Merck – Recall of Cubicin® (daptomycin)

- On October 20, 2021, the FDA announced a voluntary, user-level recall of one lot of Merck's Cubicin (daptomycin) 500 mg injection because of a customer complaint reporting that a piece of glass was found in a vial of Cubicin after reconstitution.
    - Clinical Services through the Drug Safety Notification program will conduct a mailing to members and message providers that may be affected by this recall.
    - The member letter provides instructions on how to identify the recalled product and advises members to contact their health care provider about their therapy.
    - Other Cubicin injection products that are not being recalled are available for patients to use.

- The recalled lot was distributed between June 1, 2021 and September 9, 2021.

Product Description	NDC	Lot # (Expiration Date)
Cubicin (daptomycin) 500 mg injection, 10 mL single-use vial	67919-011-01	934778 (June 2022)

- Cubicin is a lipopeptide antibacterial indicated for the treatment of complicated skin and skin structure infections in adult and pediatric patients, and *Staphylococcus aureus* bloodstream infections in adult patients including those with right-sided infective endocarditis, and *Staphylococcus aureus* bloodstream infections in pediatric patients.

- Intravenous infusion of glass particulates has the potential to cause serious health consequences if the particulate is small enough to be withdrawn from the vial and infused into the patient. Local irritation or swelling at the infusion site may occur in response to the presence of foreign material. More serious potential outcomes include blockage and clotting in blood vessels, which can be life-threatening if a critical organ is affected.

- Other clinical consequences could include prolonged hospitalization, particularly in those patients receiving an extended treatment regimen for which multiple vials of Cubicin are administered over the course of treatment. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the healthcare professional to visually inspect the product for particulate matter prior to administration.

- To date, Merck has not received any reports of adverse events related to this recall.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately. Contact Sedgwick/Stericycle at **1-877-830-9730** for return instructions.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled Cubicin injection.
- Contact Merck National Service Center at **1-800-672-6372** for more information about the recall.