

As of January 1, 2022, HealthChoice will no longer cover certain U.S. Food and Drug Administration (FDA) unapproved drugs. These drugs may be legally marketed, despite lacking approval from the FDA. Historically it has been a challenge to distinguish between legally marketed drugs and those that have grandfathered status.

In conjunction with our contracted pharmacy benefit manager (PBM) along with clinical reviews, HealthChoice has adopted the position that FDA unapproved drugs will be excluded from the HealthChoice pharmacy benefit and no longer be covered.

Those members currently on these unapproved drugs will maintain that status through calendar year 2022. Consult with your provider for alternate drug therapies. A complete list of non-covered medications can be found at the CMS website located here:

<https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-data/index.html>

Non-Covered Product Examples:

DRUG CLASS	DRUG EXAMPLES	ALTERNATIVES
ANORECTAL AGENTS	HC PRAMOXINE 2.5-1% CRE	FDA-approved Rx and/or OTC anorectal hydrocortisone, phenylephrine, pramoxine products
COUGH/COLD/ALLERGY COMBINATIONS	GUAIFENESIN AC	FDA-approved Rx codeine or hydrocodone and OTC product as required
ESTROGENS	METHYLTES/EE HS TAB	FDA-approved Rx estradiol, conjugated estrogens and estrogen/progesterone combination products for HRT
HEMATOPOIETIC AGENTS	FERREX 150 FORTE CAP	OTC iron products
HOMEOPATHIC AGENTS	T-RELIEF ARNICA TAB	FDA-approved Rx and/or OTC alternatives available
MIGRAINE PRODUCTS	ISOMETH/APAP DICHLOR CAP	FDA-approved Rx triptans or butalbital products
MULTIVITAMINS	RENAL SOFTGEL CAP	FDA-approved Rx oral folate and OTC vitamins/minerals/supplements as required

This list is not intended to be all inclusive and is subject to change. It is representative of the unapproved products that will be covered or excluded based on available information and clinical reviews. This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.

1. I am currently on one of these unapproved drugs, what should I do?

Members currently on these drugs will be “grandfathered” in. These means it does not affect you. Only members with new prescriptions for these drugs will be notified that these drugs are not covered by HealthChoice. Consult your provider for other available products that are covered by the plan.

2. Is there a list available of the non-FDA approved drugs that HealthChoice currently **covers**?

See the document “EGID Unapproved Drug List” for the current full list of non-approved products. This list can change at any time and there could be some overlap with other plan exclusions or formulary exclusions.

3. Where can I find the CMS drug data file on these non-FDA approved drugs? Do you have the name of the data file and the date of publication?

See the link Medicaid Drug Rebate Program data file that contains this information. There is a Covered Outpatient Drug (COD) status code and unapproved drugs have codes 11,12 or 13

<https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-drug-rebate-program-data/index.html>

4. Will HealthChoice be excluding all non-FDA approved drugs or will there still be some non-FDA approved drugs that HealthChoice will cover (outside of the prior use authorization or grandfather status)

No, not all non-approved drugs will be excluded, some drugs will continue to be covered some will not be covered (see EGID Unapproved Drugs List). Members may still apply for an exception or appeal.

5. Are the “certain categories and specific unapproved drugs” that HealthChoice recommends for exclusion not limited to the examples listed .

These are just some examples of the categories/drugs for exclusion, see the table “Non-covered product examples.

Non-Covered Product Examples:

