Drug Submission Requirements

MedImpact Pharmacy Compliance, FWA

Introduction

MedImpact Healthcare Systems, Inc. ("MedImpact") would like to remind pharmacies of various drug submission requirements and share the most common discrepancies found during audits to encourage the exercise of best pharmacy practices and more efficient and seamless pharmacy audits for all parties involved.

Please note that this document is not inclusive of all drug submission requirements or of MedImpact's audit guidelines. If you have any questions about the content of this document or other requirements, please send your inquiries to pad@medimpact.com. In addition, to review your contractual obligations and the terms and conditions of your participation in MedImpact's pharmacy network, please ensure that you frequently consult the Provider Manual, which is available online at: https://pharmacy.medimpact.com/Resources/ProviderManual.

MedImpact's Audit Guides are available online at:
https://pharmacy.medimpact.com/Resources/AllResources → Audit Guidelines

DRUG SUBMISSION REQUIREMENTS FOR PHARMACIES

DAY SUPPLY CALCULATIONS

If the directions from the Prescriber are in some form of "as directed", or are otherwise unclear or incalculable, Pharmacists must validate the dosing (or duration the prescribed quantity will last) with the Prescriber and document it on the prescription. Prescriptions must have calculable directions.

Pharmacies are expected to submit claims for the **actual day supply** according to proper dosing for the drug and/or calculated according to prescription directions. Please submit the actual day supply before assuming the member has a 30-day limitation. If claims reject for exceeding the Member's maximum day supply benefit, please follow these guidelines:

For Members with a **30-day supply maximum benefit**, it is acceptable to submit a 30-day supply for **unbreakable package sizes** (insulins/eye drops/topicals/inhalers). For example:

- One box of test strips: #100 TID = 33-day supply; submitting 100 as a 30-day supply is acceptable*
- One box of test strips: #100 BID = 50-day supply; dispense a 50-count package for a 25-day supply
- One box of 100 lancets: #100 BID or TID, submitting 100 as a 30-day supply is acceptable*

*In cases where the day supply on an unbreakable package has been adjusted to the Member's maximum day supply benefit, Pharmacies are responsible for ensuring that subsequent claims are not filled early. We recommend adding the actual day supply to the patient's directions (e.g., "42.5 gm to last 90 days").

CMS allows Medicare Part D claims for unbreakable package sizes to be submitted for the actual day supply (e.g., Prolia should be submitted for a 180-day supply).

Pharmacies should dispense the **smallest package size available** that will still meet the requirements of the prescription.

Medications with a dosing regimen of an active period followed by a rest period should be billed with a day supply that reflects the entire cycle (e.g., cancer treatments, oral contraceptives).

BILLING MULTIPLES OF UNBREAKABLE PACKAGES

At least 50% of the **last package quantity** billed should be used before the Member's maximum benefit day supply is reached. For example:

- Member has a 30-day supply benefit, 2 inhalers are prescribed, lasting 37 days total. It is acceptable to bill the 2 inhalers as a 30-day supply because the 2nd inhaler will be 50% used by the 30th day.

PRESCRIPTIONS SHOULD BE BILLED FOR THE DURATION OF THE TREATMENT

- A drug that is taken once monthly should be billed for a 30-day supply per dose (e.g., 1/30 or 3/90)
- A drug that is taken once weekly should be billed for 7 days per dose (e.g., 1/7 or 4/28)
- A drug that has a starter dose should be calculated appropriately, and the quantity and day supply should be adjusted on subsequent fills. For example:
  - Vagifem® dosed at 1 tablet daily for 2 weeks, then 1 tablet twice weekly thereafter:
    - Initial fill: quantity 18 for a 28-day supply
    - Subsequent fills: quantity 8 for a 28-day supply
- In general, medications with a dosing regimen of an active period followed by a rest period should be billed with a day supply that reflects the entire cycle (e.g., cancer treatments, oral contraceptives)

MANUFACTURER RECOMMENDED LIMITATIONS

- Prescriptions written for quantities, dosing, or treatment duration that exceeds the manufacturer's recommended maximum should be validated with the Prescriber and documented on the prescription.

