

05/08/2017

Compounded Products Update

Dear Pharmacist,

The Oklahoma Health Care Authority is evaluating policy for compounded prescription claims. An assessment of the peer reviewed literature regarding compounded topical medications containing multiple ingredients revealed that these products have shown limited, if any, clinical results or efficacy. OHCA has determined that there is insufficient evidence to support continued use of these products.

In general, compounded topical medications have been increasing in claims paid at OHCA. Pharmacies are engaged in the use of active pharmaceutical ingredients (APIs) as part of compounded claims. APIs are considered pharmaceutical ingredients and are not covered by CMS, therefore these are non-covered items by Medicaid (OHCA SoonerCare). According to CMS, APIs and excipients do not meet the definition of covered outpatient drugs as defined in section 1927(k)(2) of the Social Security Act (the Act).

These multiple medication combinations and active pharmaceutical ingredients (APIs) placed into single therapies are questionable from a medical rationale as well as from physical and chemical stability. There are no proven long-term randomized clinical trials that show the topical benefits or FDA approval of some of the specific ingredients utilized. There is no clinically appropriate information for topical use of many of the ingredients in the compounds used, nor any evidence that these APIs placed topically are safe or effective.

Other issues identified with the use of these compounds include the following: medical necessity, patient safety, FDA stability testing of these compounds, concentrations higher than normally found in commercially available products, duplication of medication therapy, and off-label use of medications.

In addition, all **sterile drug products**, including those from the manufacturer, must be manipulated aseptically in an ISO Class 5 environment such as a laminar flow hood or containment isolator. This would include mixing or adding diluents to a product, e.g., taking multi-dose vials of human chorionic gonadotropin and placing into smaller, patient-specific vials for SQ administration.

Other dosage forms that must be sterile include aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, irrigations for wounds and body cavities, and ophthalmic drops and ointments.

Any practice such as this is considered sterile compounding, and should abide by United States Pharmacopeia (USP) Chapter <797>.

Currently, OHCA covers several FDA approved topical formulations of single ingredient products which are available commercially. The Food and Drug Administration (FDA) allows compounding only according to a physician's prescription, and only in cases where compounding is medically necessary and the compounded formulation is not commercially available.

Thank you for the services you provide to Oklahomans insured by SoonerCare!