From the auditor’s desk

Compound Ingredients Do Not Meet USP Standards (CUSP) Error

Prime monitors claims data to identify potential billing and compliance errors. When Prime identifies pharmacy errors, Prime contacts the Participating Pharmacy and provides instruction to correct or reverse the claim. This process is intended to educate the Participating Pharmacy on Prime’s billing requirements. One example is when there is potential evidence of unprofessional or unsafe compounding practice, such as a compound for which the stability is unknown at the time of dispensing or cannot be determined by reference of a USP-approved reference material.

USP Standards

USP (U.S. Pharmacopeia) develops standards for compounding nonsterile drugs to help ensure Covered Person benefits and reduce risks such as contamination, infection or incorrect dosing. Chapter 795 of USP describes requirements for the compounding process, facilities, equipment, components, documentation, quality controls and training, along with general guidelines for assigning beyond-use dates to nonsterile preparations. Common errors include the following:

→ Ingredients used do not meet the recommended sources by USP Chapter 795 – USP or NF pharmaceutical grade chemicals

→ Ingredient sources selected do not have the expected identity, quality, and purity when compounded into a dosage form that is different than that approved by the Prescribing Provider orders or intended for the Covered Person.

Participating Pharmacy Responsibility

Pharmacists and pharmacy technicians who compound must be aware of and comply with the USP chapters and related best practices. The pharmacist is responsible for compounding preparations of acceptable strength, quality and purity, with appropriate packaging and labeling in accordance with good pharmacy practices, official standards and current scientific principles. When the recommended source of a prescribed drug for compounding is not available, the pharmacist has the option of choosing another product using his/her professional judgment. If there are changes made in the composition (formulation) or dosage form of the original or succeeding product(s), this represents a new drug product and will require consideration of new stability/potency data. Data requirements will depend on the nature and degree of change.
Prime Provider Manual

Participating Pharmacies are expected to observe state and federal laws, relevant USP chapter guidelines, professional standards and Food and Drug Administration (FDA) communications when preparing and dispensing compound prescriptions. Evidence of unprofessional or unsafe compounding found during the Participating Pharmacy’s audit process or otherwise may be reported to the applicable State Board of Pharmacy or the FDA, and may result in termination of the Pharmacy Participation Agreement.

If you have any questions regarding loading doses, you may reach the Pharmacy Audit Department at pharmacyaudit@primetherapeutics.com.

Pharmacy audit information

For more information regarding pharmacy audit, including common billing errors, pharmacy audit appeals and pharmacy audit guidelines, please visit Prime’s website: primetherapeutics.com > Resources > Pharmacy + provider > Pharmacy audits > Audit guidelines.

Medicare news/Medicaid news

Medicare E1 Eligibility Query

An E1 Eligibility Query is a real-time transaction submitted by a Participating Pharmacy to RelayHealth, the Transaction Facilitator. It helps determine a Covered Person’s Medicare Part D coverage and payer order if the Covered Person has insurance through more than one Benefit Plan Sponsor.

Participating Pharmacies generally submit E1 Queries when Covered Persons do not have their Medicare Part D Identification Card.

Additional information on E1 Transactions can be found at http://medifacd.relayhealth.com/e1

Participating Pharmacies should not submit an E1 Query for pharmaceutical manufacturer co-pay assistance coupon programs.

CMS standardized pharmacy notice

CMS requires all Medicare Part D Benefit Plan Sponsors to use a single uniform exceptions and appeals process with respect to the determination of prescription drug coverage for a Covered Person under the plan. Medicare Part D claims will be rejected when a claim cannot be covered under the Medicare Part D Benefit Plan at Point-of-Sale (POS).

Pharmacy claims will be rejected with the following POS rejection message:

→ NCPDP Reject Code 569

Participating Pharmacies are required to provide the CMS Notice of Medicare Prescription Drug Coverage and Your Rights to Covered Persons when they receive National Council for Prescription Drug Programs (NCPDP) reject code 569. The CMS Notice of Medicare Prescription Drug Coverage and Your Rights is posted on Prime’s website: primetherapeutics.com > Resources > Pharmacy + provider > Medicare > More Resources > Medicare Prescription Drug Coverage and Your Rights form.

Home Infusion Participating Pharmacies receiving the NCPDP reject code 569 must distribute the CMS notice to the Covered Person either electronically, by fax, in person or by first class mail within 72 hours of receiving the claim rejection.
Long Term Care (LTC) Participating Pharmacies receiving the NCPDP reject code 569 must contact the Prescribing Provider or LTC facility to resolve the rejected claim to ensure the Covered Person receives their medication. If the Participating Pharmacy must distribute the CMS notice, they must fax or deliver the notice to the Covered Person, the Covered Person’s representative, Prescribing Provider or LTC facility within 72 hours of receiving the rejection.

In addition, a copy of the CMS Notice of Medicare Prescription Drug Coverage and Your Rights has been included on page four of this publication.

