

SmartPA Criteria Proposal

Drug/Drug Class:	Butalbital Combinations without Codeine Clinical Edit
First Implementation Date:	July 22, 2003
Proposed Date:	December 17, 2020
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 10-01-2019 to 9-30-2020			
Drug	Claims	Spend	Average Spend per Claim
ALLZITAL (BUTALBITAL 25 MG/APAP 325 MG TAB)	3	\$1,152.08	\$384.02
BUTALBITAL 50 MG/APAP 300 MG CAPSULE	2	\$722.43	\$361.21
BUTALBITAL 50 MG/APAP 300 MG TABLET	16	\$3,324.14	\$207.75
BUTALBITAL 50 MG/APAP 325 MG TABLET	145	\$6,328.14	\$43.64
BUTALBITAL, APAP, & CAFFEINE 50-300-40 MG CAP	2,512	\$142,746.05	\$56.82
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG CAP	315	\$33,165.52	\$105.28
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG ELIX	0	-	-
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG TAB	7,880	\$195,299.62	\$24.78
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG CAP	265	\$11,261.02	\$42.49
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG TAB	0	-	-
TOTALS	11,138	\$393,999.00	\$35.37

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 ≥ 12 years **OR**
- For butalbital combination agents containing aspirin: Participant aged ≥ 18 years
- For Allzital therapy: Documented trial of 3 or more other butalbital combination products (trial defined as 60 out of 90 days)

Denial Criteria

- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

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

Default Approval Period

1 year

References

- Allzital (butalbital/acetaminophen) tablets [prescribing information]. Ocean Springs, MS: Phlight Pharma, LLC; December 2019.
- Fioricet (butalbital, acetaminophen, and caffeine) [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc; June 2020.
- Fiorinal (butalbital/aspirin/caffeine) [prescribing information]. Madison, NJ: Allergan USA, Inc.; July 2018.
- Da Silva AN, Lake AE 3rd. Clinical aspects of medication overuse headaches. *Headache*. 2014;54(1):211-217.[PubMed 24116964]10.1111/head.12223
- Facts and Comparisons. Butalbital/Acetaminophen Oral. Accessed October 27, 2020.
- Facts and Comparisons. Butalbital/Acetaminophen/Caffeine Oral. Accessed October 27, 2020.
- Facts and Comparisons. Butalbital/Aspirin/Caffeine Oral. Accessed October 27, 2020.

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