



SmartPA Criteria Proposal

Drug/Drug Class:	Butalbital Combinations without Codeine Clinical Edit
First Implementation Date:	July 22, 2003
Revised Date:	October 17, 2019
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" 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 1-1-2018 to 12-31-2018		
Drug	Claims	Spend
BUTALBITAL 50 MG/APAP 300 MG CAPSULE	0	\$0
ALLZITAL (BUTALBITAL 25 MG/APAP 325 MG TAB)	1,663	\$2,166,942.00
BUTALBITAL 50 MG/APAP 300 MG TABLET	61	\$39,924.33
BUTALBITAL 50 MG/APAP 325 MG TABLET	254	\$20,652.20
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG TAB	13,776	\$506,875.96
BUTALBITAL, APAP, & CAFFEINE 50-300-40 MG CAP	4,005	\$490,955.65
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG CAP	325	\$33,544.32
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG ELIX	1	\$26.39
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG CAP	588	\$40,548.24
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG TAB	14	\$368.44
TOTALS	20,687	\$3,299,837.53

Type of Criteria: Increased risk of ADE
 Appropriate Indications

Preferred Drug List
 Clinical Edit

Data Sources: Only Administrative Databases

Databases + Prescriber-Supplied

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Setting & Population

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

Approval Criteria

- Participant aged 12 years or older for butalbital combination agents containing acetaminophen
- Participant aged 18 years or older for butalbital combination agents containing aspirin
- Documented diagnosis of tension headache or migraine headache in past 2 years
- **For Allzital therapy: documented appropriate trial of 3 or more other butalbital combination products (trial defined as 60 out of 90 days)**

Denial Criteria

- Claim will be denied if approval criteria are not met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception code "682" (Clinical Edit)

References

- Allzital (butalbital/acetaminophen) tablets [prescribing information]. Canton, MS: Skylar Laboratories, LLC; March 2019.
- Fioricet (butalbital, acetaminophen, and caffeine) [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc; November 2016.
- Fiorinal (butalbital/aspirin/caffeine) [prescribing information]. Parsippany, NJ: Actavis Pharma Inc; February 2014.
- 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. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5988744. Accessed April 25, 2019.
- Facts and Comparisons. Butalbital/Acetaminophen/Caffeine Oral. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5549199. Accessed April 25, 2019.
- Facts and Comparisons. Butalbital/Aspirin/Caffeine Oral. https://fco.factsandcomparisons.com/lco/action/doc/retrieve/docid/fc_dfc/5549198. Accessed April 25, 2019.

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