

## Commercial Claim Payment Bulletin - Prescription Drug Benefit

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**Title:** Non-FDA Approved Products

**Policy #:** Rx.04.2

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***Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.***

***This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

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### ▸ Intent:

The intent of this policy is to communicate the prescription drug benefit coverage based on medical necessity of drugs that are not approved by the Food and Drug Administration (FDA).

### ▸ Description:

Presently, the FDA requires prescription drugs to demonstrate safety and efficacy prior to marketing, however, this was not always mandatory. In 1906, the Pure Food and Drug Act prohibited adulterated, misbranded, poisonous or deleterious drugs from being manufactured, sold or transported. The Pure Food and Drug Act was repealed and replaced with the Federal Food, Drug, and Cosmetic Act of 1938, which required evidence of safety for new drugs. The law was amended further in 1962 to strengthen the requirements for safety and add an additional requirement for a manufacturer to demonstrate efficacy of the drug.

The Orange Book identifies FDA approved drugs that have undergone the required safety and efficacy requirements of the Federal Food, Drug, and Cosmetic Act. If a medication is not included in the orange book, it has not demonstrated safety and efficacy in accordance with the Federal Food, Drug, and Cosmetic Act requirements. Drugs that entered the market based solely on safety and drugs that were on the market prior to 1938 are not included in the Orange Book.

Some drugs, mostly older products, are available on the market despite lacking FDA approval for a variety of historical reasons. Examples include, but are not limited to, a manufacturer combining two approved products into a combination product without obtaining approval and a manufacturer marketing a currently approved product without obtaining FDA approval.

Prescription Drugs are defined by the plan as:

A Legend Drug or Controlled Substance, which:

- Has been approved by the Food and Drug Administration(FDA) for a specific use; and
- Can, under federal or state law, be dispensed only pursuant to a Prescription Order

**A non-FDA approved drug will be considered for formulary inclusion if all the following criteria are met:**

- The drug entered the market prior to 1938; and
- The drug is not commercially available in an FDA approved form of the same route of administration; and
- The drug meets the criteria outlined in the Experimental/Investigational Use Policy

The prescription drug benefit covers certain prescription drugs approved by the FDA pursuant to a prescription order. Details of covered drugs may be found in the member's benefit booklet.

▸ **Policy:**

**Coverage is subject to the terms, conditions, and limitations of the member's contract.**

Prescription drugs that are commercially available but not approved by the FDA are not considered a covered benefit.

Some prescription drugs that are not FDA approved, and not otherwise excluded, will be covered under the prescription drug benefit for certain plans as required by the Patient Protection and Affordable Care Act (PPACA) or as defined in the member's benefit booklet. These items include but may not be limited to the following products as listed:

- Prenatal vitamins, oral
- Preventative vitamins and minerals as required by the PPACA
- Cholecalciferol (vitamin D3) 50,000 units\*
- Sulfuric acid/ phenosulfonic acid solution\*

Some prescription drugs that came to market prior to 1938, prior to the current FDA approval process, and not otherwise excluded, will be covered under the prescription drug benefit if they are deemed medically accepted as defined in the experimental/ investigational policy. These items include but may not be limited to the following products as listed:

- Aluminum chloride topical
- Hydrocortisone suppositories
- Phenobarbital
- Opium tincture
- Morphine suppositories
- Sodium chloride for inhalation
- Homatropine ophthalmic

\*Exceptions will be made for these products to meet essential health benefit requirements

▸ **References:**

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US Food and Drug Administration. Laws Enforced by FDA. Available from <https://www.fda.gov/regulatoryinformation/lawsenforcedbyfda/default.htm> . Accessed December 6, 2017.

US Food and Drug Administration. Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Available from: <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Accessed December 6, 2017.

US Food and Drug Administration. Orange Book Preface. Available from: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm>. Accessed December 6, 2017

US Food and Drug Administration. Unapproved Prescription Drugs: Drugs Marketed in the United States That Do Not Have Required FDA Approval. Available from: <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/enforcementactivitiesbyfda/selectdenforcementactionsonunapproveddrugs/default.htm> . Accessed December 6, 2017.

Preventive Health Services. Available from: <https://www.healthcare.gov/coverage/preventive-care-benefits/>. Accessed December 6, 2017.

Barowsky H, Schwartz SA. Method for Evaluating Diphenoxylate Hydrochloride: Comparison of Its Antidiarrheal Effect with that of Camphorated Tincture of Opium. JAMA. 1962;180(12):1058-1060.

Beckwith MC. Diarrhea in Palliative Care Patients. Journal of Pharmaceutical Care in Pain & Symptom Control. 2010;7(4):91-108.

#### Cross References:

Cost Share Exception Policy for Preventive Medications and Women's Preventive Services under the PPACA Rx.01.178

Prescription Vitamins, Dietary Supplements, and Medical Foods Rx.04.5

Experimental/Investigational policy Rx.01.33

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<b>Policy Version Number:</b>	4.00
<b>Policy Effective Date:</b>	April 1, 2018
<b>Next Required Review Date:</b>	January 01, 2019

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