



Voluntary Recall of Medications Containing the Valsartan Active Ingredient

As you may be aware, the U.S. Food and Drug Administration (FDA) announced on July 13, 2018, a nationwide voluntary recall of several drug products containing the active ingredient valsartan and/or valsartan/hydrochlorothiazide (HCTZ), used to treat high blood pressure and heart failure.

Trace amounts of N-nitrosodimethylamine (NDMA), a probable human carcinogen, have been found in the recalled products. The presence of NDMA is unexpected and thought to be related to changes in the way the active substance was manufactured. No adverse events related to this recall have been reported.

The manufacturers participating in this recall include: Major Pharmaceuticals, Solco Healthcare and Teva Pharmaceutical Industries Ltd. (labeled as Actavis). Valsartan containing products from other manufacturers are not impacted and remain available on the market. It is unknown whether this recall will impact overall market supply.

Based on a review of prescription drug claims submitted to Blue Cross and Blue Shield of Texas (BCBSTX) within the last four months, our pharmacy benefit manager, Prime Therapeutics®, will be notifying all impacted members and their prescribing physicians of the recall.

You are encouraged to discuss the recall with your patient and discuss treatment options. For additional information on the recall, please visit the [FDA's website](#) to review the press release.

If your patients have any questions or concerns about their pharmacy benefits, please have them call the number on their member ID card.

This information is for informational purposes only and is not intended to replace your clinical judgment. Pharmacy benefits and limits are subject to the terms set forth in the member's certificate of coverage. Only you, in direct consultation with your patient, can determine your patient's drug therapy, regardless of the member's benefits.

References

1. (2018, July 13). FDA News Release. FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity. Retrieved from: <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613532.htm>
2. Drug Recalls. Retrieved from: <https://www.fda.gov/Drugs/DrugSafety/DrugRecalls/default.htm> on July 17, 2018.

Prime Therapeutics LLC (Prime) is a separate pharmacy benefit management company contracted by BCBSTX to provide pharmacy benefit management and other related services. BCBSTX, as well as several Blue Cross and Blue Shield Plans, has an ownership interest in Prime Therapeutics.