**2019-C-14-REFCOM**

Amend referred 2018-C-16

**Medications in Children**

**Executive Summary of Policy Contained in this Paper**

Summaries will lack rationale and background information, and may lose nuance of

Policy. You are highly encouraged to read the entire paper.

* AAPA supports **~~regulations and legislation that PROMOTE~~** THE SAFE ~~restrict the~~ use of opioid containing medications in children.
* AAPA SUPPORTS EVIDENCE BASED RECOMMENDATIONS FROM THE U.S. FOOD AND DRUG ADMINISTRATION (FDA), **THE AMERICAN ACADEMY OF PAIN MEDICINE (AAPM),** THE AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM), THE AMERICAN PAIN SOCIETY(APS), THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) AND THE WORLD HEALTH ORGANIZATION (WHO) REGARDING THE NEED TO PROVIDE APPROPRIATE PAIN RELIEF TO CHILDREN AS WELL AS AVOIDING UNSAFE PRACTICES WHEN PRESCRIBING OPIOID CONTAINING MEDICATIONS TO CHILDREN.
* **AAPA SUPPORTS THE FDA RECOMMENDATION THAT** ~~PAS SHOULD LIMIT THE USE OF~~ PRESCRIPTION COUGH AND COLD MEDICINES CONTAINING CODEINE OR HYDROCODONE **SHOULD NOT BE UTILIZED IN CHILDREN UNDER THE AGE OF 18 YEARS.**
* ~~AAPA supports the Food and Drug Administration’s efforts~~ ~~to curtail the prescribing of opioid containing medications to children by healthcare providers.~~
* PAs should be aware of the dangers of the use of codeine and hydrocodone in children and ~~should~~ THE NEED TO limit THEIR use as ~~a medication~~ TREATMENTS for cough suppression. ~~or pain.~~

**Use of Codeine and Hydrocodone**

In 2016 the FDA examined the use of opioid medications in response to the opioid abuse epidemic. Codeine products and hydrocodone including opioid-containing antitussive (OCA) products and pain medications came under scrutiny with their use in children. As codeine is a prodrug that must be metabolized in the liver, the response to the medication is unpredictable and varies from no effect to high sensitivity. (1) A major concern with utilizing codeine in the pediatric population is the unpredictable pharmacokinetics and pharmacodynamics, particularly in CYP2D6 ultra rapid metabolizers.2 The large variations in conversion of codeine predisposes children to be at a higher risk of opioid toxicity. “The relative immaturity of hepatic enzymes systems that metabolize drugs in young children may enhance the risk of adverse effects of such medications.” (3) Potential adverse side effects from codeine are respiratory depression and death, particularly in children under the age of 12 years. (4)

It has been well established that there is limited evidence that cough suppression in children YOUNGER THAN 6 YEARS is necessary or beneficial, and that the medications available have little efficacy. (1,5,6) THERAPY SHOULD BE DIRECTED AT THE UNDERLYING CONDITION CAUSING THE COUGH FOR LASTING BENEFIT.3 WHEN USED AS RECOMMENDED, THE PRODUCTS ARE SAFE. WHEN TAKEN FOR EXTENDED PERIODS, OTC COUGH REMEDIES ARE ASSOCIATED WITH SIGNIFICANT MORBIDITY AND MORTALITY AND CAN CAUSE OVERDOSES EVEN WHEN ADMINISTERED CORRECTLY. (7) In January 2018, the FDA went a step further in stripping codeine and hydrocodone of the indication for the treatment of cough in children younger than the age of 18 years. (6)

~~It has also been reported that the use of codeine for pain post-operatively for adenotonsillectomy for obstructive sleep apnea (OSA) carried a higher risk for death.~~~~4~~ ~~Therefore in April 2017 the FDA issued a contraindication to using codeine to treat pain or cough in children under the age of 12 years, and a warning about using it in children aged 12 – 18 years who are obese or who have OSA or severe lung disease.~~ ~~In January, 2018 the FDA went a step further in stripping codeine and hydrocodone of the indication for the treatment of cough in children younger than the age of 18 years.~~

With the United States currently battling an opioid abuse epidemic, PAs need to be aware of these new recommendations and put them into practice. PAs further need to provide information to families about the FDA’s stance on the use of OCA products. Educational opportunities for PAs would include more effective treatment modalities for cough. ~~and pain management.~~

**Treatment of Acute Pain in Children**

It has been reported that the use of codeine for pain post-operatively for adenotonsillectomy for obstructive sleep apnea (OSA) carried a higher risk for death. (4) Therefore in April 2017 the FDA issued a contraindication to using codeine to treat pain or cough in children under the age of 12 years, and a warning about using it in children aged 12 – 18 years who are obese or who have OSA or severe lung disease.

