



## Management of Select Unapproved Products: A Core PBM Service

### Non-Covered and Covered Product Examples

At CVS Caremark® we are continuously evolving our approach to pharmacy benefit management to align with our clients' objectives while helping ensure quality of care and access for patients. To that end, we are pleased to announce a new core pharmacy benefit management service for commercial clients: *Management of Select Unapproved Products*.

#### Background

Under the Federal Food, Drug, and Cosmetic Act, certain drugs may be legally marketed despite lacking approval from the U.S. Food and Drug Administration (FDA) (e.g., drugs with grandfathered status). Historically, pharmacy benefit managers (PBMs) and others in the industry have been challenged with distinguishing these legally marketed drugs from other unapproved drugs. The FDA does not publicly identify legally marketed, unapproved drugs, maintaining that it is the manufacturer's responsibility to prove that a drug is legally marketed.

Lack of publicly available information has hampered PBMs' ability to effectively manage unapproved drugs. Universal exclusion of unapproved drugs is not clinically appropriate and may risk disrupting therapy for members using legally marketed drugs. Recently, the Centers for Medicare & Medicaid Services (CMS) began publishing a quarterly file of data provided by manufacturers of drugs covered by the Medicaid program. The data file includes information about unapproved drugs, including the legal authority under which the drug is marketed and the statutory basis for coverage under the Medicaid program.

Utilizing the information in the CMS data file, along with detailed clinical reviews, CVS Caremark developed coverage recommendations for unapproved drugs. These coverage recommendations will help clients appropriately manage utilization of unapproved drugs, while maintaining coverage for clinically appropriate, legally marketed<sup>1</sup> drugs.

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#### Covered Product Examples:

DRUG CLASS	DRUG EXAMPLES
THYROID	ARMOUR THYRO TAB 60 MG
PRENATAL VITAMINS	PNV PRENATAL PLUS TAB
BARBITURATE HYPNOTICS	PHENOBARBITAL TAB 32.4 MG
FLUORIDES	LUDENT CHW 0.5 MG F; FLUORIDE CHW 0.5 MG F
ANTISPASMODICS	HYOSCYAMINE SUB 0.125 MG
SALICYLATES (NSAIDs)	SALSALATE TAB 750 MG
ASTRIGENTS	HYPERCARE SOL 20%
CYCLOPLEGIC MYDRIATICS	ATROPINE SULFATE OPHTH SOLN 1%
RENAL AGENTS	Na CITRATE/K <sup>+</sup> CITRATE; K <sup>+</sup> PHOS

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<sup>1</sup>As reported by the manufacturer to CMS and utilized in making a determination of coverage under the Medicaid program.

This list is not intended to be all inclusive and is subject to change. It is a representation of the unapproved products that will be excluded or remain covered based on regulatory and clinical rules.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.

### Non-Covered Product Examples:

DRUG CLASS	DRUG EXAMPLES	ALTERNATIVES
ANORECTAL AGENTS	HC PRAMOXINE 2.5-1% CRE; HYDROCORT AC 25 MG SUP	OTC hydrocortisone, phenylephrine, pramoxine products (i.e., Preparation H, Lanacaine, etc.)
ANTISPASMODICS	DONNATAL TAB	FDA-approved Rx anticholinergic/ antispasmodic medications (i.e., Bentyl, metoclopramide)
COUGH/COLD/ALLER GY COMBINATIONS	GUAIFENESIN 100-10/5 SYP	FDA-approved Rx or OTC cough suppressants (i.e., Dimetapp products, Tessalon Perles, Tussionex, etc.)
DERMATOLOGICALS	SOD SUL/SULF 10-5% EMU	FDA-approved Rx topical antibacterials for acne/rosacea (i.e., topical clindamycin, topical EES, etc.)
ESTROGENS	METHYLTES/EE HS TAB; EST ESTROGEN TAB MTEST	FDA-approved hormone (estrogen/progestin) replacement therapy (i.e., generic estradiol, estrogen/progesterone combinations, Premarin, etc.)
GENITOURINARY AGENTS	PHENAZOPYRID 100 MG TAB	OTC phenazopyridine products
HEMATOPOIETIC AGENTS	FERREX 150 FORTE CAP; FERROUS SULF 325 MG(R) TAB	OTC iron products (i.e., OTC ferrous sulfate, ferrous fumarate, etc.)
MIGRAINE PRODUCTS	ISOMETH/APAP DICHLOR CAP	FDA-approved Rx triptans or butalbital products (i.e., Generic sumatriptan, butalbital/caffeine/APAP, etc.)
MINERALS AND ELECTROLYTES	POT CHLORIDE 20% SF LIQ; POT CL ORG 10% SF LIQ	FDA-approved Rx KCl products (i.e., Klor-Con)
MULTIVITAMINS	RENO CAP; RENAL SOFTGEL CAP	OTC multivitamins/minerals with/without folate as required (i.e., Centrum, One-A- Day, Nature's Choice, numerous generic OTC MVIs and minerals)
THYROID AGENTS	NP THYROID 30 MG TAB	FDA-approved levothyroxine products (i.e., generic levothyroxine, Synthroid, etc.)
ULCER DRUGS	CHLORD/CLIDI 5-2.5 MG CAP	FDA-approved Rx/OTC PPIs or Histamine- 2 receptor antagonists (i.e., generic omeprazole, famotidine, etc.)

The regulatory and clinical rules for recommending continued coverage (inclusion) of certain unapproved drugs were reviewed and accepted by the CVS Caremark National P&T Committee in May 2016. Additionally, there were no concerns expressed regarding the categories or specific examples of unapproved drugs recommended for exclusion.

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