I. Medication Description

In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Compounded drugs are not FDA-approved. This means that FDA does not verify the safety or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed.

II. Position Statement

Compounded medications billed under the medical and pharmacy benefits may be subject to coverage review based on the guidelines below. Coverage is determined through a prior authorization process with supporting clinical documentation to show evidence of safety and efficacy of the requested compounded product. The clinical rationale for reviewing available coverage of most compounded products through a prior authorization process is the lack of published efficacy and safety data. Also, compounded products are not Food and Drug Administration (FDA)-approved and they do not undergo the rigorous clinical review process that commercially marketed products undergo. In addition, for a majority of medical conditions, FDA-approved products in various strengths and dosage forms are already commercially available.

This policy requires most compounded claims to undergo a prior authorization review for coverage. Also, claims for bulk powders (whether as an ingredient in a compound or a single line claim) also require a coverage review, as the sole purpose of these products is for use in compounding. In addition, products whose main purpose is to serve as a base vehicle for compounded products will also render a claim to require a prior authorization request.

Contractual limitations and any pertinent Drug Therapy Guidelines apply in addition to the criteria outlined below.

III. Policy

Coverage of compounded claims can be provided when the following criteria are met:

- The diagnosis for which the compound is prescribed is clearly identified AND
- The requested route of administration is clearly identified AND
- The identified diagnosis is unable to be treated with any commercially-available FDA-approved product (i.e. patient cannot swallow oral solid dose forms, lower dose is required than is commercially available, allergy to a specific ingredient in the FDA-approved product, etc) AND
- Each active ingredient is FDA-approved or supported by clinical data for the treatment of the identified diagnosis via the requested route of administration AND
• Published safety and efficacy data are available (robust clinical studies, compendia references, nationally-recognized treatment guidelines) to support the use of the compound as a whole as treatment of the identified diagnosis.

IV. Quantity Limitations

Coverage is provided in accordance with published studies, treatment guidelines, or compendia references.

V. Coverage Duration

Coverage may be granted for up to six months and may be renewed.

VI. Coverage Renewal Criteria

Coverage of the approved compound can be renewed based upon the following criteria:
• Stabilization of disease or in absence of disease progression is shown AND
• Absence of unacceptable toxicity from the compound is shown

VII. Billing/Coding Information

J7999 may require preauthorization for coverage under the medical benefit

VIII. Summary of Policy Changes

• 6/15/14: new policy
• 7/1/15: formulary distinctions made
• 9/1/15: clarification that policy applies to claims billed under the medical benefit as well as under the pharmacy benefit.
• 9/15/15: no policy changes
• 1/1/16: drug code added for medical billing
• 7/19/16: no policy changes
• 7/15/17: updated policy to not only target products exceeding a cost of $250, but to also include most compounded products for a medical necessity and off-label use coverage review

IX. References


21. Voltaren Ophthalmic® 0.1% solution [prescribing information]. Fort Worth, TX: Alcon Laboratories, Inc.; October 2012.

22. Ocufen® 0.03% ophthalmic solution [prescribing information]. Irvine, CA: Allergan, Inc.; July 2012.


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary agent will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.