INTRA-VENOUS KETAMINE INFUSION FOR TREATMENT OF DEPRESSION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Intravenous (IV) infusions of the anesthetic ketamine have been investigated for the treatment of depression including severe and drug resistant depression.

IV infusions of ketamine are administered in an outpatient setting and may include multiple infusions.

Treatment resistant depression typically refers to major depressive episodes that do not respond satisfactorily after two trials of antidepressant monotherapy; however, the definition has not been standardized.

Treatment refractory depression typically refers to unipolar major depressive episodes that are highly resistant to treatment and do not respond satisfactorily to many sequential treatment regimens. However, the definition has not been standardized, and there is no clear demarcation between treatment resistant depression.
INTRANOVENOUS KETAMINE INFUSION FOR TREATMENT OF DEPRESSION (cont.)

Criteria:

- Intravenous ketamine for the treatment of depression is considered *experimental or investigational* based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Resources:


INTRAVENOUS KETAMINE INFUSION FOR TREATMENT OF DEPRESSION (cont.)

Resources: (cont.)


FDA Product Approval Information for Ketalar® (ketamine hydrochloride injection):

- FDA-approved indication: the sole anesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation, best suited for short procedures but it can be used, with additional doses, for longer procedures, for the induction of anesthesia prior to the administration of other general anesthetic agents and to supplement low-potency agents, such as nitrous oxide.

Ketalar (ketamine hydrochloride injection) is a registered trademark of JHP Pharmaceuticals, Inc., an independent corporation that is not affiliated with BCBSAZ.