Drug/Drug Class: Butalbital Combinations without Codeine Clinical Edit

First Implementation Date: July 22, 2003

Revised Date: April 21, 2022

Prepared for: MO HealthNet

Prepared by: MO HealthNet/Conduent

Criteria Status: ☒ Existing Criteria
☐ Revision of Existing Criteria
☐ 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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Spend</th>
<th>Average Spend per Claim</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALLZITAL (BUTALBITAL 25 MG/APAP 325 MG TAB)</td>
<td>0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BUTALBITAL 50 MG/APAP 300 MG CAPSULE</td>
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<td>-</td>
<td>-</td>
</tr>
<tr>
<td>BUTALBITAL 50 MG/APAP 300 MG TABLET</td>
<td>22</td>
<td>$3,933.88</td>
<td>$178.81</td>
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<tr>
<td>BUTALBITAL 50 MG/APAP 325 MG TABLET</td>
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<td>$4,508.13</td>
<td>$36.06</td>
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<tr>
<td>BUTALBITAL, APAP, &amp; CAFFEINE 50-300-40 MG CAP</td>
<td>2,338</td>
<td>$77,210.76</td>
<td>$33.02</td>
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<tr>
<td>BUTALBITAL, APAP, &amp; CAFFEINE 50-325-40 MG CAP</td>
<td>279</td>
<td>$23,966.72</td>
<td>$85.90</td>
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<tr>
<td>BUTALBITAL, APAP, &amp; CAFFEINE 50-325-40 MG ELIX</td>
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<td>-</td>
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<tr>
<td>BUTALBITAL, APAP, &amp; CAFFEINE 50-325-40 MG TAB</td>
<td>7,438</td>
<td>$142,317.40</td>
<td>$19.13</td>
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<td>BUTALBITAL, ASA, &amp; CAFFEINE 50-325-40 MG CAP</td>
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<td>$8,833.67</td>
<td>$38.07</td>
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<td>BUTALBITAL, ASA, &amp; CAFFEINE 50-325-40 MG TAB</td>
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<tr>
<td>TOTALS</td>
<td>10,434</td>
<td>$260,770.58</td>
<td>$24.99</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Laboratory Results:</th>
<th>Progress Notes:</th>
<th>MedWatch Form:</th>
<th>Other:</th>
</tr>
</thead>
</table>

Disposition of Edit

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

Default Approval Period

1 year

References

- Allzital (butalbital/acetaminophen) tablets [prescribing information]. Canton, MS: Larken Laboratories, Inc; October 2021.