



Effective Date 10/1/2023
Next Review Date... 10/1/2024
Coverage Policy Number IP0025

Butalbital Combination Products

Table of Contents

Overview 1
Medical Necessity Criteria 2
Reauthorization Criteria 3
Authorization Duration 3
Conditions Not Covered..... 3
Background..... 3
References 4

Related Coverage Resources

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 supports medical necessity review for the following butalbital combination products:

- **Allzital** (acetaminophen / butalbital tablet)
- **Bupap**[®] (acetaminophen / butalbital)
- Butalbital 50 mg / Acetaminophen 300 mg capsules and tablets
- **Esgic**[®] (acetaminophen / butalbital / caffeine)
- **Fioricet** (acetaminophen / butalbital / caffeine)
- **Fioricet with Codeine** (acetaminophen / butalbital / caffeine / codeine)
- **Vanatol LQ**[™] (acetaminophen / butalbital / caffeine)
- **Vanatol S**[™] (acetaminophen / butalbital / caffeine)
- **Vtol LQ**[™] (acetaminophen / butalbital / caffeine)

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage criteria are listed for products in below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
Allzital (acetaminophen / butalbital) 300 mg - 25 mg tablet	Allzital is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> Individual is 12 years of age or older Failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> acetaminophen / butalbital 325 mg – 50 mg tablets acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg capsules acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg tablets
Bupap (acetaminophen / butalbital) 300 mg - 50 mg tablet	Bupap is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> Individual is 12 years of age or older Failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> acetaminophen / butalbital 325 mg – 50 mg tablets acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg capsules acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg tablets
Butalbital 50 mg /Acetaminophen 300 mg capsules and tablets	Butalbital 50 mg /Acetaminophen 300 mg capsules and tablets is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> Individual is 12 years of age or older Failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> acetaminophen / butalbital 325 mg – 50 mg tablets acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg capsules acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg tablets
Esgic (acetaminophen / butalbital / caffeine)	EFFECTIVE 1/1/2024 Esgic is considered medically necessary when there is documentation of a trial of <u>acetaminophen / butalbital / caffeine</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Fioricet (acetaminophen / butalbital / caffeine)	EFFECTIVE 1/1/2024 Fioricet is considered medically necessary when there is documentation of a trial of <u>acetaminophen / butalbital / caffeine</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Fioricet with Codeine (acetaminophen / butalbital / caffeine / codeine)	EFFECTIVE 1/1/2024 Fioricet is considered medically necessary when there is documentation of a trial of <u>acetaminophen / butalbital / caffeine / codeine</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Vanatol LQ (acetaminophen / butalbital / caffeine) 325 – 50 – 40 mg/mL syrup	Vanatol LQ is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> Individual is 12 years of age or older Failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> acetaminophen / butalbital 325 mg – 50 mg tablets acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg capsules

Non-Covered Product	Criteria
Vanatol S (acetaminophen / butalbital / caffeine) 325 – 50 – 40 mg/mL syrup	C. acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg tablets Vanatol S is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> 1. Individual is 12 years of age or older 2. Failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> A. acetaminophen / butalbital 325 mg – 50 mg tablets B. acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg capsules C. acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg tablets
Vtol LQ (acetaminophen / butalbital / caffeine) 325 – 50 – 40 mg/mL syrup	Vtol LQ is considered medically necessary when there is documentation of BOTH of the following: <ol style="list-style-type: none"> 1. Individual is 12 years of age or older 2. Failure, contraindication, or intolerance to ONE of the following: <ol style="list-style-type: none"> A. acetaminophen / butalbital 325 mg – 50 mg tablets B. acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg capsules C. acetaminophen / butalbital / caffeine 325 mg – 50 mg – 40 mg tablets

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Continuation of butalbital combination products (Allzital, Bupap, Butalbital / Acetaminophen 50 mg – 300 mg, Esgic, Fioricet, Fioricet with Codeine, Vanatol LQ, Vanatol S and Vtol LQ) is considered medically necessary when the above medical necessity criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration: up to 12 months.
 Reauthorization approval duration: up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Guidelines

American Academy of Neurology (AAN) evidence-based guidelines for migraine headache state to limit and carefully monitor the use of butalbital-containing analgesics, based on overuse, medication-overuse headache, and withdrawal concerns.⁵

American Headache Society (AHS) recommendations for the acute treatment of migraine in adults state there is inadequate evidence for the use of butalbital and butalbital combinations.⁴

Canadian Headache Society guideline for acute drug therapy for migraine headache provides a strong recommendation to avoid the use of butalbital containing medications for the treatment of acute migraine headache.⁷

References

1. ECR Pharmaceuticals. Bupap (acetaminophen/butalbital) [product information]. Richmond, VA: ECR Pharmaceuticals; November 2013.
2. GM Pharmaceuticals, Inc. Vanatol LQ (butalbital, acetaminophen and caffeine oral solution) [product information]. Arlington, TX. GM Pharmaceuticals, Inc. Arlington, TX. March 2015.
3. GM Pharmaceuticals, Inc. Vanatol S (butalbital, acetaminophen and caffeine oral solution) [product information]. Arlington, TX. GM Pharmaceuticals, Inc. Arlington, TX. March 2015.
4. Marmura MJ, Silberstein SD and Schwedt TJ. The acute treatment of migraine in adults: the American Headache Society evidence assessment of migraine pharmacotherapies. *Headache*. 2015 Jan; 55 (1):3-20.
5. Silberstein SD. Practice parameter: evidence-based guidelines for migraine headache (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. *Neurology*. 2000 Sep 26; 55 (6):754-62.
6. Skylar Laboratories. Allzital (butalbital/acetaminophen) tablets [prescribing information]. Canton, MS: Skylar Laboratories; December 2015.
7. Worthington I, Pringsheim T, Gawel MJ, et al. Canadian Headache Society Guideline: acute drug therapy for migraine headache. *Can J Neurol Sci*. 2013 Sep; 40(5 Suppl 3):S1-S80.
8. Monarch PCM LLC. Vtol LQ (butalbital/acetaminophen/caffeine) [product information]. Fort Worth, TX. Monarch PCM LLC; August 2019.

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. © 2023 Cigna.