Sagent – Recall of levetiracetam injection

- On November 22, 2021, the FDA announced a voluntary, user-level recall of four lots of Sagent's levetiracetam injection because of a lack of container closure integrity found in reserve sample vials which may result in a non-sterile product.
    - Clinical Services through the Drug Safety Notification program did not identify any members that may be affected by this recall, thus notifications will not be sent to members and their health care providers.
    - Although Clinical Services will not send notifications for this recall, it is highly probable that pharmacies and health care facilities that dispense and/or administer levetiracetam injection already received an FDA or manufacturer communication regarding this recall.
    - Other levetiracetam injection products that are not being recalled are available for patients to use.

- The recalled lots were distributed between March 2021 and November 2021.

Product Description	NDC	Lot # (Expiration Date)
Levetiracetam 500 mg/5 mL injection	25021-780-05	B0G85VB (6/2022); B0K88VA (9/2022); B0K89VA (9/2022); B1G194A (6/2023)

- Levetiracetam injection is used to treat partial-onset seizures, myoclonic seizures in patients with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures.

- Intravenous administration of a product intended to be sterile that is not sterile could result in serious systemic infections which may be life threatening.

- To date, Sagent has not received reports of any product complaints or adverse events associated with this issue.

- Patients should contact their health care provider if they have experienced any problems that may be related to using the recalled levetiracetam.

- Anyone with an existing inventory of the recalled product should stop use, distribution and quarantine the product immediately.

- Contact Sagent at **1-866-625-1618** for more information about the recall.

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