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Unapproved Drug List-EGID

Product/Drug Name	Therapeutic Class
PHENAZOPYRIDINE HCL	URINARY ANALGESICS
PHENAZOPYRIDINE HYDROCHLO	URINARY ANALGESICS
HYDROCORTISONE ACETATE	RECTAL STEROIDS
ANUCORT-HC	RECTAL STEROIDS
METHYLTESTOSTERONE/ESTERI	ESTROGEN COMBINATIONS
SF 5000 PLUS	DENTAL PRODUCTS
ESTERIFIED ESTROGENS/METH	ESTROGEN COMBINATIONS
SODIUM SULFACETAMIDE/SULF	ACNE PRODUCTS
HYDROCORTISONE ACETATE/PR	RECTAL COMBINATIONS
SULFACLEANSE 8/4	ACNE PRODUCTS
PREVIDENT 5000 BOOSTER PL	DENTAL PRODUCTS
SODIUM FLUORIDE 5000 PPM	DENTAL PRODUCTS
DENTA 5000 PLUS	DENTAL PRODUCTS
PREVIDENT 5000 SENSITIVE	DENTAL PRODUCTS
SODIUM FLUORIDE	DENTAL PRODUCTS
EEMT	ESTROGEN COMBINATIONS
EEMT HS	ESTROGEN COMBINATIONS
CHLORDIAZEPOXIDE HCL/CLID	ANTISPASMODICS
HYDROQUINONE	PIGMENTING-DEPIGMENTING AGENTS
BENZEPRO FOAMING CLOTHS	ACNE PRODUCTS
LIDOCAINE	LOCAL ANESTHETICS - TOPICAL
PREVIDENT 5000 DRY MOUTH	DENTAL PRODUCTS
PREVIDENT 5000 ENAMEL PRO	DENTAL PRODUCTS
UREA	EMOLLIENT/KERATOLYTIC AGENTS
DENTAGEL	DENTAL PRODUCTS
SODIUM SULFACETAMIDE/SULFUR	ACNE PRODUCTS
SALSALATE	SALICYLATES
FERREX 150 FORTE	HEMATOPOIETIC MIXTURES
INTEGRA PLUS	HEMATOPOIETIC MIXTURES
PREVIDENT 5000 PLUS	DENTAL PRODUCTS
UREA	EMOLLIENT/KERATOLYTIC AGENTS
COVARYX	ESTROGEN COMBINATIONS
LIDOCAINE HCL/HYDROCORTIS	RECTAL COMBINATIONS
SM URINARY PAIN RELIEF	URINARY ANALGESICS
ANALPRAM HC	RECTAL COMBINATIONS
HYDROCORTISONE/IODOQUINOL	ANTIFUNGALS - TOPICAL
PHENOHYTRO	ANTISPASMODICS
SALICYLIC ACID WART REMOV	KERATOLYTIC/ANTIMITOTIC AGENTS
SELENIUM SULFIDE	ANTISEBORRHEIC PRODUCTS
SODIUM BICARBONATE	BICARBONATES
ANUSOL-HC	RECTAL STEROIDS
FERREX 150 FORTE PLUS	HEMATOPOIETIC MIXTURES
FERROCITE	IRON
HYDROCORTISONE ACETATE/PR	CORTICOSTEROIDS - TOPICAL
PLEXION CLEANSER	ACNE PRODUCTS
DAKINS SOLUTION HALF STRE	CHLORINE ANTISEPTICS
FERRALET 90	HEMATOPOIETIC MIXTURES
FERROUS SULFATE	IRON
SALICYLIC ACID	KERATOLYTIC/ANTIMITOTIC AGENTS
SALICYLIC ACID ER	KERATOLYTIC/ANTIMITOTIC AGENTS
ATROPINE SULFATE	ANTISPASMODICS
AVAR CLEANSER	ACNE PRODUCTS
COVARYX HS	ESTROGEN COMBINATIONS

DAKINS SOLUTION FULL STRE	CHLORINE ANTISEPTICS
DEBACTEROL	ANTISEPTICS - MOUTH/THROAT
DONNATAL	ANTISPASMODICS
FERREX 28	HEMATOPOIETIC MIXTURES
HEMATOGEN FORTE	HEMATOPOIETIC MIXTURES
HEMMOREX-HC	RECTAL STEROIDS
INTEGRA F	HEMATOPOIETIC MIXTURES
PRAMOSONE	CORTICOSTEROIDS - TOPICAL
PREVIDENT 5000 ORTHO DEFE	DENTAL PRODUCTS
SALICYLIC ACID	KERATOLYTIC/ANTIMITOTIC AGENTS
SSS 10-5	ACNE PRODUCTS
URINARY PAIN RELIEF	URINARY ANALGESICS
AVAR-E GREEN	ACNE PRODUCTS
BP 10-1	ACNE PRODUCTS
BP CLEANSING WASH	ACNE PRODUCTS
CLINPRO 5000	DENTAL PRODUCTS
CLORPACTIN WCS-90	CHLORINE ANTISEPTICS
DAKINS SOLUTION QUARTER S	CHLORINE ANTISEPTICS
HEMATOGEN FA	HEMATOPOIETIC MIXTURES
MAGNESIUM CHLORIDE	MAGNESIUM
MULTITRACE-5 CONCENTRATE	TRACE MINERALS
NITRO-TIME	NITRATES
PHENOBARBITAL/BELLADONNA	ANTISPASMODICS
PODOCON 25 IN BENZOIN TIN	KERATOLYTIC/ANTIMITOTIC AGENTS
PREVIDENT FLUORIDE	DENTAL PRODUCTS
PREVIDENT RINSE	DENTAL PRODUCTS
PYRIDIUM	URINARY ANALGESICS
SALICYLIC ACID	KERATOLYTIC/ANTIMITOTIC AGENTS
SE-TAN PLUS	HEMATOPOIETIC MIXTURES
SELRX	ANTISEBORRHEIC PRODUCTS
SODIUM SULFACETAMIDE	ANTISEBORRHEIC PRODUCTS
STERILE WATER FOR INJECTI	LIQUID VEHICLES
TANDEM	HEMATOPOIETIC MIXTURES
UREA	EMOLLIENT/KERATOLYTIC AGENTS