OPIOIDS SHOULD BE PRESCRIBED WHEN NECESSARY FOR MODERATE TO SEVERE ACUTE PAIN THAT HAS NOT RESPONDED TO OTHER MEDICATION. OPIOID MEDICATION SHOULD ALWAYS BE PRESCRIBED AT THE LOWEST EFFECTIVE DOSE AND FOR THE SHORTEST DURATION NECESSARY. ONLY SHORT ACTING OPIOID MEDICATIONS SHOULD BE UTILIZED FOR ACUTE PAIN ISSUES. FOR ACUTE PAIN NOT RELATED TO TRAUMA OR MAJOR SURGERY, OFTEN NO MORE THAN THREE DAYS OF OPIOID MEDICATION IS REQUIRED FOR APPROPRIATE PAIN CONTROL. UTILIZATION OF NON-OPIOID PAIN MEDICATION AS WELL AS NON-PHARMACOLOGICAL MANAGEMENT OF PAIN SHOULD BE ENCOURAGED AND UTILITZED IN COMBINATION WITH PRESCRIBED OPIOID MEDICATIONS. (8)

**Treatment of Chronic Pain in Children**

SAFE AND PRUDENT TREATMENT OF CHRONIC PAIN IN CHILDREN SHOULD INCLUDE EFFORTS TO UTILIZE NON-PHARMACOLOGICAL APPROACHES TO ACHIEVE PAIN RELIEF. FOR EXAMPLE, THE CDC GUIDELINES CITE EVIDENCE INDICATING THAT COGNITIVE BEHAVIORAL THERAPY AND OTHER MODALITIES CAN BE EFFECTIVE IN TREATING CHRONIC PAIN IN CHILDREN. (9) PAS SHOULD BE AWARE OF STATE AND NATIONAL GUIDELINES, LAWS AND REGULATIONS PERTAINING TO SAFE OPIOID PRESCRIBING PRACTICES.

WHILE EXTREME CARE AND CAUTION IS WARRANTED IN THE TREATMENT OF CHILDERN WITH OPIOIDS, THERE IS ALSO EVIDENCE THAT CHRONIC PAIN IS OFTEN UNDERTREATED IN PEDIATRIC POPULATIONS. A COALITION OF ORGANIZATIONS INCLUDING AAPA HAVE NOTED THAT THE USE OF EXTENDED RELIEF/LONG ACTING OPIOID MEDICATIONS MAY BE INDICATED IN THE TREATMENT OF CHRONIC PAIN IN CHILDREN. WHEN WELL PRESCRIBED AND USED AS PRESCRIBED, OPIOIDS CAN BE A VALUABLE TOOL TO EFFECTIVELY TREAT PAIN. (10) PAS SHOULD USE THE LOWEST EFFECTIVE DOSE TO PROVIDE ANALGESIA WHILE PROVIDING ADEQUATE PAIN CONTROL. FOR LONG TERM PAIN, MANAGEMENT IS AUGMENTED WITH CONSULTATION WITH A PALLIATIVE CARE TEAM, PAIN SPECIALIST, OR REFERRAL TO A SPECIALIZED MULTIDISCIPLINARY PAIN CLINIC.

A 2017 DOCUMENT FROM THE AMERICAN SOCIETY OF REGIONAL ANESTHESIA NOTES THE CHALLENGE OF TREATING CHRONIC PAIN IN CHILDREN. THE DOCUMENT NOTED:

“CHRONIC PAIN INVOLVES COMPLEX INTERACTIONS OF BIOLOGICAL, PSYCHOLOGICAL, AND SOCIAL FACTORS. UNTREATED PAIN DURING INFANCY AND CHILDHOOD LEADS TO HYPERSENSITIVITY PAIN THROUGH A “REWIRING” OF THE PERIPHERAL AS WELL AS CENTRAL NERVOUS SYSTEM LEADING TO LONG CHANGES IN PAIN PERCEPTION. FAILURE TO CONTROL PAIN CAN HAVE LIFELONG IMPLICATIONNS INCLUDING POOR COPING STRATEGIES. PEDIATRIC CHRONIC PAIN MANAGEMENT REQUIRES A COMPREHENSIVE, MULTIDISCIPLINARY APPROACH. THIS INCLUDES BOTH NON-PHARMACOLOGIC AND PHARAMCOLOGIC TREATMENT AS NECESSARY, WITH A TEAM OF PAIN MANAGEMENT PHYSICIANS, INTEGRATIVE HEALTH SPECIALISTS, CHILD LIFE SPECIALISTS, PHYSICAL THERAPISTS, PSYCHOLOGISTS, SOCIAL WORKERS, AND ACUPUNCTURISTS”. (11)

