The *voice* of the community pharmacist.

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The PBM Audit Targets You Encounter Daily and How Your Team Can Avoid them in Workflow

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Disclosure

There are no relevant financial relationships with ACPE defined commercial interests for anyone who was in control of the content of the activity.

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Pharmacist Learning Objectives

1. List the fundamentals of invoice audits and bulk purchase complications
2. Discuss audit risks for dispensing prescriptions off-label
3. Describe how support staff can be an integral part of audit prevention strategies

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Technician Learning Objectives

1. List common pitfalls with invalid prescriptions
2. Demonstrate how to navigate common days' supply discrepancies
3. Discuss audit considerations and requirements for Medicare Part B

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Why So Many Audits?

- Escalating Healthcare Costs
- Opioid Epidemic
- Contractual Requirements
- Fraud, Waste & Abuse
- Common Billing Errors
- Data Analytics/Outliers
- PBM Revenue Source = $$$

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Audit Penalties

- Financial Recovery
- Corrective Action Plans
- Network Termination
- Reputation
- License
- OIG Exclusion
- Fines
- Prison

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April 2023 Audit Penalty Examples (Bad Actors)

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Wednesday, April 5, 2023

Pharmacist Pleads Guilty to Medicare Fraud Scheme

A California man pleaded guilty today to submitting fraudulent claims to Medicare for prescription drugs that were never dispensed to patients.

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Friday, April 7, 2023

North Carolina Pharmacy Agrees to Resolve False Claims Act Allegations

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Friday, April 14, 2023

Nine Defendants Sentenced in $126M Compounding Fraud Scheme

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE — Friday, April 14, 2023

Podiatrist and Patient Recruiter Convicted for $8.5M Compounding Fraud Scheme

A federal jury convicted two Texas men today for their role in a scheme to fraudulently bill TRICARE – the health care program for U.S. service members and their families – for compounded creams that were medically unnecessary and procured through kickbacks and bribes.

PRESS RELEASE

Pharmacy Student and Pharmacist Indicted by Grand Jury

Wednesday, April 12, 2023

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For Immediate Release

U.S. Attorney's Office, Western District of Louisiana

PRESS RELEASE

Physician and pharmacy settle claims for unnecessary medications

Monday, April 24, 2023

Share

For Immediate Release

U.S. Attorney's Office, Southern District of Texas

Audit Trends 2018 - 2022

- 25% increase in audits over the last 3 years; 30% YOY Q1 2023!
- Many invoice audits are in tandem with desk/onsite or credentialing audits

	Desk	Rx Validation Requests	Virtual	Onsite	Stand Alone Invoice Audits
2018	84%	3%*		12%	1%
2019	64%	21%		13%	2%
2020	62%	23%	7%	6%	2%
2021	67%	20%	11%	0%	2%
2022	67%	21%	5%	5%	2%

PAAS National® Statistics from 2018 - 2022

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Big Picture

Prescription	Do you have a prescription? Is prescription legal/valid per state and federal laws?
Data Entry & Filling	Did you fill and bill accurately?
Dispensing	Do you have proof of dispensing? Do you have proof of copay collection?
Invoices	Did you purchase enough inventory from an appropriate source?

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Common Audit Discrepancies

Prescription	Missing Elements (e.g., controlled substance requirements , transfer elements) Mid-level Practitioners (do they need supervising MD, license #, etc)
Data Entry & Filling	Overbilled Quantity Refill Too Soon Incorrect DAW Code
Dispensing	Missing/Invalid Signature Log Dispensed > 10 days Copay Collection
Invoices	NABP Accredited Drug Distributor (formerly VAWD) Licensed as a Wholesaler in your state for OTC items dispensed as Rx Authorized Distributor for Diabetic Testing Supplies

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Workflow Prevention Strategies

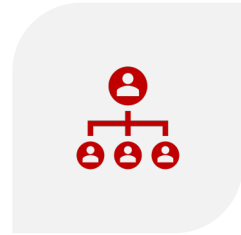
1. RX DROP OFF

2. DATA ENTRY

3. FILLING

4. VERIFICATION

5. CASHIER



6. OTHER SUPPORT STAFF/MANAGERS

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Rx Drop Off

Verify apparent alterations

Clarify “use as directed” for insulin or topicals with prescriber

Implement Rx scanning if possible

Suggested *Clinical Note* Format:

