Exela – Recall of sodium bicarbonate injection

- On March 13, 2025, Exela Pharma Sciences announced a consumer level recall of two lots of 8.4% sodium bicarbonate injection because a defective crimp on the vial in certain instances may lead to the stopper to dislodge from the vial when the fliptop is being removed.
    - Clinical Services identified potentially impacted members and will send notifications to the members and their prescribers.
    - The member letter advises members to contact their prescribers or pharmacy for questions.
- Sodium bicarbonate injection was distributed nationwide from February 5, 2025 to February 20, 2025.

Product Description	NDC#	Lot# (Expiration Date)
8.4% Sodium Bicarbonate Injection, 50 mEq/50 mL, 50 mL single-dose vial	51754-5001-4 51754-5001-1	10006417 (10/2026); 10006418 (10/2026)

- Sodium bicarbonate injection is used for the treatment of metabolic acidosis which may occur in severe renal disease, uncontrolled diabetes, circulatory insufficiency due to shock or severe dehydration, extracorporeal circulation of blood, cardiac arrest and severe primary lactic acidosis. Sodium bicarbonate is also indicated in the treatment of certain drug intoxications, in poisoning by salicylates or methyl alcohol, severe diarrhea and in hemolytic reactions.
- The defective crimp on the vial may expose the drug product to the environment and could potentially impact the sterility and purity of the product.
- To date, Exela has not received any reports about known sterility failures or adverse health events.
- Anyone with the affected lots on hand should stop distribution and return product.
- Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.
- Contact Exela by phone at **1-828-341-6118** or by email at **recall@exela.us** for questions regarding this recall.