Novo Nordisk – Recall of GlucaGen® HypoKit®

- On September 8, 2016, Novo Nordisk announced a consumer-level recall of GlucaGen HypoKit (glucagon [rDNA origin] for injection) due to two customer complaints involving detached needles on the syringe with sterile water for injection (SWFI). A syringe with a detached needle cannot be used as prescribed.
    - GlucaGen HypoKit is used to treat severe hypoglycemic reactions which may occur in patients with diabetes mellitus treated with insulin.
    - GlucaGen is also indicated for use during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract.
- The recall includes the following GlucaGen HypoKit batch numbers which were distributed starting February 15, 2016:

Product Description	NDC #	Batch #	Expiration Date
GlucaGen Hypokit includes 1 vial containing 1 mg glucagon [rDNA origin] for injection and 1 disposable syringe containing 1 mL SWFI	00169-7065-15	FS6X270, FS6X296 FS6X538, FS6X597 FS6X797,FS6X875	9/30/2017

- Untreated hypoglycemia can eventually lead to unconsciousness and seizures, which can prove fatal. If the blood glucose levels are not quickly restored, continuing hypoglycemia can lead to a decline in brain glucose levels which manifests through a variety of symptoms including cognitive dysfunction, sweating, tremors, convulsion and eventually coma or death.
- Novo Nordisk conducted an investigation which showed that a small number (0.006%) of needles could be detached from the syringe in certain batches of GlucaGen HypoKit. It is estimated that out of the 71,215 pens being recalled, four pens could be defective.
- Patients or caregivers should check the batch number to see if their GlucaGen HypoKit is affected. The batch number is printed on the GlucaGen HypoKit.
- Patients with recalled product should contact Novo Nordisk at **1-888-840-1137** for reimbursement information. Novo Nordisk will provide reimbursement for out-of-pocket costs incurred for the purchase of recalled GlucaGen HypoKit with proof of purchase.
    - Patients that received a GlucaGen HypoKit through the Novo Nordisk Patient Assistance Program will receive a replacement device.
- If a patient has a GlucaGen HypoKit with a batch number not mentioned above, the product is not subject to the recall and may be used as prescribed.

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- Novo Nordisk is working as quickly as possible and in collaboration with the FDA to recall affected products from the marketplace, including those in the possession of patients. To date, Novo Nordisk is not aware of any known adverse events resulting from the use of the recalled batches.

Action Plan

- Clinical Services will conduct mailings to member(s) that may be affected by the GlucaGen HypoKit recall, and to providers who prescribed for the drug recently.
- Information regarding the GlucaGen HypoKit will be posted on the optumrx.com portals