Ketalar

Description

Ketalar (ketamine)

Background
Ketamine is a rapid-acting anesthetic that can produce anesthesia while maintaining skeletal muscle tone, laryngeal-pharyngeal reflexes, and cardiovascular and respiratory stimulation (1).

Regulatory Status
FDA-approved indication: Ketamine is indicated as the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. Ketamine injection is indicated for the induction of anesthesia prior to the administration of other general anesthetic agents. Ketamine is indicated to supplement low-potency agents, such as nitrous oxide (1).

Ketamine is contraindicated in those in whom a significant elevation of blood pressure would constitute a serious hazard. Cardiac function should be continually monitored during the procedure in patients found to have hypertension or cardiac decompensation (1).

Because pharyngeal and laryngeal reflexes are usually active, Ketalar should not be used alone in surgery or diagnostic procedures of the pharynx, larynx, or bronchial tree (1).

There are several off-label uses that have been studied for ketamine including, but not limited to, chronic pain, including chronic neuropathic pain, restless legs syndrome and phantom limb syndrome. Alternative routes of administration, including oral, intranasal, transdermal, rectal...
and subcutaneous have been studied. However, these routes of administration and uses are investigational and are not supported by the FDA (2).

**Off-Label Uses:**
Off-label (non-FDA approved) compounded topical preparations of ketamine have not been shown to be superior to commercially available topical diclofenac preparations (2).

Safety and effectiveness in pediatric patients under the age of 16 years have not been established (1).

**Related policies**
Lidocaine

**Policy**
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Ketalar may be considered **medically necessary** in patients 16 years of age or older for the induction of anesthesia prior to the administration of other general anesthetic agents or for conscious sedation for minor surgical procedures or diagnostic procedures.

Ketalar may be considered **investigational** in patients under the age of 16 years and for all other indications.

**Prior-Approval Requirements**

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<th>Age</th>
<th>16 years of age or older</th>
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<td><strong>Diagnoses</strong></td>
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Patients must have **ONE** of the following:

1. Induction of anesthesia prior to the administration of other general anesthetic agents
2. Conscious sedation prior to minor surgical or diagnostic procedures

**Prior – Approval Renewal Requirements**
Same as above

**Policy Guidelines**
Pre - PA Allowance
None

Prior - Approval Limits
Duration  12 months

Prior – Approval *Renewal* Limits
Duration  12 months

Rationale

Summary
Ketamine is a rapid-acting anesthetic that can produce anesthesia while maintaining skeletal muscle tone, laryngeal-pharyngeal reflexes, and cardiovascular and respiratory stimulation (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Ketalar while maintaining optimal therapeutic outcomes.

References

Policy History

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<thead>
<tr>
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<td>December 2011</td>
<td>Annual editorial review and reference update</td>
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<td>December 2012</td>
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<td>March 2013</td>
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<tr>
<td>June 2013</td>
<td>Language added on topical products</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 18, 2016 and is effective April 1, 2016.

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