Who you spoke with (name and title)
When you spoke with them
What you spoke about
Who is writing the note

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Data Entry

QUANTITY	1. Verify correct NCPDP billing unit (EA, GM, ML) 2. Quantity unit of measure is present/appropriate for eRx 3. Some products must be dispensed in original container
DAYS' SUPPLY	1. **Must be calculable based on quantity and SIG** 2. Call PBM helpdesk for override if smallest unbreakable packages
DAW CODES	1. Only submit if supported by documentation

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Filling

Match 11-digit NDC on stock bottle against billing label

Confirm quantity prepared matches billing label

If time allows spot check DAW, Day Supply, Origin Code

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Verification

MATCH	Match 11-digit NDC on stock bottle against billing label using barcode technology if possible
CHECK	Double check days' supply estimate as per documented calculations • Pay close attention to insulin, topicals, eye drops, inhalers
VERIFY	Verify additional Data Entry elements such as DAW, SIG and Origin Code • Suggest adding elements to "backtag" if doing paper verification

Cashier/Dispensing

- Conduct Return to Stock on a regular basis
- Obtain patient signature for Proof of Delivery
- For mail, make sure Rx # is “tied to” carrier tracking ID #
- **Collect copays at dispensing, maintain proof**
- In-house charge accounts must have good accounting practices

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Other Support Staff/Managers

- Create reports to audit high risk claims (DAW 1, days' supply for targeted products, SCC or DUR documentation)
- Review adherence to Return to Stock procedures
- Ensure Proof of Delivery and Proof of Copay Collection are available and retrievable, in accordance with PBM requirements (e.g., mailing, delivery and any A/R accounts)
- Incorporate audit training and prevention strategies (including pharmacy consequences) to all staff

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Common Days' Supply Discrepancies

Workshop Examples

- Insulin
- GLP-1s
- Vaginal Creams
- Pancreatic Enzymes

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Medicare B DMEPOS Order Requirements

- Transition from a Detailed Written Order (DWO) to Standard Written Order (SWO)
  - Chapter 5 of Medicare Program Integrity Manual
  - Effective January 1, 2020
  - Elements include:
    - Beneficiaries name OR Medicare Beneficiary Identifier (MBI)
    - Order date*
    - A description of the items ordered
    - Quantity to be dispensed, if applicable
    - Treating practitioner's name OR NPI
    - Treating practitioner's signature*

*Signature stamps and date stamps are not allowed

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c05.pdf

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Medicare B DMEPOS Order Requirements

- Standard Written Order
  - Can be written, faxed, or electronic
  - No transfers or telephone orders
  - Pharmacy providers are now permitted to add elements to clarify issues, such as:
    - Length of need
    - Frequency of use
    - Dosage form/strength
    - Refills
    - Diagnosis not required on the order, but needed to ensure accurate billing

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Medicare B DMEPOS Proof of Delivery

- Must include
  - Beneficiary Name
  - Delivery address (even if dispensed at your pharmacy counter)
  - A detailed description of the item
  - Quantity delivered
  - Date delivered
  - Signature of beneficiary or representative

- Note
  - Date of delivery should match date of service
  - Consider adding duplicate dispensing label

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Medicare B DMEPOS Proof of Refill Request

- Required for items that are mailed or delivered
- Not required for items picked up at your pharmacy
- Must include:
  - Name of beneficiary (or representative) making request
  - Description of item requested
  - Date of request
  - Quantity that beneficiary still has remaining

- Note:
  - Cannot be obtained more than 14 days prior to exhaustion of current supply, nor delivered more than 10 days prior

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Medicare B DMEPOS Medical Records

- Must be created within 12 months prior to the prescription
  - Some items < 6 months
- Records must support the underlying diagnosis or condition
- Each DMEPOS product category requires different/unique elements
- Best practice is to obtain records before dispensing items to patients

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Medicare B DMEPOS Orders with Quantities Above Policy Limits

- Review Local Coverage Determinations (LCD) and Policy Articles set by DME Medicare Administrative Contractors (DME MAC)
- Contact prescriber to alert them of the Medicare policy limit
  - Confirm the extra quantity is needed. If so,
    - Ensure medical records have appropriate documentation to support medical necessity of the extra quantity
    - Best practice is to obtain prior to dispensing to ensure they meet policy requirements
  - Can use pre-drafted Clinician Resource Letters
    - If not medically necessary, request to update order accordingly
  - If prescriber/patient insist on needing the extra quantity and the medical records do not support, consider completing an Advance Beneficiary Notice of Non-Coverage (ABN) prior to dispensing

