THE NEWSLETTER OF PAAS NATIONAL®
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Monthly Edition

Newsline

HELPING COMMUNITY PHARMACIES GAIN CONFIDENCE AND PEACE OF MIND

Additional *eNewsline* Content available on the PAAS Member Portal:

- All Pharmacies Face Medicare Part A vs Part D Billing Risks, Especially Combo Shops
- You've Got Mail! Post-COVID-19 Mailing & Delivery Considerations
- Avoid the Creon Chargeback Catastrophe by Following THIS Billing Rule
- PBM Audits: Letters to Patients for Prescription Verification
- Specialty Pharmacy Paying the Price: $20 Million Settlement for Kickbacks and Copay Waivers
- Use As Directed—What is Your Attack Plan?

Audit Target: Linzess® Prescriptions

PAAS National® analysts have noticed an increase in audits targeting Linzess®. Linzess® is a focus of PBM audits not only because of the high cost, but also the manufacturer dispensing requirements. Not following FDA approved guidelines when dispensing this medication will likely result in full recoupment.

Allergan, the manufacturer of Linzess®, has not provided evidence to the FDA for the safety and efficacy of this medication outside the original container. PAAS has reached out to Allergan looking for additional stability information to appeal audit recoupments; however, they have only confirmed the current requirements. Pharmacies can visit DailyMed for medication information, including *How Supplied/Storage and Handling* requirements under Section 16 of the drug label information.

While Linzess® is not the only medication required to be dispensed in the original container, it is frequently prescribed for patients in long-term care and for those who have medications in compliance packaging. Unfortunately, there are no exceptions for these situations, and the original container must be given.

Billing Linzess® for quantities other than increments of 30 capsules will make the claim an easy audit target for any PBM to identify the medication was not dispensed in the original container. This is true for many other medications with specific dispensing requirements as well. PAAS has created our *Dispense in Original Container Chart*, based on the medications we frequently see audited.

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Zepbound™ (tirzepatide) Means Decreased Audit Risk…Right?

On November 3, 2023, Eli-Lilly was granted the highly anticipated weight loss indication on their tirzepatide injection, Zepbound™. Zepbound™ is indicated as an adjunctive therapy for adults with a body mass index (BMI) of 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) plus at least one weight-related comorbidity, such as type 2 diabetes mellitus, dyslipidemia, or hypertension - the same indication as Wegovy® and Saxenda®. Although this is an exciting advancement in the realm of GLP-1 agonist prescribing, PAAS National® would like to take this opportunity to update our members on what PBM trends we have seen thus far, draw attention to the guidelines laid out by PBMs and regulations in which we can rely on, and give our thoughts on the current audit situation in the hopes of allowing you to make the most informed business decision.

As of this publication, recoupments on type 2 diabetes mellitus (T2DM) GLP-1 agonists due to off-label indication use, defined as anything other than being used as an adjunct therapy for adults with T2DM, is nominal. Elixir communicated via their Pharmacy Audit Whisperer from April 2023 that Ozempic® and Mounjaro™ being used for an indication of obesity or weight loss would not be covered and they have pursued recoupment of such claims. Caremark has been sending notices to pharmacies dispensing GLP-1 agonist at a volume identified as an outlier in their region. We've also seen OptumRx/EXL Health flag Ozempic® for off-label use. Notably, PAAS is aware of nine state Medicaid programs that were negotiating prices for Wegovy® earlier this year.

