Ohio Administrative Code

Rule 5160-9-07 Pharmacy services: drug coverage review process.

Effective: April 1, 2017

(A) For a drug to be considered for coverage without prior authorization in accordance with rule 5160-9-03 of the Administrative Code, the following information may be requested from the manufacturer or labeler:

(1) Trade name of the drug.

(2) Generic name of the drug.

(3) National drug code number (NDC).

(4) Package sizes available.

(5) Strengths.

(6) Therapeutic use(s).

(7) List of therapeutic ingredients.

(8) Direct, average wholesale price, wholesale acquisition cost and average manufacturer price.

(9) Bioavailability and bioequivalency data.

(10) Letter(s) of approval of new drug application (NDA), or abbreviated new drug application (ANDA).

(11) Product labeling as approved by the food and drug administration.

(12) A statement of justification for coverage without prior authorization including cost effectiveness

and relative merits.

(B) Final determination by the Ohio department of medicaid (ODM) of a drug's inclusion on or removal from the list described in paragraph (C) of rule 5160-9-03 of the Administrative Code will be based on a review and analysis of the information required in paragraph (A) of this rule in addition to an analysis of such factors as:

(1) Specific attributes and/or benefits of the drug.

(2) Availability and cost effectiveness of the drug in relation to alternative products.

(3) Availability of bioequivalent generic products.

(4) Provision of a supplemental rebate payment for a drug that reduces the acquisition cost.

(C) Newly-marketed drugs

(1) New products with the same active ingredient, dosage form, and brand or generic designation as a product that is already covered by ODM will be added to coverage under the same conditions as the existing covered product.

(2) New products within a therapeutic category listed on the "ODM Preferred Drug List" (PDL) will be added to coverage with prior authorization using the same criteria outlined in the PDL document until the new product is reviewed by the ODM pharmacy and therapeutics committee.

(3) New products not within a therapeutic category listed on the ODM PDL will be added to coverage with prior authorization criteria consistent with the product labeling approved by the federal food and drug administration.