Pfizer – Recall of aminophylline injection

- On September 27, 2022, Pfizer announced a voluntary recall of one lot of aminophylline injection to the user level due to a confirmed report of a visible particulate observed in a single vial.
    - Clinical Services did not identify any impacted members thus notifications will not be sent.
    - Other aminophylline injection products made by Pfizer are available for use.
- The recalled lot was distributed October 25, 2021, through April 1, 2022.

Product Description	NDC#	Lot# (Expiration Date)
Aminophylline injection 250 mg per 10 mL (25 mg/mL), single dose vial	Vial: 0409-5921-16 Carton: 0409-5921-01	30-137-DK (12/1/2022)

- Per Pfizer, use of the impacted product has an unlikely probability of being associated with limited adverse events such as end-organ granuloma or tissue ischemia, tissue inflammation or phlebitis, decreased blood flow to the brain, heart attack, tissue necrosis, hypersensitivity reactions and infections. The overall potential risk to patients arising from this issue is considered to be low.
- Aminophylline injection is indicated as an adjunct to inhaled beta-2 selective agonists and systemically administered corticosteroids for the treatment of acute exacerbations of the symptoms and reversible airflow obstruction associated with asthma and other chronic lung diseases, e.g., emphysema and chronic bronchitis.
- Anyone with an existing inventory of the recalled product should stop distribution and quarantine the product immediately.
- Patients should contact their physician or health care provider if they have experienced any problems that may be related to using the recalled products.
- Contact Sedgwick at **1-800-805-3093** for return information. Contact Pfizer at **1-800-438-1985** for questions regarding the recall.

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