

Cigna Drug and Biologic Coverage Policy



**Subject Step Therapy – Legacy
Prescription Drug Lists
(Employer Group Plans)**

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Table of Contents

Coverage Policy.....1
General Background.....11
Coding/Billing Information.....12
References.....12

Related Coverage Resources

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations

Coverage Policy

Employer Group Plans have a Prescription Drug List that subjects certain brand name drugs to step therapy requiring medical necessity review.

Cigna approves coverage for these brand name drugs as medically necessary when there is a documented failure, inadequate response, contraindication per FDA label, or intolerance to the number of Step 1 and/or Step 2 drugs, or as otherwise specified in the table below.

Step Therapy (ST) definitions:

- **Step 1 Medications** – These medications do not require Step Therapy, are automatically covered, and do not require prior authorization.
- **Step 2 Medications** – Usually brand name medications. These medications do not require Step Therapy, are automatically covered, and do not require prior authorization.
- **Step 3 Medications** – Usually brand name medications. These medications require Step Therapy. If the physician determines the treatment plan should begin with a Step 3 medication, a request for authorization will need to be submitted and approved.

(Note: Not all plans will use all Step Therapy classes in the table below. Where noted, certain benefit plans may require different numbers of alternatives as prerequisite therapy.)

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

**Cigna Employer Group Plans:
Legacy Prescription Drug Lists**

Acne, Oral Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
Claravis™ Myorisan™ Zenatane™		Absorica®
5-Aminosalicylates (5-ASAs) Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
balsalazide Pentasa® mesalamine		Asacol® HD Apriso® Colazal® Delzicol® Dipentum® Giazol® Lialda®
Angiotensin Converting Enzyme Inhibitors/Angiotensin Receptor Blockers (ACE/ARB) Complete Plan: Requires TWO Step 1 agents Essential Plan: Requires TWO Step 1 agents Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
benazepril benazepril/HCTZ candesartan candesartan/HCTZ captopril captopril/HCTZ enalapril enalapril/HCTZ eprosartan fosinopril fosinopril/HCTZ irbesartan irbesartan/HCTZ lisinopril lisinopril/HCTZ losartan losartan/HCTZ moexipril moexipril/HCTZ olmesartan olmesartan/HCTZ perindopril quinapril quinapril/HCTZ ramipril telmisartan		Accupril® Accuretic® Altace® Atacand® Atacand HCT® Avalide® Avapro® Benicar® Benicar HCT® Cozaar® Diovan® Diovan HCT® Edarbi™ Edarbyclor™ Hyzaar® Lotensin® Lotensin HCT® Mavik® Micardis® Micardis HCT® Prinivil®/Zestril® Vaseretic® Vasotec® Zestoretic®

telmisartan/HCTZ trandolapril valsartan valsartan/HCTZ		
Antidepressants		
<i>An exception to the criteria will be provided when an individual is not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) the Step Therapy requirements set forth below. (Note: receipt of samples does not satisfy criteria requirements for coverage)</i>		
Complete Plan: Requires THREE Step 1 agents		
Essential Plan: Requires THREE Step 1 agents		
Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
bupropion citalopram desvenlafaxine succ ER (generic Pristiq®) duloxetine escitalopram fluoxetine fluvoxamine paroxetine sertraline venlafaxine/venlafaxine ER		Aplenzin® Celexa® Cymbalta® Desvenlafaxine ER (Khedezla™) Drizalma™ Effexor XR® Fetzima™ Forfivo™XL Khedezla™ Lexapro® Paxil®/Paxil CR® Pexeva® Pristiq® Prozac® Sarafem® Trintellix® Viibryd™ Wellbutrin SR®/XL® Zoloft®
Antiemetic		
Complete Plan: Requires ONE Step 1 agent		
Essential Plan: Requires ONE Step 1 agent		
Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
ondansetron oral		Zuplenz®
Anti-Parkinsonism Drugs		
Complete Plan: Requires ONE Step 1 agent		
Essential Plan: N/A		
Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
selegiline		Xadago®
Attention Deficit Hyperactive Disorder (ADHD)		
<i>An exception to the criteria will be provided when an individual is not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) the Step Therapy requirements set forth below. (Note: receipt of samples does not satisfy criteria requirements for coverage)</i>		
Complete Plan: N/A		
Essential Plan: Requires ONE Step 1 agent and ONE Step 2 agent		
Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
amphetamine amphetamine/dextroamphetamine amphetamine/dextroamphetamine ER d-amphetamine	Vyvanse® Capsule [Covered when there is a documented diagnosis of binge-eating disorder (BED) without step therapy requirements.]	Adderall® Adderall® XR Adhansia XR™ Aptensio XR™ Concerta®

