

October 16, 2017

Dear SoonerCare Provider,

The purpose of this fax is to provide information regarding a recent Drug Safety Communication issued by the U.S. Food and Drug Administration (FDA) regarding the use of codeine pain and cough medicines or tramadol in children and breastfeeding women. The FDA is restricting the use of codeine and tramadol in children. These medications carry serious risks, including slowed or difficult breathing and death. The risk appears to be greater in children younger than 12 years of age, and therefore should not be used in these children.

The FDA required several changes to the labels of all prescription medications containing codeine or tramadol. The label changes include the following:

- Codeine and tramadol are now contraindicated for use in children younger than 12 years of age due to the risk of slowed or difficult breathing.
- Tramadol is now contraindicated in children under the age of 18 years when used to treat pain following surgery to remove the tonsils and/or adenoids.
- Codeine or tramadol are not recommended in breastfeeding mothers due to the risk of excess sleepiness, difficulty breastfeeding, or serious breathing problems in the breastfed infant.

Based on the updated warnings from the FDA, an age restriction for all tramadol and codeine products will apply for members younger than 12 years of age. Members younger than 12 years of age currently utilizing tramadol or codeine products will **not** be “grandfathered” and all members younger than 12 years of age will require a manual prior authorization be submitted by their prescriber. If a member requires tramadol or codeine products, a prior authorization request can be submitted for consideration to SoonerCare Pharmacy Services, including patient-specific, clinically significant supporting information for use of these products despite the medication being contraindicated for the member’s age.

Prior authorization request forms can be found online at www.okhca.org/forms (PHARM-04).

Thank you for the services you provide to Oklahomans insured by SoonerCare!

References:

1. U.S. Food and Drug Administration (FDA). FDA Drug Safety Communication: FDA restricts use of prescription codeine pain and cough medicines and tramadol pain medicines in children; recommends against use in breastfeeding women. Available online at: <https://www.fda.gov/Drugs/DrugSafety/ucm549679.htm>. Issued 04/20/2017. Last accessed 10/03/2017.
2. Lowes, R. Don't Use Tramadol and Codeine in Kids Under 12, FDA Warns. *Medscape*. Available online at: <http://www.medscape.com/viewarticle/878880>. Issued 04/20/2017. Last accessed 10/03/2017.