Clinical Policy: Pharmacy Compounds

Reference Number: OH.PHAR.PPA.03
Effective Date: 04/2016
Last Review Date: 07/2020
Line of Business: Medicaid

Revision Log

Description
This policy applies to medications which are compounded by a retail or mail order pharmacy and adjudicated by our contracted PBM. The intent of the criteria is to ensure that patients follow selection elements established by Buckeye Health Plan medical policy for pharmacy compounded topical medications.

FDA Approved Indication(s)
Multiple indications exist for compounded products.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Buckeye Health Plan to review compound topical medications for medical appropriateness. This policy will not cover oral medications or bulk powders compounded to external formulations due to an overall lack of absorption and lack of clinical evidence of efficacy. Buckeye Health Plan will not pay compounding fees on medications compounded with non-PDL products.

I. Initial Approval Criteria

A. Oral medications compounded to external dosage forms will not be covered.

B. During review, certain compounds would not be covered. Examples include but are not limited to bulk powders and compounds containing non formulary products only.

C. Compounds for any medications removed or discontinued in a certain form by the FDA for safety concerns would not be permitted for compounding back to the original form.

D. If medication(s) is/are listed on the PDL and used in the requested compound the PBM Pharmacist will review for:

1. The prescription ingredient is FDA-approved for medical use in the United States and #2 or #2 and #3. Bulk powders are not FDA approved.
2. The compounded product is not a copy of commercially available FDA-approved drug product
3. The safety and effectiveness of use for the prescribed indication is supported by adequate medical and scientific evidence in the medical literature. Dosing, indication and rationale for use are checked for appropriateness as part of the review process. Examples of appropriate medical literature include but are not limited to peer reviewed, medical and scientific literature published in or accepted for publication by medical journals that meet nationally recognized requirements, biomedical compendia, and other medical literature appearing for example in the National Institute of Health's National Library of Medicine, or other such index, etc.

E. During the review process, the burden of proof noting efficacy will fall to the requesting Provider. Provider must document a) why a commercially available product on the PDL is not appropriate AND 2) demonstrate studies of clinical effectiveness of the compound requested.

Approval duration: 12 months

II. Continued Therapy

A. Currently receiving medication via Centene benefit or member has previously met initial approval criteria.

Approval duration: 12 months

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy	03/16	04/16
Annual Review - No changes deemed necessary	04/17	04/17
Annual Review - No changes deemed necessary	04/18	04/18
Annual Review - No changes deemed necessary	07/19	07/19
Annual Review - No changes deemed necessary	07/20	07/20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to

applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.