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5.70.013

Section:	Prescription Drugs	**Effective Date:**	July 1, 2024
Subsection:	Analgesic and Anesthetics	**Original Policy Date:**	December 7, 2011
Subject:	Ketalar	**Page:**	1 of 4

Last Review Date: June 13, 2024

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 is best suited for short procedures but it can be used, with additional doses, for longer procedures. 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, Ketamine 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 (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
Ketamine Powder, 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** if the conditions indicated below are met.

Ketalar may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 16 years of age or older

Diagnoses

Patient 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

Same as above

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

1. Ketamine Injection [package insert]. Lake Forest, IL: Hospira, Inc.; March 2021.
2. Kronenberg RH. Ketamine as an analgesic: parenteral, oral, rectal, subcutaneous, transdermal and intranasal administration. *J Pain Palliat Care Pharmacother.* 2002;16 (3):27-35.

Policy History

Date	Action
December 2011	Annual editorial review and reference update
December 2012	Annual editorial review and reference update
March 2013	Annual editorial review
June 2013	Language added on topical products
December 2013	Annual editorial review and reference update
June 2014	Annual editorial review and reference update
June 2015	Annual review and reference update
March 2016	Annual editorial review
	Policy code changed from 5.02.13 to 5.70.13
March 2017	Annual review
March 2018	Annual editorial review and reference update
March 2019	Annual review

March 2020	Annual review
June 2021	Annual review and reference update
June 2022	Annual review
June 2023	Annual review. Changed policy number to 5.70.013
June 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 13, 2024 and is effective on July 1, 2024.