



DATE: June 9, 2026

TO: Commonwealth of Kentucky Medicaid Pharmacy Network

FROM: MedImpact Healthcare Systems

Subject: Omnipod® Insulin Delivery Systems Medical Device Correction

Status: Insulet Corporation has issued a voluntary Medical Device Correction for specific lots of the following insulin delivery systems:

- Omnipod® 5 Automated Insulin Delivery System
- Omnipod DASH® Insulin Management System
- Omnipod® Insulin Management System (Omnipod Eros)

The correction is due to a manufacturing issue that may result in insulin under-delivery. Patients using affected Pods may experience insulin leakage caused by a small tear in the cannula tubing, which could lead to elevated blood glucose levels and, in severe cases, diabetic ketoacidosis (DKA).

Insulet advises patients not to use Pods from affected lots and to immediately transition to replacement Pods if impacted product is identified. Replacement Pods will be provided directly by Insulet at no cost to patients and do not require a new prescription.

Some affected Pods may develop a small tear in the cannula tubing between the Pod and the insertion site. If this occurs, insulin may leak outside the body instead of being delivered as intended.

Patients may experience:

- Unexpected hyperglycemia (high blood glucose levels)
- Blood glucose levels that do not respond appropriately to insulin delivery
- Wetness around the Pod or adhesive
- Odor of insulin near the infusion site
- Increased risk of diabetic ketoacidosis (DKA)

In the most severe cases, prolonged insulin under-delivery may result in hospitalization due to DKA. Insulet has reported 24 serious adverse events globally associated with this issue, including hospitalization and DKA. No deaths have been reported.



Insulet has not provided a list of which specific NDCs are affected. Therefore, below is a list of all Omnipod Pods that were found in our system and potentially may be impacted. Members currently utilizing these devices should be directed to the link below to determine if their Omnipod Pod is affected.

Product	NDC
OMNIPOD DASH INTRO KIT (GEN 4)	08508-2000-32
OMNIPOD DASH PODS (GEN 4)	08508-2000-05
OMNIPOD DASH PDM KIT (GEN 4)	08508-2000-00
OMNIPOD 5 DEXG7G6 INTRO (GEN 5)	08508-3000-01
OMNIPOD 5 INTRO(G6/LIBRE2PLUS)	08508-3000-88
OMNIPOD 5 DEXG7G6 PODS (GEN 5)	08508-3000-21
OMNIPOD 5 DEXG7G6 PODS (GEN 5)	08508-3000-75
OMNIPOD 5 (G6/LIBRE 2 PLUS)	08508-3000-42

Recommendations for Healthcare Providers:

- Immediately notify patients using Omnipod 5, Omnipod DASH, or Omnipod Eros systems of this issue.
- Instruct patients to verify whether their Pod lot number is affected.
- Advise patients NOT to use Pods from affected lots.
- If a patient is currently wearing an affected Pod, advise them to replace the Pod immediately with one from a non-affected lot.
- Remind patients to continue monitoring blood glucose levels closely and seek medical attention if persistent hyperglycemia occurs.
- Patients experiencing symptoms of hyperglycemia or suspected DKA should seek immediate medical care.

Insulet is contacting affected patients directly and providing replacement Pods at no cost.

Patients can determine whether their Pods are affected and request replacement Pods by visiting:

<https://www.omnipod.com/mdc/check-pod-lot>

Patients should check the lot number located on:

- Pod tray lid
- Pod box
- Pod itself

Note: All Pods within a single box are from the same lot. If the lot is affected, none of the Pods in that box should be used.



Patients or healthcare professionals with adverse reactions, quality concerns, or questions regarding this correction should contact:

Insulet Product Support
1-800-641-2049 (available 24 hours a day, 7 days a week)

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA MedWatch Adverse Event Reporting Program:

- Online: www.fda.gov/medwatch
- Phone: 1-800-332-1088
- Fax: 1-800-FDA-0178

For additional information regarding this Medical Device Correction, healthcare professionals may contact Insulet Medical Affairs at medicalinformation@insulet.com.

For more information, please review the following FDA notification: <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

Providers are encouraged to reference the Kentucky Medicaid Diabetic Supplies Preferred Drug list found on the MedImpact Provider Portal at: <https://kyportal.medimpact.com/provider-documents/drug-information>.

For any additional information or questions that you may have, please contact the Kentucky MedImpact team at KYMFFS@medimpact.com for Fee-for-Service members or at KYMCOPBM@medimpact.com for Managed Care Organization (MCO) members.

KY MCO Contact Information

Program Questions	KYMCOPBM@MedImpact.com
Pharmacy Help Desk	(800) 210-7628 [24 hours per day/ 7 days per week]
Prior Authorizations	Phone (844) 336-2676 [8:00AM - 7:00PM EST/ 7 days per week]; Fax (858) 357-2612
Pharmacy Portal	https://kyportal.medimpact.com/
BIN: 023880 / PCN: KYPROD1 / GROUP: KYM01	

KY FFS Contact Information

Program Questions	KYMFFS@MedImpact.com
Pharmacy Help Desk	(877) 403-6034 [24 hours per day/ 7 days per week]



TEAM KENTUCKY

Prior Authorizations	Phone (877) 403-6034 [8:00AM - 7:00PM EST/ 7 days per week] Fax (858) 357-2612
Pharmacy Portal	https://kyportal.medimpact.com/
BIN: 026309 / PCN: KYPROD1 / GROUP: KYF01	