Florida news

Repatha® NDCs coverage update
Effective January 1, 2019, coverage changes will occur for BCBS of Florida Blue Commercial Covered Persons who fill the medication Repatha®:

→ Repatha® NDCs 72511-0760-01 and 72511-0760-02 will be covered at retail pharmacies

→ Repatha® NDCs 55513-0760-01 and 55513-0760-02 will only be covered at specialty pharmacies

Prior Authorization will be required for all Repatha® products. If you have any questions about claims processing, please call the Prime Contact Center at 800.821.4795.

Florida Blue utilization management programs
Utilization management program updates for the upcoming quarter, when available, will be posted at primetherapeutics.com > Resources > Pharmacy + provider > Pharmacy providers > UM program updates.
Medicare Prescription Drug Coverage and Your Rights

**Your Medicare rights**

You **have the right to request a coverage determination** from your Medicare drug plan if you disagree with information provided by the pharmacy. You also **have the right to request a special type of coverage determination called an “exception”** if you believe:

- you need a drug that is not on your drug plan’s list of covered drugs. The list of covered drugs is called a “formulary;”
- a coverage rule (such as prior authorization or a quantity limit) should not apply to you for medical reasons; or
- you need to take a non-preferred drug and you want the plan to cover the drug at a preferred drug price.

**What you need to do**

You or your prescriber can contact your Medicare drug plan to ask for a coverage determination by calling the plan’s toll-free phone number on the back of your plan membership card, or by going to your plan’s website. You or your prescriber can request an expedited (24 hour) decision if your health could be seriously harmed by waiting up to 72 hours for a decision. Be ready to tell your Medicare drug plan:

1. The name of the prescription drug that was not filled. Include the dose and strength, if known.
2. The name of the pharmacy that attempted to fill your prescription.
3. The date you attempted to fill your prescription.
4. If you ask for an exception, your prescriber will need to provide your drug plan with a statement explaining why you need the off-formulary or non-preferred drug or why a coverage rule should not apply to you.

Your Medicare drug plan will provide you with a written decision. If coverage is not approved, the plan’s notice will explain why coverage was denied and how to request an appeal if you disagree with the plan’s decision.

Refer to your plan materials or call 1-800-Medicare for more information.

**PRA Disclosure Statement** According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this collection is 0938-0975. The time required to complete this information collection is estimated to average 1 minute per response, including the time to review instructions, search existing data resources, and gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

CMS does not discriminate in its programs and activities: To request this form in an accessible format (e.g., Braille, Large Print, Audio CD) contact your Medicare Drug Plan. If you need assistance contacting your plan, call: 1-800-MEDICARE.
HCSC news

Utilization Management Frequently Asked Questions for Blue Cross® and Blue Shield® of Illinois, Blue Cross and Blue Shield of Montana, Blue Cross and Blue Shield of New Mexico, Blue Cross and Blue Shield of Oklahoma, and Blue Cross and Blue Shield of Texas*

Participating Pharmacies may receive questions from Medicare Part D Covered Persons regarding their drug coverage. The Q&A below serves as a tool to provide context to CoveredPersons who experience a Point-of-Sale (POS) reject due to utilization management criteria. Below are some common questions you may encounter:

Q: **What is a Prior Authorization?**
A: Prior authorization (sometimes called pre-approval) means that your medicine must be approved by your health plan before it will be covered. You or your Prescribing Provider will need to request an approval so that your health plan can review and determine if coverage can be provided. Your Prescribing Provider will explain why you need this particular medicine and why it is the best option for you. The health plan may request that your Prescribing Provider provide additional information in order to make a decision.

Q: **Why does a drug need a Prior Authorization?**
A: A drug may be used for only certain health conditions. The information your Prescribing Provider gives for a prior authorization allows the health plan to determine if the medicine is being used to treat the appropriate condition and that it also meets other health plan or Medicare requirements. Sometimes medicines/treatments may be covered under Medicare Part B. A Prior Authorization request can help determine whether a medicine is covered under Medicare Part B or Part D.

Q: **What do I need to do if my prescription requires a Prior Authorization?**
A: You or your Prescribing Provider will need to request an approval of the prescription from your health plan. Pharmacist — I have already contacted your Prescribing Provider to start the prior authorization process for you. You should also contact your Prescribing Provider to ensure that they have started the prior authorization process.

Q: **What is Step Therapy?**
A: Step Therapy means you must try a different medication before you can “step up” to the one that your Prescribing Provider prescribed. If you don’t follow the process for step therapy when it’s required, the medicine may not be covered by your health plan. You or your Prescribing Provider can request an exception to step therapy if you have already tried the other drugs or if they are not appropriate for you.

Q: **Why does this drug have a Step Therapy?**
A: Step therapy programs help manage the rising cost of prescription drugs and the overall cost of health care. A “step” approach encourages the safe, cost-effective use of medication by first trying lower-cost medications whenever appropriate.

Q: **What is a Quantity Limit?**
A: Your prescription benefit limits the quantity that you can get filled at once or how often this drug can be dispensed. In order to obtain quantities above this amount, you or your Prescribing Provider will need to request a quantity limit exception from your health plan.