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Medicare B DMEPOS Targeted Probe and Educate (TPE)

- Targeted
  - Suppliers with high claim denial rates
  - Product categories with high error rates
- Probe
  - Review of 20-40 claims in 3 “rounds”
    - Initial 10 claim review before 1st round
  - Opportunity to exit loop if successful
- Educate
  - 1-on-1 education offered by DME MAC to facilitate improvement
  - 45 days between rounds to implement corrective measures

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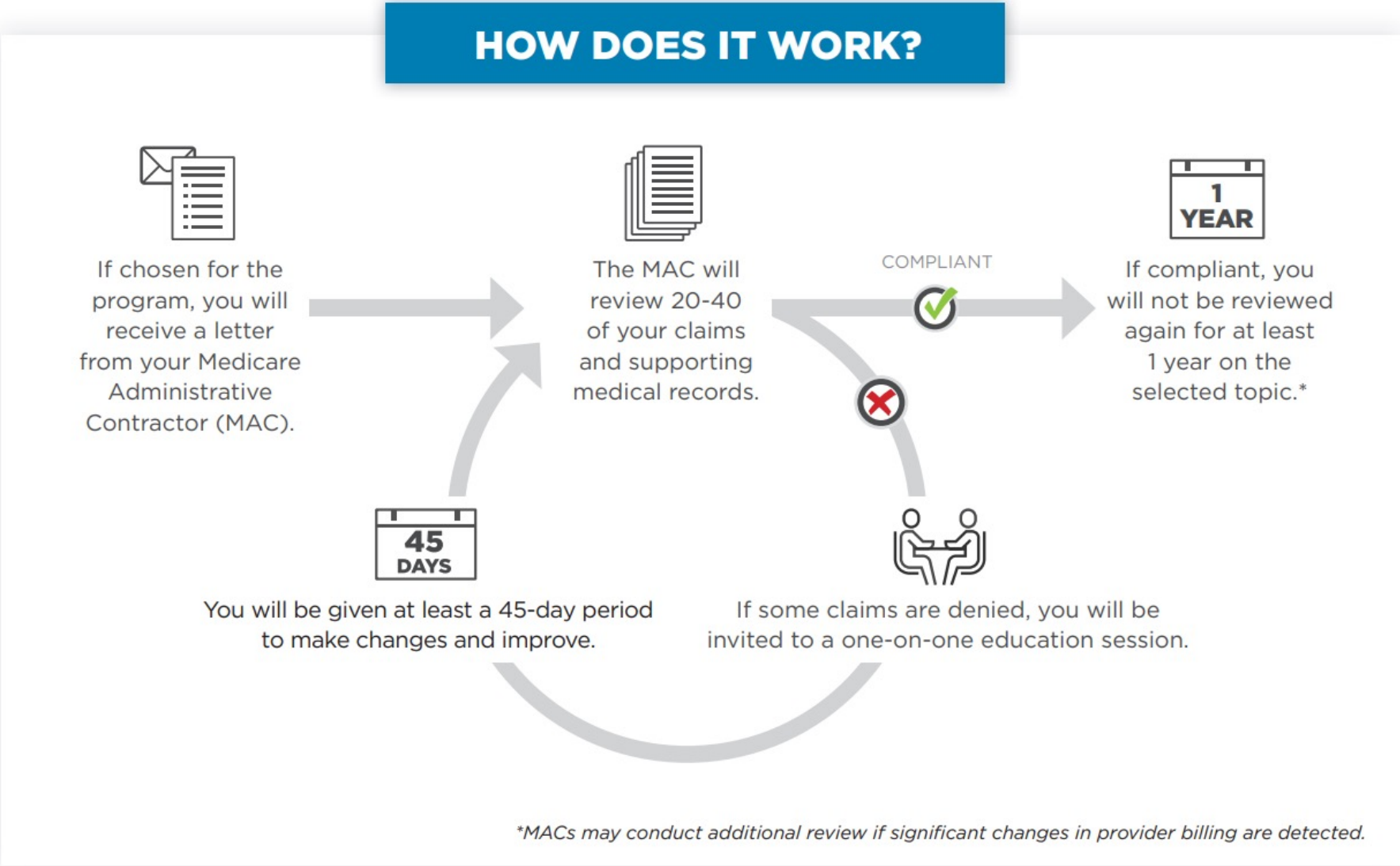
Medicare B DMEPOS Targeted Probe and Educate (TPE)



https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/What_Is_TPE-Infosheet.pdf

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Invoice Audits

Why do PBMs conduct invoice audits?