dexamethylphenidate methamphetamine methylphenidate		Desoxyn® Dexedrine® Evekeo® Focalin® Focalin® XR Jornary PM™ Mydayis® Ritalin® Ritalin LA® Zenzedi™
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Atypical Antipsychotic Agents

An exception to the criteria will be provided when an individual is not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) the Step Therapy requirements set forth below. (Note: receipt of samples does not satisfy criteria requirements for coverage)

Complete Plan: Requires ONE Step 1 agent

Essential Plan: Requires ONE Step 1 agent

Limited Plan: N/A

Step 1 Medications	Step 2 Medications	Step 3 Medications
aripiprazole clozapine clozapine ODT olanzapine/olanzapine ODT paliperidone pimozide quetiapine quetiapine ER risperidone risperidone ODT ziprasidone		Abilify® Clozaril® Fanapt® Fazaclo® Geodon® Invega® Orap® Rexulti® Risperdal®/Risperdal M® Saphris® Seroquel® Seroquel XR® Versacloz™ Vraylar™ Zyprexa®/Zyprexa Zydis®

Beta-Blockers

**An exception to the Step Therapy requirement criteria set forth below may be provided if individual has documented inability to take tablet formulations*

Complete Plan: Requires TWO Step 1 agents

Essential Plan: Requires TWO Step 1 agents

Limited Plan: N/A

Step 1 Medications	Step 2 Medications	Step 3 Medications
Acebutolol Atenolol Betaxolol Bisoprolol Carvedilol Labetalol Metoprolol Succinate ER Metoprolol Tartrate Nadolol Pindolol Propranolol Sotalol Timolol		Betapace® Betapace AF® Bystolic® Coreg Coreg CR Corgard® Dutoprol® Inderal LA® Inderal XL® InnoPran XL® *Kaspargo Sprinkle™ Lopressor Lopressor HCT® *Sotylize Tenormin® Tenoretic® Toprol XL®

		Ziac®
Bone Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
alendronate ibandronate risedronate		Actonel® Atelvia® Binosto™ Boniva® Fosamax® Fosamax Plus D®
Fibrates-Standard Dose Complete Plan: Requires THREE Step 1 agents Essential Plan: N/A Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
fenofibrate 120 mg, 150 mg, 160 mg fenofibrate nanocrystallized 145 mg fenofibrate micronized 130 mg, 134 mg, 200 mg fenofibric acid 105 mg fenofibric acid DR 135 mg		Antara® 90 mg Fenoglide® 120 mg Fibricor® 105 mg Lipofen® 150 mg Tricor® 148 mg Triglide® 160 mg Trilipix™ 135 mg
Fibrates-Low Dose Complete Plan: Requires THREE Step 1 agents Essential Plan: N/A Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
fenofibrate 40 mg, 50 mg, 54 mg fenofibrate nanocrystallized 48 mg fenofibrate micronized 43 mg, 67 mg fenofibric acid 35 mg fenofibric acid DR 45 mg		Antara® 30 mg Fenoglide® 40 mg Fibricor® 35 mg Lipofen® 50 mg Tricor® 48 mg Trilipix™ 45 mg
Hypnotics Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
eszopiclone ramelteon zaleplon zolpidem/zolpidem ER		Ambien®/Ambien CR® Belsomra® Edluar® Intermezzo® Lunesta® Rozerem® Silenor® Sonata® ZolpiMist™
Nasal Steroids Complete Plan: Requires TWO Step 1 agents Essential Plan: Requires TWO Step 1 agents Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications

