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Newsletter

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TO: Providers of Pharmaceutical Services – **For Action**
Physicians, Podiatrists, Federally Qualified Health Centers,
Independent Clinics, Advanced Practice Nurses, Health
Maintenance Organizations – **For Information Only**

SUBJECT: **Removal of Active Pharmaceutical Ingredients and Excipients
as Covered Outpatient Drugs**

EFFECTIVE: Immediately

PURPOSE: To notify providers of pharmaceutical services of a decision by the New Jersey Division of Medical Assistance and Health Services to discontinue coverage of active pharmaceutical ingredients (APIs) and excipients used to compound prescriptions as covered outpatient drugs.

BACKGROUND: Section 1927 (k)(2) of the Social Security Act (SSA) provides the definition for a covered outpatient drug. Covered outpatient drugs are subject to the terms and conditions for the federal Medicaid Drug Rebate Agreement which requires drug manufacturers to provide drug rebates to state Medicaid agencies (SMAs). SMAs shall only reimburse pharmacies for covered outpatient drugs.

The Centers for Medicare and Medicaid Services (CMS) is responsible for determining which drugs are considered covered outpatient drugs. CMS provided clarification regarding the classification of APIs and excipients as covered outpatient drugs.

An API is a “bulk drug substance” which is defined by the Food and Drug Administration as any substance when used in the manufacturing, processing or packaging of a compound prescription becomes an active ingredient in that compound. APIs do not meet the definition of a covered outpatient drug as defined in Section 1927 (k)(2) of the SSA. As such APIs are not considered covered outpatient drugs and shall not be covered by State Medicaid Agencies (SMAs). In addition, excipient products, used in compounded prescriptions, are also considered non-covered outpatient drugs and shall not be covered by SMAs.

It is important to note that these limitations also apply to claims for compound prescriptions submitted to the Aids Drug Distribution Program (ADDP), Pharmaceutical Assistance to the Aged and Disabled (PAAD) and the Senior Gold Prescription Discount Programs.

ACTION: **Effective immediately**, APIs and excipients used in the manufacturing, processing or packaging of a compound prescription shall not be covered by the Medicaid/NJ FamilyCare program. A listing of NDCs for non-covered APIs and excipients may be found at www.njmmis.com under “Rate and Code Information,”

“Procedure Code Listing – Non-covered APIs/Excipients.” Note that this list may be subject to change.

Compounded prescriptions that report a non-covered API or excipient for rebate reasons shall be denied by **Error Codes 549 or 570**. Pharmacies may re-submit these claims reporting the Submission Clarification Code value ‘08’ in NCPDP Field 420-DK indicating that the pharmacy is dispensing the compound acknowledging that the compound payment will not cover the cost of the denied ingredient(s).

Frequently Asked Questions:

What compound prescriptions are covered by the State Pharmacy Benefit Programs?

Any active pharmaceutical ingredient and/or excipient used to prepare a compound will not be covered by a State pharmacy benefit program. However, coverage will continue for compounds not prepared using bulk chemicals or bulk ointment/cream bases. For example, combining a 30 gram tube of clotrimazole cream with a 30 gram tube of betamethasone would be a covered compound. However, if the pharmacy prepared a solution of omeprazole powder (from capsules) and sodium bicarbonate (bulk) powder in cherry syrup (excipient), only the NDC of the omeprazole capsules would be covered.

May the pharmacy bill a Medicaid recipient for the cost of the denied active pharmaceutical ingredient and/or excipient?

Yes, since APIs and excipients are non-covered services, the pharmacy may bill the beneficiary for the cost of the denied active pharmaceutical ingredient and/or excipient.

When all the ingredients in a compound consist of active pharmaceutical ingredients and/or excipients, may the pharmacy bill the beneficiary its usual and customary charge for the compound?

Yes, if all the ingredients/excipients in a compound are not covered, the pharmacy may bill the beneficiary its usual and customary charge for the compound.

If a pharmacy is aware of an active pharmaceutical ingredient and/or excipient that is not reported on the website, should the pharmacy bill the State for the cost of the ingredient?

Pharmacists have knowledge of which products are considered active pharmaceutical ingredients and/or excipients. If these products are not found on the website, they should not be billed to a State pharmacy benefit program.

How will a pharmacy know which ingredient in a compound has been determined to be non-covered?

When one or more of the ingredients in a billed compound is not covered, the POS response received by the pharmacy will include the “Ingredient Counter Number” derived from the sequence of ingredient information reported in the original pharmacy claim. For example, if ingredient No. 2 is denied, the response will read, “Ingredient counter #02 not covered.”

If there are any questions regarding this Newsletter, please contact Molina Medicaid Solutions (formerly Unisys) Provider Services at (800) 776-6334.

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