- Invoice audits are the primary method to identify false/phantom claims
  - Billing for medications that are never dispensed, including failure to reverse claims not picked up
  - Also helps to identify billing discrepancies (e.g., billing for brand, dispensing generic)
- Invoice audits are a lot of work on the pharmacy, and the auditor
  - Tracking down wholesalers to submit invoices to PBM
  - Requires data analysis to confirm sufficient purchases
    - Bulk purchases complicates an already sophisticated analysis (i.e., PBMs don't want to do more work than what is necessary)

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FOR IMMEDIATE RELEASE

Thursday, May 26, 2022

Queens Man Sentenced to 51 Months in Prison for Defrauding Pharmaceutical Manufacturer

Defendant Submitted Approximately $7.2 Million in Fraudulent Claims Under Co-Pay Reimbursement Program

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LEXINGTON HERALD-LEADER

CRIME

Former Kentucky legislator pleads guilty in case involving $2.7 million in health fraud

BY BILL ESTEP

UPDATED MAY 26, 2022 1:54 PM

Miami Herald

Coronavirus News Sports Business Personal Finance Public Notices

HEALTH CARE

A handyman, wives, Escalades, ghost pharmacies: A $9 million Miami drug coupon fraud

BY DAVID J. NEAL

JUNE 12, 2022 12:41 PM

"The pharmacies did not purchase prescription drugs for sale, did not have real customers who presented real prescriptions, and did no actual, legitimate pharmacy business"

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Invoice Audit Fundamentals

- PBMs/payors want to validate that pharmacies purchased more than (or equal to) what they billed in claims
  - Defined date range (typically 12-18 months)
- Characteristic Caremark invoice audit
  - Claims Date Range: 5/1/2021 – 4/30/2022
  - Invoice Date Range: 5/1/2021 – 4/30/2022
    - Upon request, will allow an extra 30 days of invoices on the front end
    - Revised Invoice Date Range: 4/1/2021 – 4/30/2022
  - While some PBMs may request the pharmacy to submit a full dispensing history, Caremark invoices generally focus on Caremark claims
    - No need to provide a dispensing report
    - Don’t have to prove purchases for all dispensings within the claims date range

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Invoice Audit Fundamentals

Workshop Examples

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Invoice Audit Fundamentals

Scenarios that represent higher risk:

- Medications with low turnover
- Medications where Caremark is the main PBM that covers the drug (consequently representing a high % of total utilization at your pharmacy)
- Situations where you have a single patient taking a particular medication and they discontinue the medication only to have you stuck with inventory on the shelf

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Off-Label Use

Off-label prescribing is a fundamental component of patient care

- Allows and encourages innovation
- Enables discovery of benefits not otherwise known
- Tenet of care for patient populations not routinely included in clinical studies
  - pediatrics, pregnancy, geriatrics
- Areas of concern include:
  - Absence of therapeutic benefit
  - Risks outweigh benefits
  - Excluded diagnosis for which payments are not allowed

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Off-label Use Audit Risk by Payor

Medicare Part D

- Definition of a Part D Covered Drug: A Part D covered drug is available only by prescription, approved by the FDA, used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act).1
- Section 1927(k)(6) states a medical accepted indication is “any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations include or approved for inclusion in any compendia described in subsection (g)(1)(B)(i)”
  - Section 1927(g)(1)(B)(i) lists the three compendia including:
    - American Hospital Formulary Service Drug Information (AHFS)
    - United States Pharmacopeia-Drug Information (or its successor, which is Micromedex)
    - DRUGDEX Information System (also Micromedex)

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Off-label Use Audit Risk by Payor

Medicaid

- Section 1927(d)(1)(b)(i) states a Medicaid Program "may exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not a medically accepted indication (as defined in subsection (k)(6))."

