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PRIME THERAPEUTICS®

Prime Audit Advisor — Considerations for Appropriate Dispensing Procedures

When dispensing medications, pharmacies should be diligent in determining that claims are submitted for a valid use of a medication. Prime advises network pharmacies to be aware of prescription orders that are prescribed and dispensed for dosage strengths and routes of administration that are not consistent with manufacturer prescribing information.

For example, a recent prescribing trend has included large amounts of antibiotics and antifungal products that are diluted in concentration when mixed with water and utilized in a footbath. This scenario changes the intended strength of these medications to unstudied/unsupported concentration levels.

When reviewing claims, auditors may request documentation to support appropriate dispensing of medications based on standard industry practice.

Documentation of scientific evidence that meets the expectation will demonstrate efficacy and safety for the requested use. The documented evidence must show:

- Consistent and adequate number of well-designed studies with sufficient numbers of patients in relation to the incidence of the disease.
- Publication in major peer-reviewed journals that only publish original manuscripts after the manuscripts have been critically reviewed by unbiased independent experts for scientific accuracy, validity, and reliability.
- Consistent results across all studies for that specific disease and treatment.
- Positive health outcomes including demonstration that the drug is as effective as or more effective than FDA-approved alternatives.

The following types of documentation do not meet the expectation of standard industry practice:

- Clinical studies administered without direct correlation to intended use, strength, dosage form, and/or route of administration.
- Manufacturer sponsored studies with results that have not been approved by the FDA.
- Off-label use does not have a level of evidence for the indication that is Class I or Class IIa in Truven Health Analytics Micromedex DRUGDEX®.
- Patient case reports.

In addition, Medicare Part D requirements must be followed when submitting claims for members enrolled in this federal program. More information regarding acceptable off label drug use can be found at https://www.medicareadvocacy.org/cma-report-medicare-coverage-for-off-label-drug-use/.

This information is intended to educate Participating Pharmacies on Prime's billing requirements.

For additional information please visit Prime's website PrimeTherapeutics.com and navigate to:
Resources > Pharmacy + provider > Pharmacy providers > Provider manual

Thank you,

Your Pharmacy Audit & FWA team

If you have any questions, please contact the Pharmacy Audit department at pharmacyaudit@primetherapeutics.com.