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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Claims</th>
<th>Spend</th>
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<tbody>
<tr>
<td>BUTALBITAL 50 MG/APAP 300 MG CAPSULE</td>
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<td>$0</td>
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<td>ALLZITAL (BUTALBITAL 25 MG/APAP 325 MG TAB)</td>
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<td>BUTALBITAL 50 MG/APAP 300 MG TABLET</td>
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<td>BUTALBITAL 50 MG/APAP 325 MG TABLET</td>
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<td>TOTALS</td>
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Type of Criteria: ☒ Increased risk of ADE  ☐ Preferred Drug List  ☐ Appropriate Indications  ☒ Clinical Edit  ☐ Databases + Prescriber-Supplied

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: 
- Progress Notes: ✗
- MedWatch Form: 
- Other: 
- Disposition of Edit

Denial: Exception code “682” (Clinical Edit)

References

- Allzital (butalbital/acetaminophen) tablets [prescribing information]. Canton, MS: Skylar Laboratories, LLC; March 2019.
- Fiorinal (butalbital/aspirin/caffeine) [prescribing information]. Parsippany, NJ: Actavis Pharma Inc; February 2014.