FDA Warnings on Codeine and Tramadol in Pediatrics

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FDA Drug Safety Communication

• On April 20, 2017, the FDA issued a drug safety communication about the risks of using codeine and tramadol products in pediatrics and requiring several changes to the labels of those products.

• An evidence review by the FDA found serious risks associated with these medications and a greater risk for children younger than 12 years of age¹.

• All single-ingredient codeine products and all tramadol products are FDA-approved for use only in adults.
List of Prescription Codeine and Tramadol Pain and Cough Medicines

<table>
<thead>
<tr>
<th>Medicines Containing Codeine</th>
<th>Medicines Containing Tramadol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Codeine Sulfate</td>
<td>Conzip</td>
</tr>
<tr>
<td>Butalbital, Acetaminopen, Caffeine, and Codeine phosphate</td>
<td>Ultracept</td>
</tr>
<tr>
<td>Fiorinal with codeine</td>
<td>Ultram</td>
</tr>
<tr>
<td>Soma Compound with codeine</td>
<td>Ultram ER</td>
</tr>
<tr>
<td>Tylenol with codeine</td>
<td>Generic products containing tramadol</td>
</tr>
<tr>
<td>Promethazine with codeine (cough)</td>
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<tr>
<td>Prometh VC with codeine (cough)</td>
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<tr>
<td>Triacin-C (cough)</td>
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<tr>
<td>Tuxarin ER (cough)</td>
<td></td>
</tr>
<tr>
<td>Tuzistra-XR (cough)</td>
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<tr>
<td>Generic products containing codeine</td>
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<tr>
<td>Medicines Containing Dihydrocodeine</td>
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<tr>
<td>Synalgos-DC</td>
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</tbody>
</table>

FDA Label Changes

• April 20, 2017 FDA label changes include:
  – **Contraindication** for codeine to be used to treat pain or cough in children younger than 12 years of age*
  – **Contraindication** for tramadol to be used to treat pain in children younger than 12 years of age AND to be used to treat pain after surgery to remove the tonsils and/or adenoids in children younger than 18 years of age
  – **Warning** against use of codeine and tramadol in adolescents between 12 and 18 years of age who are obese or have conditions such as obstructive sleep apnea or severe lung disease
  – Strengthened the **Warning** against mothers breastfeeding while taking codeine or tramadol due to the risk of serious adverse events in breastfed infants.

• *2013 FDA label changes included:
  – **Contraindication** for codeine to be used to treat pain after surgery to remove the tonsils and/or adenoids in children younger than 18 years of age
FDA Drug and Safety Communication

• According to the FDA, in 2014:
  – Nearly 1.9 million patients age 18 and younger received a prescription for codeine
    • 1.4 million as analgesic products
    • 483,000 as codeine cough-and-cold products
  – Nearly 167,000 patients age 18 and younger received a prescription for tramadol.
Codeine and Tramadol Utilization

Amount Paid

- ACETAMINOPHEN W/ CODEINE
- TRAMADOL
- CODEINE SULFATE
- TRAMADOL-ACETAMINOPHEN
- BUTALBITAL-ASPIRIN-CAFFEINE W/COD

Users

- ACETAMINOPHEN W/ CODEINE
- TRAMADOL
- CODEINE SULFATE
- TRAMADOL-ACETAMINOPHEN
- BUTALBITAL-ASPIRIN-CAFFEINE W/COD

2016 2015

$0 $20,000 $40,000 $60,000 $80,000

0 5000 10000

Washington State Health Care Authority
Codeine and Tramadol Utilization

- **Codeine Utilization**
  - 0-11 age group: 250 in 2015, 200 in 2016
  - 12-17 age group: 150 in 2015

- **Tramadol Utilization**
  - 0-11 age group: 50 in 2015, 150 in 2016
  - 12-17 age group: 150 in 2015, 200 in 2016
Recommendations

Based on the review of the FDA communication, label changes, and WA FFS utilization, we recommend:

– codeine and tramadol be placed on prior authorization for patients ages 17 and younger.

– prior authorization will seek a valid medical reason for why non-pharmacologic, non-opioid pharmaceuticals cannot or should not be used.
Motion

• **Motion:** “I move the Medicaid Fee-for-Service Program implement the limitations for codeine-products and tramadol-products listed on slide 8 as recommended.”

• Motion: Figueroa

• 2nd: Brown

• Vote: Passed
Questions?

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