Despite the de minimis recoupments seen thus far, PBMs and insurance companies have put out communications advising pharmacies they reserve the right to report suspected improper dispensing practices to federal or state agencies, which may result in an additional level of scrutiny placed on pharmacies. As it states in Section 10.6 – "Medically-Accepted Indication" of the Medicare Part D Manual, "Part D sponsors are responsible for ensuring that covered Part D drugs are prescribed for medically-accepted indications using the tools and data available to them to make such determinations." Therefore, according to this guideline, Medicare Part D may pay for a GLP-1 agonists prescribed for its appropriate indication but will not pay for a GLP-1 agonist with an indication that does not match the patient's intended use. In addition to being mindful of the CMS billing guidelines, pharmacies must be mindful of individual PBM's expectations for billing practices. Some PBM's have explicit language in their Provider Manuals that define "clean claims" as one that is used for a medically accepted indication or outlines "appropriate dispensing practices", both alluding to claims that are for medically accepted indications. Yet pharmacies have processed prescriptions for off-label use without issue. If Medicare Part D states they will not pay for off label use, then why are these claims to go through without issue? If commercial plans state they will only cover medication for certain indications, why not put diagnosis restrictions in place to stop claims from going through at the point of adjudication? We know that PBMs have highly intricate algorithms that can focus in on prescription specifications; why aren't they targeting GLP-1 agonists being used off-label on audits? One could speculate due to the vast amount of administration fees and rebates they are currently reaping there isn't a reason to impose their regulation at this time, but these claims may be in the PBM's crosshairs in the coming years. After all, audits typically target claims from previous years and PBMs do not mind using a "pay and chase" approach because they can just withhold future payments.

Beyond audits originating from PBMs for off-label use, manufacturers can initiate audits as well. Eli Lilly has pursued medi-spas, clinics, and compounding pharmacies who are utilizing semaglutide for purposes other than for the treatment of T2DM.

Ultimately, we urge you to consider the following when deciding how to handle adjudicating GLP-1 agonist prescriptions for off-label use: "**How much do you trust the PBM to act favorably to your pharmacy - now and in the future?**" While the future of GLP-1 agonist audits is obscure, our guidance remains conservative - tread cautiously.

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USP 800 - The Struggle is Real…

Are you compliant with USP 800? While USP 800 became official on December 1, 2019, it was informational only and not compendially applicable. With the recent updates to USP 795, Nonsterile Compounding and USP 797, Sterile Compounding in November 2022, USP 800 was effective as of November 1, 2023.

USP 800 is not just for compounding pharmacies as it defines the quality standards for the safe handling of hazardous drugs in all healthcare settings, with the goal to minimize exposure to **healthcare personnel, the patients in your pharmacy, and to the environment.**

You might still ask, does my pharmacy need a USP 800 program? The answer is yes! All healthcare settings, including community pharmacies, should now have a "handling of hazardous drugs" program in place and while, USP itself is not an auditing entity, there are other agencies that may audit including OSHA, EPA and most likely State Boards of Pharmacy, many of which have already committed to doing so. The safe handling of hazardous drugs is now considered a "standard of practice" so implementation is essential to protect the health and safety of your employees.

Are you struggling with the multitude of requirements? This isn't one of those "throw it together in an afternoon" type of programs. PAAS can help! PAAS' customized USP 800 Compliance Program provides:

- A detailed Program Guide walking you through everything from the why to the how
- Annual web-based training to keep the team up to date including a quiz to assess competency
- A USP 800 Compliance Program Policy & Procedure manual tailored to the unique needs of your pharmacy with minimum interruption to workflow
- An easy-to-use Assessment of Risk (AoR) tool to help you create custom containment strategies for each drug and its unique dosage form.

Call (608) 873-1342 to sign up for PAAS' USP 800 Compliance Program and you can immediately get started on setting up your program in hours, not days!

PAAS Battles MedImpact for DAW 0 Reimbursement on Semglee®

MedImpact sent a memo to network pharmacies dated May 22, 2023, with the subject line *Semglee-YFGN (Preferred U-100 Long Acting Insulin)*. For their participating Medicare Part D plans, MedImpact requested pharmacies to dispense Semglee® (YFGN) at the brand reimbursement. Other insulin glargine products were considered non-formulary with a claim rejection response. The memo goes on to indicate that this 'brand' claim must be submitted with a DAW of 9 to get correctly reimbursed, meaning pharmacies that use a default DAW 0 could be incorrectly paid!

