Washington State Health Care Authority

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 age[1].

- All single-ingredient codeine products and all tramadol products are FDA-approved for use only in adults.

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List of Prescription Codeine and Tramadol Pain and Cough Medicines

Medicines Containing Codeine	Medicines Containing Tramadol
Codeine Sulfate	Conzip
Butalbital, Acetaminopen, Caffeine, and Codeine phosphate	Ultracet
Fiorinal with codeine	Ultram
Soma Compound with codeine	Ultram ER
Tylenol with codeine	Generic products containing tramadol
Promethazine with codeine (cough)	
Prometh VC with codeine (cough)	
Triacin-C (cough)	
Tuxarin ER (cough)	
Tuzistra-XR (cough)	
Generic products containing codeine	
Medicines Containing Dihydrocodeine	
Synalgos-DC	

1. Food and Drug Administration. FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Department of Health and Human Services. Apr 20 2017.

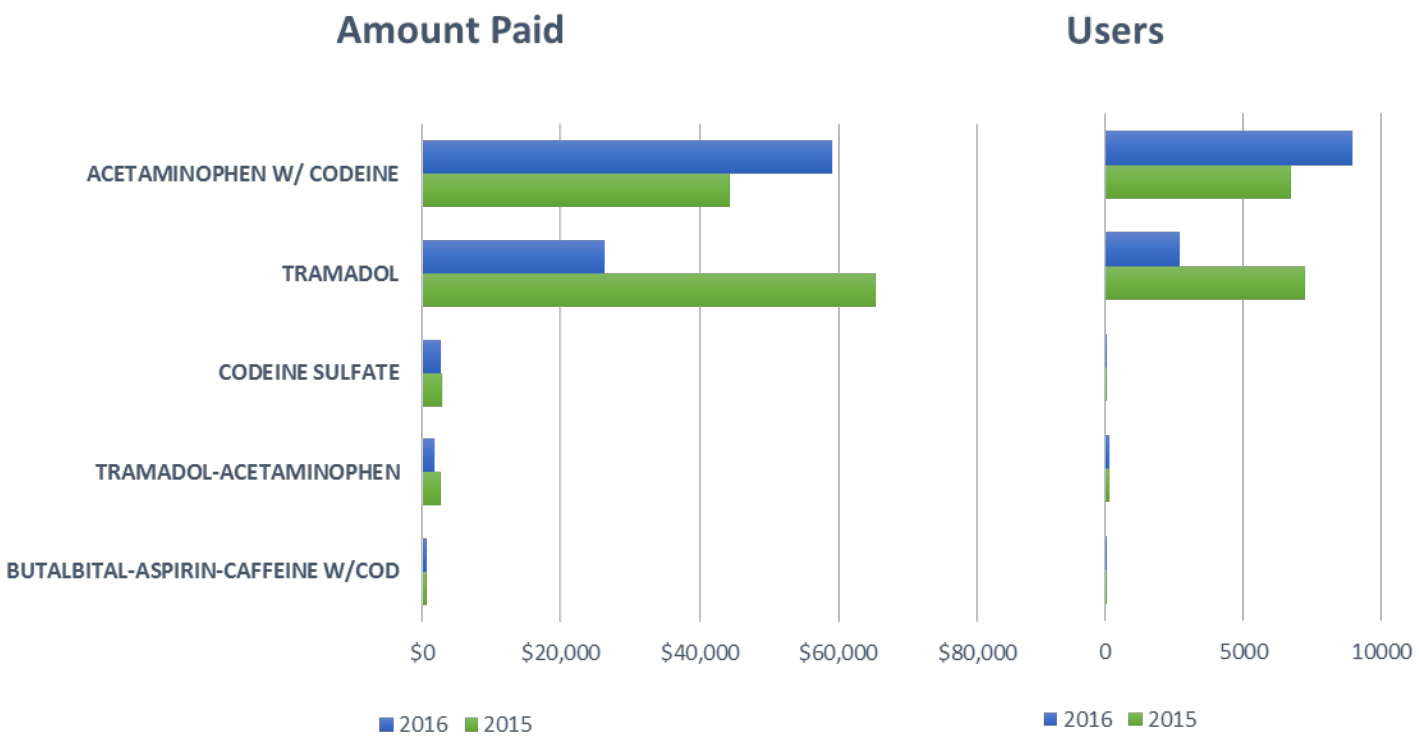
FDA Label Changes

- 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



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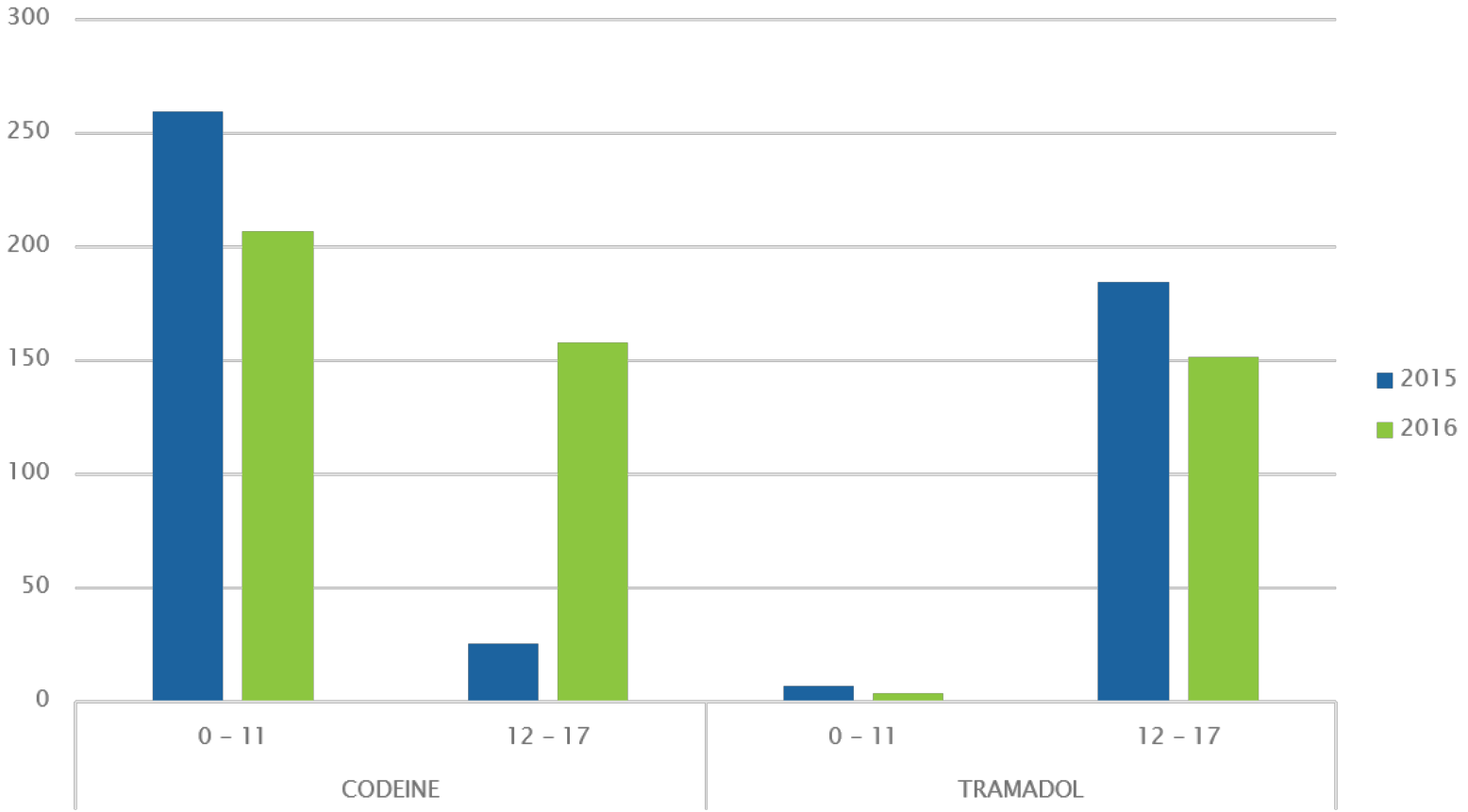
Codeine and Tramadol Utilization



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

Citations

1. Food and Drug Administration. FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Department of Health and Human Services. Apr 20 2017.

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Questions?

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