**Recommendations**

* AAPA supports **~~regulations and legislation that PROMOTE~~** THE SAFE ~~restrict the~~ use of opioid containing medications in children.
* AAPA SUPPORTS EVIDENCE BASED RECOMMENDATIONS FROM THE U.S. FOOD AND DRUG ADMINISTRATION (FDA), **THE AMERICAN ACADEMY OF PAIN MEDICINE (AAPM)**, THE AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM), THE AMERICAN PAIN SOCIETY(APS), THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) AND THE WORLD HEALTH ORGANIZATION (WHO) REGARDING THE NEED TO PROVIDE APPROPRIATE PAIN RELIEF TO CHILDREN AS WELL AS AVOIDING UNSAFE PRACTICES WHEN PRESCRIBING OPIOID CONTAINING MEDICATIONS TO CHILDREN
* **AAPA SUPPORTS THE FDA RECOMMENDATION THAT** ~~PAS SHOULD LIMIT THE USE OF~~ PRESCRIPTION COUGH AND COLD MEDICINES CONTAINING CODEINE OR HYDROCODONE **SHOULD NOT BE UTILIZED IN CHILDREN UNDER THE AGE OF 18 YEARS.**
* ~~AAPA supports the Food and Drug Administration’s efforts~~ ~~to curtail the prescribing of opioid containing medications to children by healthcare providers.~~
* PAs should be aware of the dangers of the use of codeine and hydrocodone in children and ~~should~~ THE NEED TO limit THEIR use as ~~a medication~~ TREATMENTS for cough suppression. ~~or~~ ~~pain.~~

**Conclusion**

AAPA supports regulations and legislation that PROMOTE THE SAFE ~~restricts the~~ use of codeine and hydrocodone in children under the age of 18 years, WHILE SUPPORTING THE NEED TO REMOVE POTENTIAL OBSTACLES TO THE APPROPRATE TREATMENT OF PAIN IN CHILDREN. AAPA stands in support of the FDA’s ~~new~~ recommendations for the restriction of the use of CODEINE AND HYDROCODONE ~~opioid containing medications~~ for ~~the treatment~~ of cough suppression ~~and pain~~ in children. AAPA encourages all PAs be aware of the ~~dangers~~ RISKS AND BENEFITS OF OPIOID CONTAINING ~~of these~~ medications FOR THE MANAGEMENT OF PAIN in children. AAPA further encourages all PAs to keep prescribing practices in line with evidence-based GUIDELINES WHEN ADDRESSING PAIN MANAGEMENT IN CHILDREN. ~~medicine and the recommendations of the FDA.~~

**References**

1. Gardiner, S, Chang, A, Marchant, J, Petsky, H. Codeine versus placebo for chronic cough in children. *Cochrane Database of Systematic Reviews* 2016, Issue 7.
2. Gammal, RS, Crews, KR, Haidar, CE, et al. Pharmacogenetics for Safe Codeine Use in Sickle Cell Disease*. Pediatrics. 2016;138(1): E20153479*
3. Committee on Drugs, American Academy of Pediatrics. Use of Codeine and Dextromethorphan containing cough remedies in children. *Pediatrics* 1997; 99;918
4. Tobias, JD, Green TP, Cote, CJ. Codeine: Time to Say “No”. *Pediatrics*. 2016;138(4): e1-e6.
5. Carr, BC. Efficacy, abuse, and toxicity of over-the-counter cough and cold medicines in the pediatric population. *Current Opinion in Pediatrics*. 2006; 18:184-188.
6. Food and Drug Administration News Release. FDA acts to protect kids from serious risks of opioid ingredients contained in some prescription cough and cold products by revising labeling to limit pediatric use. January 11, 2018.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm>

1. Gunn, V. Taha, S. Liebelt, E. Servint, J. Toxicity of Over-the-Counter Cough and Cold Medications. *Pediatrics*. 2001; 108:1-5.
2. American Academy of Orthopaedic Surgeons®, Information Statement. Opioid Use, Misuse, and Abuse in Orthopaedic Practice. October 2015. Information Statement 1045 [https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion\_Statements/advistmt/1045 %20Opioid%20Use,%20Misuse,%20and%20Abuse%20in%20Practice.pdf](https://www.aaos.org/uploadedFiles/PreProduction/About/Opinion_Statements/advistmt/1045%20%20Opioid%20Use,%20Misuse,%20and%20Abuse%20in%20Practice.pdf) Accessed January 26, 2019
3. Dowell, D, Haegerich, TM, Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain. *Morbidity & Mortality Weekly Report*. 3/18/2016;65(1);1-49.
4. American Pain Society, A Position Statement from the American Pain Society. Assessment and Management of Children with Chronic Pain. 2012. <http://americanpainsociety.org/uploads/about/position-statements/Pediatric%20Pain%20Policy.pdf> Accessed February 26, 2019
5. Chae, F. Integrated Approach to Pediatric Chronic Pain Management. *American Society of Regional Anesthesia and Pain Medicine News.* August 2017.
6. <https://www.asra.com/asra-news/article/82/integrated-approach-to-pediatric-chronic> Accessed January 26, 2019

Submitted by

Author’s Name Delegation Date & Time

Seconded by

Name Delegation Date & Time