CarePlus HEALTH PLANS

Impact of ongoing angiotensin II receptor blocker (ARB) drug recalls

With the large scale of angiotensin II receptor blocker (ARB) drug recalls, CarePlus anticipates the recalls to continue. To reduce impact to your patients, please consider switching them from ARB medications to other clinically appropriate drug therapies such as angiotensin-converting enzyme inhibitors (ACE-I).

Due to the ongoing investigation, monitor the FDA's website for the most up-to-date ARB recall information: www.fda.gov/Drugs/DrugSafety/ucm613916.htm.

ACE-I recommendations

Medication generic name	Tier MAPD
lisinopril	1
benazepril	1
enalapril	1
quinapril	1
ramipril	1
lisinopril/hydrochlorothiazide (HCTZ)	1
benazepril/HCTZ	2
enalapril/HCTZ	1/2
quinapril/HCTZ	2
benazepril/amlodipine	2

Medication generic name	Initial and maintenance range for hypertension[5]		
	Initial dosing		Maintenance range
lisinopril	Monotherapy	10 mg daily	10–40 mg/day
	Combo w/diuretic	5 mg daily	
benazepril	Monotherapy	10 mg daily	10–40 mg/day
	Combo w/diuretic	5 mg daily	
enalapril	Monotherapy	5 mg daily	5–40 mg/day
	Combo w/diuretic	2.5 mg daily	
quinapril	Monotherapy	10–20 mg daily	20–80 mg/day
	Combo w/diuretic	5 mg daily	
ramipril	Monotherapy	2.5 mg daily	2.5–20 mg/day
	Combo w/diuretic	1.25 mg daily	

For formulary information, please visit www.CarePlusHealthPlans.com/Medicare-Plans/2020-Prescription-Drug-Guides

Information for your patients

- Patients should visit the FDA website or their pharmacy to see the latest ARB recall updates.
- To determine if a specific medicine is part of the recall, look at the drug name and National Drug Code (NDC) on the label of their prescription bottles.
  - If the information is not on the bottle, contact the pharmacy that dispensed the medicine.
  - If the NDC is included in the recall, contact the dispensing pharmacy to identify, by lot, if their medicine is impacted.
- If patient's medicine is recalled, they should:
  - Continue to take the recalled medicine until they have a replacement.
  - Contact their healthcare professionals to discuss treatment options.
- The Center for Drug Evaluation and Research (CDER) has skilled pharmacists and nurses available to the public for questions via phone at a toll-free number 1-855-543-3784 or email at druginfo@fda.hss.gov.
- Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.
  - **Online**: Complete and submit the report at **www.accessdata.fda.gov/scripts/medwatch/ index.cfm?action=reporting.home**, select "Consumer/Patient (FDA Form 3500B)."
  - **Regular mail or fax**: Download form at **www.fda.gov/node/360547** , Select "Form FDA 3500B – Voluntary Reporting for Consumers" and submit by mail to the address on the form or by fax to **1-800-FDA-0178**.

Background:

The FDA initially announced a recall on select valsartan-containing medications on July 13, 2018. It has continued to expand recalls to additional valsartan-, irbesartan- and losartan-containing medications. These recalls occurred due to trace amounts of nitrosamine impurities, including N-nitrosodimethylamine (NDMA) and N-nitrosodiethylamine (NDEA), identified in the active pharmaceutical ingredients (API) manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd. in China. These impurities are classified as a probable human carcinogen by the International Agency for Research on Cancer (IARC). NDMA and NDEA are found in trace amounts in water and some foods; however, the amounts identified in the drug products are at unacceptable levels.

References:

1. FDA Drug Recall Updates on ARBs: www.fda.gov/Drugs/DrugSafety/ucm613916.htm
2. FDA News Release, Jan. 25, 2019: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629796.htm
3. FDA News Release, Aug. 30, 2018: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm619024.htm
4. FDA News Release, Dec. 11, 2018: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628189.htm
5. Pharmacist Letter ACE-Inhibitor Dose Comparison: https://pharmacist.therapeuticresearch.com/Content/Segments/PRL/2009/Aug/ACE-Inhibitor-Antihypertensive-Dose-Comparison-1719
6. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Evaluation, and Management of High Blood Pressure in Adults. Hypertension. Nov. 13, 2017.
7. Pharmacist's Letter. September 2018. No. 340901.