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Off-label Use Audit Risk by Payor

Commercial payers

- Have more flexibility to cover off-label uses, if they choose, as coverage criteria is not limited by federal law
- However, many private insurers do not cover “lifestyle drugs”
  - For example: sexual dysfunction, wrinkles, or weight loss
- Pharmacies should not assume that a claim paid at adjudication will remain paid.
  - Even with the absence of utilization management tools such as prior authorization or diagnosis code restriction

Off-label Use Audit Risk

Payors assume prescriptions are for the medically accepted indication and respond with paid claims, often without special coverage hurdles to jump through.

- Pay and chase audit method
- PBMs could come back in an audit 1-2 years later stating that the pharmacy “should have known” the drug wasn’t truly covered.

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Off-label Use What PBMS Have to Say…

- **OptumRx** defines a “Clean Claim as follows:
  - Prescription claims with active ingredients [active ingredients not defined] which are not being used for a documentable medically accepted indication or for which the Prescriber is unable to provide adequate documentation for the basis of use may not be considered a Clean Claim. For example, a claim that utilizes atypical directions for drug products which conflict with typical drug information available in pharmacy systems for patient education without medical necessity and of limited clinical value.
- **Express Scripts** – Section 10 of the Provider Manual discusses Plan Sponsor Specific Requirements, and 10.5 address Prime Therapeutics. Under General Claims Submission Policies, Prime addresses “Appropriate Dispensing Practices” and puts the onus on Providers to determine if “claims are submitted for a valid use of a medication”. Auditors may request documentation to support appropriate dispensing of medications.
- **Caremark** – does not directly address off-label use within the Provider Manual but states the Provider must comply with the Terms and Conditions of any Pharmaceutical Manufacturer Coupon Program being used.

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Off-label Use What PBMS Have to Say…

elixir

2. **Submission of Accurate Claims – Medicare Part D Considerations**

   a. Pharmacies must be aware of Medicare Part D requirements when submitting claims for Part D beneficiaries.
   b. Covered Part D drugs are prescribed for "medically accepted indications", i.e. use of medication according to FDA approved labeling or off label use if the drugs is identified as effective and safe for that use in one of the officially recognized drug compendia: American Hospital formulary Service (AHFS-DI) and DRUGDEX® Information system.
   c. Payments for Part D drugs that are not for medically accepted indications are considered potential fraud or abuse.

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Off-label Use What PBMS Have to Say…

Pharmacy Audits & Fraud, Waste, and Abuse

elixir

Auditor Comments
Medically-accepted indication in the treatment of pain via topical route for Diclofenac tablets, Gabapentin tablets and the use of Halobetasol cream for pain, is not medically supported. Not considered a Part D drug for purposes of coverage. No post audit documentation accepted.

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Off-label Use What PBMS Have to Say…

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CRAFTED Rx SOLUTIONS

To: Network Pharmacy
From: Elixir Pharmacy Audit and FWA Team
Date: Thursday, April 20, 2023
RE: The Pharmacy Audit Whisperer

Drug	Diagnoses not covered by Medicare Part D	Audit chargeback reason
Ozempic® (semaglutide) injection 0.5 mg, 1 mg, or 2 mg	Obesity, weight loss	Medicare Part D-approved coverage is for the drug's FDA label use, i.e., the adjunct treatment of type 2 diabetes mellitus. Medicare Part D does not cover weight loss drugs per legislation.
Mounjaro® (tirzepatide) injection 0.5 mL | 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg	Obesity, weight loss	Medicare Part D-approved coverage is for the drug's FDA label use, i.e., the adjunct treatment of type 2 diabetes mellitus. Medicare Part D does not cover weight loss drugs per legislation.

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Off-label Use What PBMS Have to Say…

Discrepancy		Standard Comments
CLN		Outpatient drugs without a medically accepted indication are not reimbursable under this plan. No documentation to denote the clinical appropriateness was validated. Please provide medical literature that supports the indications and usage for the claim submission.
CLN		Outpatient drugs without a medically accepted indication are not reimbursable under this plan. No documentation to denote the clinical appropriateness was validated. Please provide medical literature that supports the indications and usage for the claim submission.
CLN		Outpatient drugs without a medically accepted indication are not reimbursable under this plan. No documentation to denote the clinical appropriateness was validated. Please provide medical literature that supports the indications and usage for the claim submission.

