



Drug and Biologic Coverage Policy

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Coverage Policy Number IP0557

Nembutal [pentobarbital] injection

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INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy addresses the usage of (Nembutal® [pentobarbital] injection) in an outpatient setting. The policy does not address potential use for individuals in an in-patient or hospitalized setting.

Coverage Policy

The use of Nembutal [pentobarbital] injection in an outpatient setting for any use is considered not medically necessary.

Note:

Nembutal [pentobarbital] injection is FDA approved for the short-term management of insomnia or as pre-anesthesia; however, current clinical practice guidelines do not support these uses.

Background

OVERVIEW

Nembutal (pentobarbital) injection¹ is FDA approved for the following indications:

- Sedatives
- Hypnotics, for the short-term treatment of insomnia
- Preanesthetics

- Anticonvulsant, in anesthetic doses, in the emergency control of certain acute convulsive episodes

Guidelines

American Academy of Sleep Medicine (AASM) clinical practice guidelines state that although included as an FDA-approved use in the manufacturer's prescribing information for the short-term treatment of insomnia, the use of barbiturates, such as pentobarbital and secobarbital, is no longer recommended for the treatment of insomnia. The guidelines provide a weak recommendation to use doxepin, eszopiclone, ramelteon, suvorexant, temazepam, triazolam, zaleplon or zolpidem for the treatment for sleep maintenance insomnia, versus no treatment, in adults.²

American Epilepsy Society (AES) guidelines list several medications for the third therapy phase of treatment of status epilepticus. Among the drugs listed is pentobarbital at anesthetic doses with continuous EEG (electroencephalography) monitoring. The guidelines note that there is no clear evidence to guide therapy in this third phase, and the conclusion level is "U," which indicates that there is no recommendation. There is no supportive citation for the outpatient use of pentobarbital injection.³

References

1. Nembutal (pentobarbital) [prescribing information]. Lake Forest, IL: Akorn Inc; February 2020.
2. Sateia MJ, Buysse DJ, Krystal AD, Neubauer DN, Heald JL. Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2017;13(2):307-349
3. Glauser T, Shinnar S, Gloss D, et al. Evidence-Based Guideline: Treatment of Convulsive Status Epilepticus in Children and Adults: Report of the Guideline Committee of the American Epilepsy Society. *Epilepsy Currents*. 2016;16(1):48-61. doi:10.5698/1535-7597-16.1.48

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