Over the past several months, PAAS has been chiding the MedImpact Clinical Services team about this reimbursement decision and the correct biosimilar terminology with DAW utilization.

As pharmacies may be aware, Semglee® (YFGN) is not a brand, but an **interchangeable biosimilar**. As such, it does not require a DAW code and requiring a DAW 9 for Semglee® (YFGN) would be incorrect according to NCPDP guidance (see definitions in our eNewsline).

While MedImpact considers Semglee® (YFGN) a brand for reimbursement purposes, it is classified by the FDA as an interchangeable biosimilar. The DAW code definitions (pasted above) from NCPDP state that DAW 0 would be appropriate. Pharmacies should not be negatively impacted financially for failing to use the DAW 9 code. This is not consistent with the industry and is an inappropriate use of DAW 9. DAW 9 states that an interchangeable biosimilar is permitted, but the Plan wants a brand or reference product. Semglee is not a reference product in this definition (in reference to biologic drugs), Lantus® would be.

After months of back and forth, PAAS was just informed by MedImpact that at the end of August, the POS message referencing DAW 9 for Semglee® (YFGN) was removed from all 2023 and 2024 Part D formularies. They are removing all messaging related to DAW 9 for insulin glargine and referencing "Please Dispense Brand for Generic Copay" with no requirement for a DAW 9 reference.

Your membership in PAAS helps us continue to advocate and fight for fair treatment.

Recent DEA Rule Change - Transferring Electronic Prescriptions for Controlled Substances for Initial Fill

The DEA published a couple rule changes recently which pharmacies need to be aware of. In the September 2023 Newsline, the updated rule regarding partial fills for controlled substances was discussed. The other recent change published in the Federal Register was titled, Transfer of Electronic Prescription for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling. This rule went into effect August 28, 2023, and clarified the DEA's previous rule on the transferring of controlled substances. Pursuant to 21 CFR § 1306.08, Electronically Prescribed Controlled Substances (EPCS) can be transferred for initial filling on a one-time basis, upon the request of the patient and all authorized refills on C-III, C-IV and C-V prescriptions are transferred along with the original prescription. All the following additional requirements must also be met:

1. The transfer must be communicated directly between two licensed pharmacists, which includes any person (e.g., pharmacist intern) who is authorized by a State to dispense controlled substances under the supervision of a pharmacist licensed by such State.
2. The prescription must remain in its electronic form with no intermediary conversion to another form (e.g., facsimile).
3. The contents of the prescription required by 21 CFR part 1306 must be unaltered during the transmission. Any change to the data, including truncation or removal of data, will invalidate the prescription.
4. The transfer for EPCS for initial dispensing is permissible only if allowable under existing State or other applicable law.

According to the Federal Register notice, NCPDP confirmed SCRIPT Standard Version 20177071 had the appropriate functionality to allow the electronic transfer of an EPCS. Since this SCRIPT Standard is widely used among software vendors for chain and independent pharmacies, the capability to electronically transfer these prescriptions should be available; however, pharmacies may need to talk with their vendors about activating this functionality.

When a patient requests the transfer, the receiving pharmacy must initiate the process by electronically requesting the transfer. **The "transferring pharmacy" must update their records to show the prescription was transferred out and include:**

- Name, address, and DEA number of the receiving pharmacy.
- Names of the transferring and receiving pharmacists.
- Date of the transfer.
- Note: The transferring pharmacy is not responsible for maintaining proof of the patient's request to transfer the prescription.

The "receiving pharmacy" must document:

- The word "transfer" in the electronic prescription file.
- Name, address, and DEA number of the transferring pharmacy.
- Names of the transferring and receiving pharmacists.
- Date of the transfer.

The software system may pre-populate the data entry fields if the pharmacist verifies the accuracy of the information.

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