



DATE: September 13, 2023
TO: Commonwealth of Kentucky Medicaid Pharmacy Network
FROM: MedImpact Healthcare Systems
Subject: Topical Foot Treatment Claims

Status: The Centers for Medicare & Medicaid Services (CMS), in collaboration with the Investigations Medicare Drug Integrity Contractor (I-MEDIC) continues to warn against the use of oral capsules, typically antibiotics and antifungal medications, used in a regimen for topical foot treatments. The use of these drug combinations in topical foot treatments is a recognized fraud scheme similar to the telemarketing scheme associated with topical compounded pain creams.

According to CMS, these medications may be harmful to patients if used as dispensed. The purported indications for use of these drug combinations, used topically, may not be medically accepted indications and are, at best, investigative and experimental treatments.¹

Topical soaks are not the standard of care in treatment of foot infections such as diabetic ulcers and could be harmful to the healing process. Patients may be confused about the complex directions for drug products which conflicts with typical drug information available in pharmacy systems for patient education. In addition, harm can occur from misunderstanding of these directions. For example, a patient may mistakenly ingest a capsule orally, as indicated by the pharmacy drug information printouts because this is the usual route of administration; however, this may result in the disruption of normal gastrointestinal bacteria, thereby causing symptoms such as abdominal pain, nausea, and diarrhea by overgrowth of abnormal bacteria, including those that are potentially drug resistant. Furthermore, the development of systemic antibiotic resistance in a patient through topical absorption in open wounds may result in a life-threatening infection.

As many of the oral capsules used in these topical foot treatments are not approved for topical use by either CMS-recognized compendia or generally accepted national standards, MedImpact will continue to aggressively review and audit claims being submitted for use in topical foot treatments. MedImpact will also review pharmacies for further disciplinary action if they are suspected of inappropriate billing.

Contact Information: If you have any questions, please contact MedImpact's Kentucky Team at:

Program Questions: KYMCOPBM@MedImpact.com
BIN: 023880 / PCN: KYPROD1 / GROUP: KYM01

¹ CMS Alert: Foot Baths and Soaks, issued November 20, 2019.