

Fraud, Waste and Abuse Alert - Questionable use of Footbaths

What?

The Centers for Medicare & Medicaid Services (CMS) has identified questionable use of drugs, primarily antibiotics and antifungals, which are being used in a foot bath. Beneficiaries are being instructed to mix these drugs with water and then soak their feet. This footbath claims to treat or prevent diseases such as diabetic ulcers, bone infections, ingrown toenails, pitted keratolysis and cellulitis.

Millions of dollars have been paid for potentially fraudulent combinations of drugs. The following drugs are known to be involved in this footbath scheme:

Corticosteroids	Antifungals	Antibiotics
Budesonide	Ciclopirox Olamine	Ciprofloxacin HCl
Clobetasol Propionate	Clotrimazole	Clindamycin HCl
Fluocinonide	Econazole Nitrate	Clindamycin Phosphate (Topical)
	Itraconazole	Daptomycin
	Ketoconazole	Doxycycline Hyclate
	Ketoconazole (Topical)	Erythromycin (Acne Aid)
	Nystatin (topical) Oxiconazole Nitrate	Gentamicin Sulfate (Ophth)
	Terbinafine HCl	Gentamicin Sulfate (Topical)
	Voriconazole	Linezolid
		Meropenem
		Mupirocin
		Streptomycin Sulfate
		Sulfacetamide Sodium
		Tetracycline HCl
		Tobramycin
		Tobramycin Sulfate
		Vancomycin HCl

Why?

Prescribing and dispensing of these drugs is often occurring without true medical relationships. The alleged indications for the use of these combinations in this manner are not medically accepted indications (MAIs). These drugs may have limited ability to work topically in a footbath as prescribed and dispensed. In addition, they may be harmful to patients if used as dispensed and may contribute to drug resistance.

Reasons Not to Use

No clinical benefit	These drugs may have limited ability to work topically in a footbath as prescribed and dispensed.
Not approved/recommended	Foot baths are not the standard of care when treating foot infections such as cellulitis or diabetic ulcers.
Increased risk of harm	Harm can occur if patients are confused regarding the atypical directions for drug products which conflicts with typical drug information and patient education provided at the pharmacy.
Increased healthcare system costs	Millions of dollars have been paid for potentially fraudulent combinations of these drugs.

References

1. Department of Health & Human Services: Centers for Medicare & Medicaid Services
2. Blue Peak Advisors. (2019, August 2). CMS Fraud Conference—Working Together to Combat Fraud. Retrieved March 11, 2020, from <https://bluepeakadvisors.com/cms-fraud-conference-working-together-to-combat-fraud/>