



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Butalbital Combinations Excessive Therapy Edit
<b>First Implementation Date:</b>	October 17, 2019
<b>Revised Date:</b>	April 21, 2022
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<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

**Why Issue Selected:** Butalbital combination products 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 contain butalbital mixed with a combination of caffeine, codeine, acetaminophen, and/or aspirin. Because butalbital and codeine are habit-forming and contain a potential for abuse, caution is warranted to insure proper usage. In addition, the American Migraine Prevalence and Prevention study found that use of butalbital combinations for 5 or more days per month may lead to medication overuse headaches. For these reasons, MO HealthNet will limit butalbital combination products by dosage and length of therapy.

### Program-Specific Information:

Date Range FFS 10-01-2020 to 9-30-2021			
Drug	Claims	Spend	Avg 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	22	\$3,933.88	\$178.81
BUTALBITAL 50 MG/APAP 325 MG TABLET	125	\$4,508.13	\$36.06
BUTALBITAL, APAP, & CAFFEINE 50-300-40 MG CAP	2,338	\$77,210.76	\$33.02
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG CAP	279	\$23,966.72	\$85.90
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG ELIX	0	-	-
BUTALBITAL, APAP, & CAFFEINE 50-325-40 MG TAB	7,438	\$142,317.42	\$19.13
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG CAP	232	\$8,833.67	\$38.07
BUTALBITAL, ASA, & CAFFEINE 50-325-40 MG TAB	0	-	-
BUTALBITAL, APAP, CAFF, & CODEINE 50-300-40-30 MG CAP	157	\$19,417.24	\$123.67
BUTALBITAL, APAP, CAFF, & CODEINE 50-325-40-30 MG CAP	127	\$3,760.53	\$29.61
BUTALBITAL, ASA, CAFF, & CODEINE 50-325-40-30 MG CAP	89	\$3,541.66	\$39.79
<b>TOTALS</b>	<b>10,807</b>	<b>\$287,490.01</b>	<b>\$26.60</b>

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Fiscal Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

### SmartPA Fiscal Proposal Form

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## Setting & Population

- Drug class for review: Butalbital Combinations
- Age range: All appropriate MO HealthNet participants aged 12 years and older

## Approval Criteria

- Claim billed is within maximum daily limits – see Appendix A
- Claim billed is within maximum monthly limits – see Appendix A

## 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 “0716” (DUR Therapy Exceeded)  
 Rule Type: PD

## Default Approval Period

1 day

## Appendix A - Butalbital combination products with maximum units per day and maximum units per month

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
BUTALBITAL, APAP, CAFFEINE, & CODEINE 50-300-40-30 MG CAP	6 CAPS	30 CAPS
BUTALBITAL, APAP, CAFFEINE, & CODEINE 50-325-40-30 MG CAP	6 CAPS	30 CAPS
BUTALBITAL, ASA, CAFFEINE, & CODEINE 50-325-40-30 MG CAP	6 CAPS	30 CAPS

## References

- 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 November 5, 2021.
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- Facts and Comparisons. Butalbital/Acetaminophen/Caffeine/Codeine Phosphate Oral. Accessed November 5, 2021.