OPTUMRx®

Preliminary Findings
Full Recoupment. Outpatient drugs without a medically accepted indication are not reimbursable under this plan. No documentation to denote the clinical appropriateness was validated.

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MedImpact

The diagnosis code of the corresponding medical claim does not support the billing of this medication. Please provide a signed prescriber statement written by the prescriber on their letter head or provide supporting medical records from the prescriber's office. Origin code submitted was 2- Phone, but prescription provided was 1- Written.

There is no corresponding medical claim does not support the billing of this medication. Please provide a signed prescriber statement written by the prescriber on their letter head or provide supporting medical records from the prescriber's office.

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Quality health plans & benefits
Healthier living
Financial well-being
Intelligent solutions

aetna®

FAX - CONFIDENTIAL

Subject: Medicare Part D coverage of topical Lidocaine

We've noticed an increase in the dispensing of topical lidocaine and lidocaine/Prilocaine compounds. As a reminder, our Medicare Part D plans don't cover Lidocaine 5% ointment and Lidocaine/Prilocaine 2.5-2.5% (either alone or as part a compound) for indications that aren't FDA-approved.

Confirm the patient's diagnosis

We may ask you for documentation showing you confirmed the diagnosis for which a provider prescribed Lidocaine 5% ointment or Lidocaine/Prilocaine 2.5-2.5%.

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PRIME THERAPEUTICS

Prime Therapeutics, LLC
2900 Ames Crossing
Eagan, MN 55121-2498
Fax 877.290.1516
Phone 612.777.5113
www.PrimeTherapeutics.com

****

Claim(s) Error Notification:

The claim(s) below Ineligible for Medicare Part D. Not being used for a CMS medically accepted indication.

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Prescriptions for Off-Label Use

Yes, products can always be used (prescribed, dispensed) “off-label”, but insurance plans don’t have to cover them

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Off-label Use Semaglutide (Ozempic®) and Liraglutide (Victoza®)

- Companion products of Semaglutide (Wegovy™) and Liraglutide (Saxenda®)
  - Identical ingredients marketed for different FDA-approved indications (weight loss)
- Prescriptions for Semaglutide (Wegovy™) / Liraglutide (Saxenda®) are often denied at Point-of-Sale
  - Prescribers are tempted to help patients and will prescribe the companion product
    - Pharmacies carry the financial risk of their decision and are put in the middle

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GLP-1 Off-Label Use, Confirm & Document

We advise pharmacies to confirm (and document) whether patients have a diagnosis of type 2 diabetes

- If you have a diabetes diagnosis, or antidiabetic medications on the patient's profile, you have less to worry about and should not need to do any extra work.
- Keep in mind pre-diabetes is not an approved diagnosis code

Options for weight loss:

- Try to bill Semaglutide (Wegovy™) or Liraglutide (Saxenda®)
  - Call PBM and speak with Clinical RPh to confirm coverage for specific patient/Plan
  - Encourage patient to call Plan to confirm or request coverage for weight loss

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Off-label Use What PBMS Have to Say…

NAVITUS HEALTH SOLUTIONS

PHARMACY DESKTOP AUDIT PRELIMINARY RESULTS

Drug Name	Discrepancy	Financial Action	Estimated Recovery
OZEMPIC INJ 4MG/3ML	OKC Clinically Questionable	Full Recovery	$830.50
Per manufacturer, the highest recommended dosing is 1mg once per week. Patient is using 2mg once per week.			
1 OZEMPIC INJ 4MG/3ML	OKC - Clinically Questionable	Full Recovery	$830.50
Per manufacturer, the highest recommended dosing is 1mg once per week. Patient is using 2mg once per week.			
			$1661.00

The image shown above is an example shared for instructional purposes only.

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Off-label Use What PBMS Have to Say…

SCRIPT CARE, LTD.

Drug Name	Discrepancy	Financial Action	Estimated Recovery
MOUNJARO SOPN 5.000 MG/0.5ML	CI - Clinically Inappropriate	Full Recovery	$942.11
This medication is only FDA-approved for a Type II diabetes indication.			

The image shown above is an example shared for instructional purposes only.

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Game Plan

All pharmacy staff can help to reduce and prevent audits from occurring throughout the pharmacy workflow.

Off-label dispensing and bulk purchasing can carry audit risks.

Calculating an accurate days' supply is pivotal to audit prevention. Use the worksheet to help train additional staff at your pharmacy.

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