Name of CEO (print)

Signature of CEO

Date

Sent completed report by due date to:

New York State Department of Health, Bureau of Emergency Medical Services
 433 River Street 6th Fl., Troy, NY 12180
 Telephone 518-402-0996 x2



Drug Formulary

KETAMINE

Class

Anesthetic Induction

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.

Container	Concentration	Fill	Quantity
Fliptop Vial	100 mg/mL	5 mL	Box of 10
Fliptop Vial	50 mg/mL	10 mL	Box of 10

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

MA XX	Adult Pain Management
MA XX	Pediatric Pain Management

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.