



Office of Health Services

Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201

Parris N. Glendening, Governor - Georges C. Benjamin, M.D., Secretary

MARYLAND MEDICAL ASSISTANCE PROGRAM
Managed Care Organization Transmittal No. 20

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Managed Care Organizations

FROM: Joseph M. Millstone, Executive Director

Coverage of Newly Approved FDA Drug Therapies & Vaccines

NOTE: Please ensure that appropriate staff members in your organization are informed of the contents of this memo.

Purpose

The purpose of this transmittal is to remind Managed Care Organizations (MCOs) that they are required to expand their formularies for new drugs or equivalents and vaccines (immunizations) approved by the Food and Drug Administration (FDA). Additionally, approved drugs prescribed for unapproved uses are also covered if prescribed for a medically accepted indication and supported by at least one of the official drug compendia consisting of the American Hospital Formulary Service Drug Information, DRUGDEX and the United States Pharmacopeia Drug Information.

HealthChoice Formulary Requirement

MCOs are required to expand their drug formularies to include new products approved by the Food and Drug Administration (COMAR 10.09.67.04D(3)) in addition to maintaining drug formularies that are at least equivalent to the standard benefits of the Maryland Medical Assistance Program on the implementation date of the HealthChoice Program (COMAR 10.09.67.04D(1)). This requirement pertains to new drugs or equivalent drug therapies, routine childhood immunizations, vaccines prescribed for high risk and special needs populations and vaccines prescribed to protect individuals against vaccine-preventable diseases.



Preauthorization and Denial

Coverage may be subject to preauthorization to ensure the medical necessity and appropriateness for specific therapies. For formulary drugs requiring preauthorization by the MCO or its designee, a decision must be made within 72 hours after the initial request. If the service is denied, the MCO must notify the prescriber and the enrollee in writing of the denial (COMAR 10.09.66.07B(4) and COMAR 10.09.71.02).

Non-Formulary Drugs

When a prescriber believes that a non-formulary drug is medically indicated, MCOs must have procedures in place for non-formulary requests (COMAR 10.09.67.04F(2)(a)). The Program expects a non-formulary drug to be approved if documentation is provided indicating the formulary alternative is not medically appropriate. Requests for non-formulary drugs cannot be automatically denied or delayed with repeated requests for additional information. The MCOs must follow an established reasonable review time for all non-formulary requests to comply with the minimum performance standards for drug use management programs established by the Department.

Vaccines and Vaccines For Children (VFC) Program

Many of the routine childhood immunizations are furnished under the Vaccines For Children (VFC) Program administered through the public health Center for Immunizations. The VFC Program provides free vaccines for health care providers who participate in the VFC Program. Certified Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) Program primary care providers are required to participate in the VFC Program. When new vaccines are approved by the Food and Drug Administration, the VFC Program is not obligated to make the vaccine available to VFC providers. Therefore, the recipient's MCO is responsible for including new vaccines under the new HealthChoice formulary requirement (COMAR 10.09.67.04D(3)).

Questions

Please contact the following programs or service departments if you have any questions regarding this memo.

Pharmacy Services - (410)-767-1455
EPSDT Program - (410)-767-1485
VFC Program - (410)767- 6030