ANNOVERA®

- One ring is a 364-day supply (13 cycles)
- Submitting a 1-day supply is NOT acceptable
- Acceptable day supply: 30-364 days, depending on the Member's benefit day supply maximum
  - Pharmacy should initially submit the claim with a 364-day supply
  - If a 364-day supply is rejected, resubmit with the Member's benefit day supply maximum in the day supply field
    - It is the Pharmacist's responsibility to ensure proper refill frequency and claim spacing

COMPOUNDS

- Compound ingredients must be submitted using the actual NDC used in preparing the compounded product
- **ALL** ingredient NDCs used in preparing the compounded product must be submitted on the **same claim**, even when some ingredients are not covered under the Member's benefit
- Compounding a copy of a commercially available manufactured product is NOT acceptable

CONTRACEPTIVES

- Continuous use (no rest period) of oral and transdermal forms **must** be documented on the prescription
- In general, medications with a dosing regimen of an active period followed by a rest period should be billed with a day supply that reflects the entire cycle (e.g., 28 days per cycle)
- See also **Billing Multiples of Unbreakable Packages**, above

DIABETIC SUPPLIES

- When dispensing a glucometer kit that contains multiple components, the pharmacy should NOT submit separate claims for items already contained in the kit, such as a lancing device or control solution, until such time as is appropriate to dispense refills for those items

- Glucose meters/readers/receivers should be filled no more often than once per year
- Lancing devices should be filled no more often than once every six months
- Control solution should be filled no more often than once every three months
- Omnipod DASH®
    - Each Pod holds 200 units of insulin
    - The manufacturer recommends changing the Pod every 3 days

EPINEPHRINE INJECTION (EPIPEN®, AUVI-Q®)

- UD or "as directed" are acceptable directions
- One box for home and one box for school are acceptable (max of two boxes per fill), and should be documented on the prescription
- Acceptable Day Supply: 1 to 30 per fill (variable)

ERECTILE DYSFUNCTION (ED) DRUGS

- If the directions from the Prescriber are in some form of "as directed", or are otherwise unclear or incalculable, Pharmacists must validate the dosing (or duration the prescribed quantity will last) and document it on the prescription

ESTROGENS

- Premarin® dosed at 1 tablet daily for 21 days, then off 7 days should be submitted as a 28-day supply
- Vagifem® (estradiol) dosed at 1 tablet daily for 2 weeks, then 1 tablet twice weekly thereafter:
    - Initial fill: quantity 18 for a 28-day supply
    - Subsequent fills: quantity 8 for a 28-day supply
- In general, medications with a dosing regimen of an active period followed by a rest period should be billed with a day supply that reflects the entire cycle
- See also **Vaginal Creams**, below

EYE/EAR SOLUTIONS AND SUSPENSIONS

- Calculate the day supply using 15 drops per mL
- Submitting claims as a 1-day supply is NOT acceptable
- Dispense the **smallest package size available** that will still meet the requirements of the prescription

FERTILITY DRUGS

- UD or "as directed" are acceptable directions for **injectable** fertility drugs
- Specific directions are required for oral forms
    - If no directions are provided on the prescription, directions must be validated with the Prescriber and documented on the prescription

FLUOCINONIDE 0.1% CREAM (VANOS®)

- Maximum recommended dosage by manufacturers is 60 gm per week for no more than 2 weeks
- Prescriptions written for quantities, dosing, or treatment duration that exceeds the manufacturer's recommended maximum should be validated with the Prescriber and documented on the prescription

FOOT BATHS AND TOPICAL SOAKS

- CMS, in collaboration with the I-MEDIC, has stated, "Topical soaks are not the standard of care in treatment of foot infections such as diabetic ulcers, and could be actively harmful to the healing process". Further, "The purported indications for use of these combinations used in this manner, may not be medically accepted indications (MAIs) and are, at best, investigative and experimental treatments".
- MedImpact aggressively reviews claims submitted for drugs being used in foot baths or soaks. Actions will be taken against pharmacies determined to be billing for these treatments.