Q: **Why do they have a Quantity Limit on this drug?**
A: Quantity Limit programs promote safe and cost-effective drug use. They also help reduce waste and overuse.

Q: **What if my medicine is not covered?**
A: First talk with your Prescribing Provider. There may be another medicine that is on your plan’s drug list (formulary) that your Prescribing Provider can prescribe. If there is no other medicine or if you would like your Prescribing Provider to request a formulary exception for this medicine, you or your Prescribing Provider will need to contact your health plan to process the request.

Q: **What is a Formulary Exception request?**
A: This request would be used to get coverage for a medicine not listed on the drug list (formulary). Such a request may be made when your Prescribing Provider believes a non-formulary drug is best for you.
Q: **How do I request a Formulary Exception for a drug?**

A: If your Prescribing Provider believes that the original medicine (non-formulary medication) is best for you, your Prescribing Provider can submit a request for a formulary exception and include a statement supporting the request. The Prescribing Provider statement must explain how:

- This drug is medically necessary to treat your condition
- The drugs on your plan would not be as effective or would have unwanted effects

Q: **How will I know if my request has been approved?**

A: Once a decision is made, your health plan will send a letter to you and your Prescribing Provider. If you have questions regarding the decision, contact your health plan or your Prescribing Provider for information.

*Divisions of Health Care Service Corporation, a Mutual Legal Reserve Company, an Independent Licensee of the Blue Cross and Blue Shield Association*

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**Prime news**

**Pharmacy licensure**

Participating Pharmacies with independent contracts must provide Prime with the following on an annual basis:

- Certificate of Insurance with proof of General and Professional Liability Insurance

To update our records, please visit our website at: https://www.primetherapeutics.com/en/resources/pharmacists/ac.html.

Choose “Pharmacy Certificate of Insurance Renewal” from the options, and follow the instructions to upload and submit a PDF of your current or renewed Certificate of Insurance.

**Provider Manual update**

The new Provider Manual will be effective March 1, 2019, and will be posted in February 2019 on Prime’s website: primetherapeutics.com › Resources › Pharmacy + provider › Provider manual.
MAC list updates

If a Participating Pharmacy would like access to Prime’s Maximum Allowable Cost (MAC) lists, weekly MAC changes, the sources used to determine MAC pricing and the appeals process, please refer to Prime’s website for registration instructions. After network participation is verified, the Participating Pharmacy will receive a secure user name and password via email.

How to reach Prime Therapeutics

As a service to Participating Pharmacies, Prime publishes the Prime Perspective quarterly to provide important information regarding claims processing. Prime values your opinion and participation in our network. If you have comments or questions, please contact us:

→ By phone: Prime Pharmacy Contact Center **800.821.4795**
  (24 hours a day, seven days a week)

→ By email: pharmacyops@primetherapeutics.com

The corporate headquarters of Prime Therapeutics LLC has relocated effective October 15, 2018 to:

  2900 Ames Crossing Road
  Eagan, MN 55121

Looking for formularies?

For Commercial formularies, access either the Blue Cross Blue Shield plan website or primetherapeutics.com > Resources > Pharmacy + provider > Pharmacy providers > Formularies – Commercial.

For Medicare Part D formularies access primetherapeutics.com > Resources > Pharmacy + provider > Pharmacy providers > Formularies – Medicare Part D.

Keep your pharmacy information current

Prime uses the National Council for Prescription Drug Programs (NCPDP) database to obtain key pharmacy demographic information. To update your pharmacy profile, go to www.ncpdp.org > NCPDP Provider ID (on the left side).

Report Compliance, Privacy, or Fraud, Waste and Abuse concerns

Prime offers the following hotlines to report compliance, privacy, and Fraud, Waste and Abuse (FWA) concerns:

**Compliance**

Report suspected compliance concerns:

→ Phone: **612.777.5523**
→ Email: compliance@primetherapeutics.com

**Privacy**

Report privacy concerns or potential protected health information (PHI) disclosures to Prime:

→ Privacy Hotline: **888.849.7840**
→ Email: privacy@primetherapeutics.com

**Fraud, Waste and Abuse**

If you suspect Fraud, Waste or Abuse (FWA) by a Covered Person, Prescribing Provider, Participating Pharmacy or anyone else, notify Prime:

→ Phone: **800.731.3269**
→ Email: fraudtiphotline@primetherapeutics.com

**Anonymous Reporting**

Report a compliance concern or suspected Fraud, Waste or Abuse anonymously by contacting Prime’s 24-hour anonymous compliance hotline:

→ Phone: **800.474.8651**
→ Email: reports@lighthouse-services.com
→ Third-party vendor’s website: www.lighthouse-services.com/prime

Product names listed are the property of their respective owners.
Time Sensitive

Information from Prime Therapeutics

→ Claims processing instructions
→ Utilization management updates from Blue Cross and Blue Shield plans
→ Prime audit requirements
→ Medicare Part D and Medicaid requirements