



SmartPA Criteria Proposal

Drug/Drug Class:	Butalbital Combinations without Codeine Clinical Edit
First Implementation Date:	July 22, 2003
Proposed Date:	December 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of butalbital combination products without codeine

Why Issue Selected: Butalbital combination products without codeine are only FDA approved for the relief of the symptom complex of tension (or muscle contraction) headache. No evidence is available to support the efficacy and safety of these combination products in the treatment of multiple recurrent headaches; however, these products have long been used to treat acute migraine. These products may contain butalbital mixed with acetaminophen alone or butalbital mixed with a combination of caffeine and acetaminophen or aspirin. Butalbital is a short to intermediate-acting barbiturate that works with acetaminophen, an antipyretic non-salicylate agent, aspirin, a pain-relieving NSAID, and/or caffeine, a stimulant that works in the CNS, to decrease pain by a mechanism that isn't well understood. Because butalbital is habit-forming and contains a potential for abuse, caution is warranted to insure proper usage.

Program-Specific Information:

Date Range FFS 10-01-2021 to 9-30-2022			
Drug	Claims	Spend	Average Spend per Claim
ALLZITAL (BUTALBITAL 25 MG/APAP 325 MG TAB)	0	-	-
BUTALBITAL 50 MG/APAP 300 MG CAPSULE	0	-	-
BUTALBITAL 50 MG/APAP 300 MG TABLET	1	\$150.45	\$150.45
BUTALBITAL 50 MG/APAP 325 MG TABLET	140	\$4,901.14	\$35.01
BUTALBITAL, APAP, & CAFFEINE 50-300-40 MG CAP	1,956	\$53,233.86	\$27.22
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG CAP	75	\$5,982.78	\$79.77
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG ELIX	0	-	-
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG TAB	7,301	\$116,724.74	\$15.99
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG CAP	218	\$7,570.64	\$34.73
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG TAB	0	-	-
TOTALS	9,691	\$188,563.61	\$19.46

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Butalbital Combinations without Codeine
- Age range: All appropriate MO HealthNet participants aged 12 years and older

Approval Criteria

- Documented diagnosis of tension headache or migraine headache **AND**
- For butalbital combination agents containing acetaminophen: Participant aged \geq 12 years **OR**
- For butalbital combination agents containing aspirin: Participant aged \geq 18 years
- For Allzital therapy: Documented trial of 3 or more other butalbital combination products (trial defined as 60 out of 90 days)
- **Clinical Consultant review required: Bupap 50 mg/300 mg Tablet, Butalbital 50 mg/APAP 300 mg Cap, Esgic 50-325-40 mg Cap**

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Claim exceeds quantity limitations:

Drug Description	Max Units Per Day	Max Units Per Month
ALLZITAL (BUTALBITAL 25 MG/APAP 325 MG TAB)	12 TABS	60 TABS
BUTALBITAL 50 MG/APAP 300 MG CAPSULE	6 CAPS	30 CAPS
BUTALBITAL 50 MG/APAP 300 MG TABLET	6 TABS	30 TABS
BUTALBITAL 50 MG/APAP 325 MG TABLET	6 TABS	30 TABS
BUTALBITAL, APAP, & CAFFEINE 50-300-40 MG CAP	6 CAPS	30 CAPS
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG CAP	6 CAPS	30 CAPS
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG ELIX	90 MLS	450 MLS
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG TAB	6 TABS	30 TABS
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG CAP	6 CAPS	30 CAPS
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG TAB	6 TABS	30 CAPS

Required Documentation

Laboratory Results:

Progress Notes:

MedWatch Form:

Other:

Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)
Rule Type: CE

Default Approval Period

1 year

References

SmartPA Clinical Proposal Form

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Other company trademarks are also acknowledged.

- Allzital (butalbital/acetaminophen) tablets [prescribing information]. Canton, MS: Larken Laboratories, Inc; October 2021.
- Fioricet (butalbital, acetaminophen, and caffeine) [prescribing information]. Parsippany, NJ: Teva Pharmaceuticals USA, Inc.; January 2021.
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- Da Silva AN, Lake AE 3rd. Clinical aspects of medication overuse headaches. *Headache*. 2014;54(1):211-217.[PubMed 24116964]10.1111/head.12223
- Clinical Pharmacology. Butalbital/Acetaminophen Oral. Accessed November 7, 2022.
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