INHALERS

- Specific directions must be documented; “as directed” is NOT acceptable
- Dispensed quantities must be in line with the number of actuations in each inhaler
- One for home and one for school must be clearly documented on the prescription, if applicable
- ProAir® and Ventolin® are NOT AB-rated (not therapeutically equivalent for substitution) and cannot be substituted one for the other (e.g., cannot substitute ProAir for Ventolin and vice versa). The Pharmacist must verify substitution with the prescriber’s office and document the change on the prescription. **Authorized generics** are available for each of these products and are considered interchangeable with their respective brand name product.
- See also **Billing Multiples of Unbreakable Packages**, above

INSULIN

- If the directions from the Prescriber are in some form of “as directed”, or are otherwise unclear or incalculable, Pharmacists must validate the dosing (or duration the prescribed quantity will last) and document it on the prescription
- For sliding scale insulin, Pharmacists must obtain duration or maximum units per day from the Prescriber’s office
- Treatment duration is acceptable in lieu of daily directions, e.g., “use as directed, #2 vials per month”
- Do not submit a day supply that is longer than the in-use expiration date per vial/pen, for example:
    - Lantus 10 mL with directions of 25 units daily would last 40 days; however, each vial expires 28 days from first use. Therefore, the claim should be submitted as 10 mL for 28 days.
- See also **Billing Multiples of Unbreakable Packages**, above

INSULIN PENS

- Splitting boxes of insulin pens
    - MedImpact recommends following the manufacturer’s recommendations in the prescribing information (aka, package insert)
    - MedImpact will not penalize a pharmacy during an audit based solely on whether they split, or did not split, a box of insulin pens
    - If the submitted quantity on a claim indicates that the pharmacy chose to split the box to dispense individual pens, and the quantity was overbilled, MedImpact will adjust the claim and decrease the submitted quantity by multiples of the pen size during an audit
    - If the submitted quantity on a claim indicates that the pharmacy dispensed multiples of the box size, and the quantity was overbilled, MedImpact will adjust the claim and decrease the submitted quantity by multiples of the box size during an audit
    - See also **Billing Multiples of Unbreakable Packages**, above

PERMETHRIN CREAM (ELIMITE™)

- One 60 gm tube per individual patient is a 7-day supply
  - Manufacturer notes that "Usually 30 grams is sufficient for an average adult…one application is generally curative."
- Submitting 60 gm as a 1-day supply is NOT acceptable

PROLIA® INJECTION

- One injection is a 180-day supply
- Submitting a 1-day supply is NOT acceptable
- Acceptable day supply: 30-180 days, depending on the Member's benefit day supply maximum
  - Pharmacy should initially submit the claim with a 180-day supply
  - If a 180-day supply is rejected, resubmit with the Member's benefit day supply maximum in the day supply field
    - It is the Pharmacist's responsibility to ensure proper refill frequency and claim spacing
- CMS allows Medicare Part D claims for unbreakable package sizes to be submitted for the actual day supply (e.g., Prolia should be submitted for a 180-day supply)

TOBRAMYCIN 300 MG/5 ML NEBULIZER SOLUTION (TOBI®)

- One carton of 56 ampules is a 56-day supply (28 days on and 28 days off)
- Acceptable day supply: 30-56, depending on the Member's benefit day supply maximum
  - Pharmacy should initially submit the claim with a 56-day supply
  - If a 56-day supply is rejected, resubmit with the Member's benefit day supply maximum in the day supply field
    - It is the Pharmacist's responsibility to ensure proper refill frequency and claim spacing
- In general, medications with a dosing regimen of an active period followed by a rest period should be billed with a day supply that reflects the entire cycle (e.g., 56 days), as noted above

