KERN HEALTH SYSTEMS

PROVIDER bulletin

March 11, 2020

Dear Provider:

KFHC wishes to inform you of recent changes the FDA is making with Singulair (montelukast). KFHC has always covered the drug only for the asthma indication, in accordance to the step guidelines outlined by GINA, and has not covered the drug for the allergic rhinitis indication.

The following has information concerning the new warnings issued by the FDA.
https://www.fda.gov/drugs/drug-safety-and-availability/fda-requires-boxed-warning-about-serious-mental-health-side-effects-asthma-and-allergy-drug

The biggest takeaway from the new guidelines is this:

"The U.S. Food and Drug Administration (FDA) is strengthening existing warnings about serious behavior and mood-related changes with montelukast (Singulair and generics), which is a prescription medicine for asthma and allergy.

We are taking this action after a review of available information led us to reevaluate the benefits and risks of montelukast use. Montelukast prescribing information already includes warnings about mental health side effects, including suicidal thoughts or actions; however, many health care professionals and patients/caregivers are not aware of the risk. We decided a stronger warning is needed after conducting an extensive review of available information and convening a panel of outside experts, and therefore determined that a *Boxed Warning* was appropriate.

Because of the risk of mental health side effects, the benefits of montelukast may not outweigh the risks in some patients, particularly when the symptoms of disease may be mild and adequately treated with other medicines. For allergic rhinitis, also known as hay fever, we have determined that montelukast should be reserved for those who are not treated effectively with or cannot tolerate other allergy medicines. For patients with asthma, we recommend that health care professionals consider the benefits and risks of mental health side effects before prescribing montelukast."

Sincerely,

Bruce Wearda, R.Ph.
Director of Pharmacy