VACCINES

- Vaccines should be billed per mL (e.g., 0.5 mL, 0.7 mL, 1.0 mL)
- Submitting a 1-day supply is acceptable for vaccines
- It is the Pharmacist's responsibility to ensure proper claim spacing between vaccine doses

VAGINAL CREAMS

- Estradiol® 42.5 gm includes a calibrated plastic applicator for delivery of 1 gm, 2 gm, 3 gm, or 4 gm. The plastic applicator can be washed and reused.
- Premarin® Vaginal Cream 30 gm includes plastic applicator(s) calibrated in 0.5 gm increments to a maximum of 2 gm. The plastic applicator can be washed and reused.
- Metronidazole® Vaginal Gel contains 70 gm; 1 applicatorful is equivalent to 5 gm. The plastic applicator can be washed and reused.
- Elestrin® pump container delivers 30 metered doses after priming

TOPICALS

- One fingertip unit (FTU) is equal to 0.5 gm
- Pharmacist documentation must include dosing and area(s) of application, if it is not noted on the prescription by the Prescriber
- Dispense the **smallest package size available** that will still meet the requirements of the prescription

AUDITS

Below are answers to frequently asked questions and common discrepancies found during audits.

APPEALS

- Only written appeals are accepted
- Appeal documents must be received by the appeal deadline to be considered
- **Prescriber attestations** submitted to support claim submissions **must** be **written by** the Prescriber on the Prescriber's office letterhead, dated, and signed by the Prescriber, specify the details of the prescription, and include the elements needed to appeal the assigned discrepancy/ies
- **Member attestations** submitted to support claim submissions **must** be **written by**, dated, and signed by the Member, specify the details of the fill, and include the elements needed to appeal the assigned discrepancy/ies

DATE WRITTEN/ISSUE DATE

- The written date is the date the Prescriber signed/authorized the prescription, called it in to the pharmacy, or sent the prescription electronically; or as defined in applicable state/federal regulations
- This is **not** the date the pharmacy fills the prescription or receives the fax
    - The fax header date is NOT acceptable as the date a prescription was written
- Prescriptions expire per state/federal regulations based on the date the prescription was written
- Subsequent clarification of prescription elements with the Prescriber **does not** change the written date

DAW (DISPENSE AS WRITTEN) CODE

- DAW 1 (or "Y") must **only** be used when the prescription **clearly** displays a dispensing directive ("DAW," "Dispense as Written," "No substitution allowed," "Brand medically necessary," etc.)
- Support for submitting DAW 2 (patient requested brand), or any other DAW Code, must be documented on the prescription, or in the pharmacy's software system, and must be provided for audits
- DAW 0 should be submitted on the following products, regardless of whether the Prescriber indicates that no substitution is allowed:
    - All generics, unless the prescriber specifies a manufacturer
    - All single-source brand name drugs because substitution is not possible
    - **All non-drug products, such as diabetic testing supplies**

E-SCRIPTS

- Electronic prescriptions must be transmitted electronically, as defined by state/federal regulations, in order for an e-signature to be valid (e.g., a scanned prescription sent via email is NOT considered an electronically transmitted prescription and therefore requires a manual signature)
- If an e-script is provided to a pharmacy in any other manner, it is considered a written/faxed prescription and a manual signature is required

INVOICE/INVENTORY AUDITS

- To satisfy requests for Invoice Audits, pharmacies should provide MedImpact with a complete listing of wholesalers, distributors, reverse distributors, direct buys, and other sources of procurement (e.g., pharmacy transfers), that the pharmacy has used in the previous two (2) years
    - Information must include corresponding account numbers and current contact information
    - Upon receipt of the pharmacy's signed consent, MedImpact will contact the pharmacy's wholesalers directly for a complete listing of purchases and returns

OVERBILLED QUANTITY AND INCORRECT DAY SUPPLY

- This may result in Refill Too Soon discrepancies when the Member should not have received the next fill because a claim was submitted with an incorrect day supply or quantity
- If the quantity billed exceeds the Member's benefit day supply maximum, the claim will be adjusted and the submitted quantity will be reduced to be commensurate with the allowable day supply

PATIENT RESIDENCE CODE

- The submitted Patient Residence Code must accurately reflect the Member's residence at the time the drug was dispensed

PRESCRIBER IDENTIFICATION

- The NPI number of the Prescriber who signed/authorized the prescription must be submitted on the claim
- Pharmacies may resubmit claims with "Incorrect prescriber ID submitted" discrepancies using the **correct Prescriber ID**. In the event a claim denies for "Claim Too Old", please contact us via email (deskaudits@medimpact.com) or fax (858-790-6051) to request assistance. Please include in the subject line "Prescriber ID Reprocessing Assistance".

PRESCRIPTION ORIGIN CODE

- The Origin Code that corresponds to how the pharmacy **initially** received the prescription must be accurately submitted
- Subsequent clarification of prescription elements with the Prescriber **does not** change the Origin Code

PROFESSIONAL SERVICE CODES/DUR CODES

- Pharmacies must document interactions with Prescribers/Members when that is the basis for submission of Professional Service Codes to override claim rejections
- Such documentation must be maintained, either on the prescription or in the pharmacy's software system, and must be provided for audits or upon request

PROOF OF MEMBER'S CONSENT TO PROCESS A FILL OR REFILL OF A PRESCRIPTION

- Pharmacies that deliver prescriptions via courier, or are in receipt of a transferred prescription, must obtain the Member's consent to have prescription claims billed to their insurance **PRIOR** to submitting the claim(s). This prior consent must be documented by the pharmacy and provided for audits upon request.
    - The Pharmacy's receipt of a prescription alone is not sufficient proof of member consent
- "Test Claims" require a valid prescription, as well as the Member's consent, **prior** to claim submission
- Use of solicitation or telemarketing to obtain patients and/or prescriptions is prohibited
- Member attestations submitted to appeal Missing/invalid proof of member's consent to fill/refill RX discrepancies **must** be written by, dated, and signed by the Member, specify the details of the fill, and indicate that the Member authorized the fill prior to claim submission

PROOF OF MEMBER'S COST SHARE PAYMENT

- In general, documentation must **prove** that the pharmacy collected the copayment from the Member and that the amount charged was correct, according to the claim
- The pharmacy label showing the copay amount is NOT acceptable as proof that the Member paid their copay
- Unless allowed by law, waiving of copayments is prohibited
- If a copay assistance program or a prescription discount card was billed as secondary coverage, a copy of the adjudication must be submitted during an audit to verify cost share payment
- Member attestations submitted to appeal Missing Proof of Cost Share Payment discrepancies **must** be written by, dated, and signed by the Member, specify the details of the fill, payment amount, date of payment, and method of payment used

SIGNATURE LOGS/PROOF OF DELIVERY

- The person picking up or receiving a prescription fill on behalf of a Member **must sign his/her own name** in the signature/delivery log, along with their relationship to the Member
- **Delivery driver or courier signature is NOT acceptable as proof of delivery**
- Date of pick-up or delivery must be documented
- Commercial Carrier shipping receipts or tracking numbers must show proof of delivery
    - If online proof of delivery is not available for a tracking number, the pharmacy must provide written documentation from the Carrier, or a Member attestation, to prove delivery
- Member attestations submitted to appeal Missing Signature Log/Proof of Delivery discrepancies **must** be written by, dated, and signed by the Member, and specify the details of the fill, including the date received

UNDOCUMENTED SUBSTITUTION

- Drugs that are NOT AB-rated (not therapeutically equivalent for substitution) require verification with the Prescriber's office and must be documented on the prescription in order to dispense the substituted drug