budesonide flunisolide fluticasone mometasone		Beconase AQ® Dymista™ Nasonex® Omnaris® QNASL™ Zetonna™
Neuroleptics, Miscellaneous Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
Diagnosis of postherpetic neuralgia: gabapentin pregabalin (generic for Lyrica®) Diagnosis of restless leg syndrome: pramipexole ropinirole		Horizant® Lyrica® (pregabalin)
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) Complete Plan: Requires TWO Step 1 agents Essential Plan: Requires TWO Step 1 agents Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
celecoxib diclofenac diclofenac/misoprostol etodolac fenoprofen calcium flurbiprofen ibuprofen indomethacin ketoprofen meclofenamate sodium mefenamic acid meloxicam nabumetone naproxen oxaprozin piroxicam sulindac tolmetin		Anaprox® Arthrotec® Cambia® Daypro® diclofenac 1.5% topical solution diclofenac epolamine 1.3% topical patch Duexis® Feldene® Fenortho® Klofensaid II™ Mobic® Nalfon® Naprelan® Naprosyn®/EC-Naprosyn® Pennsaid® Ponstel® Qmiiz™ ODT Tivorbex™ Vimovo® Vivlodex™ Voltaren® Zipsor® Zorvolex®
Ophthalmic Prostaglandins Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
latanoprost Travatan Z®		Zioptan®

Oral Antifungal		
Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
itraconazole		Onmel®
Oral Corticosteroid		
Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
Prednisone		Rayos®
Overactive Bladder		
Complete Plan: Requires ONE Step 1 agent and ONE Step 2 agent Essential Plan: Requires ONE Step 1 agent and ONE Step 2 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
darifenacin ER flavoxate oxybutynin solifenacin succ. tolterodine tolterodine LA trospium	Toviaz®	Detrol®/Detrol LA® Ditropan XL® Enablex® Gelnique® Myrbetriq™ Oxytrol® Vesicare®
Proton Pump Inhibitors (PPI)		
Complete Plan: Requires ONE Step 1 agent and ONE Step 2 agent Essential Plan: Requires ONE Step 1 agent and ONE Step 2 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
esomeprazole esomeprazole strontium lansoprazole omeprazole omeprazole/sod bicarb 20mg, 40mg capsules pantoprazole rabeprazole	Dexilant®	Aciphex® Nexium® Prevacid® Protonix® Zegerid®
Respiratory		
Complete Plan: Requires ONE Step 2 agent Essential Plan: Requires ONE Step 2 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
Inhaled Corticosteroid (ICS)		
	Asmanex® Flovent® Pulmicort Flexhaler™ Qvar®	Aerospan® Alvesco® Arnuity™ Ellipta®
Inhaled Corticosteroid (ICS) with Long-Acting Beta Agonist (LABA)		
	Advair® HFA Breo® Ellipta® Dulera® fluticasone/salmeterol (authorized generic for Advair™ Diskus)	Advair® Diskus Airduo™ Respiclick®

	fluticasone/salmeterol (authorized generic for Airduo™ Respiclick®) Symbicort® Wixela™ Inhub™ (generic for Advair® Diskus)	
Long-Acting Beta Agonist (LABA)		
	Arcapta® Neohaler® Serevent® Diskus	Striverdi® Respimat®
Long-Acting Muscarinic Antagonist (LAMA) for Asthma		
<i>*An exception to the Step Therapy criteria set forth below may be provided if an individual is currently receiving an inhaled corticosteroid plus another controller therapy (for example, leukotriene receptor antagonist)</i>		
	Advair® HFA Asmanex Twisthaler Breo® Ellipta® Dulera® Flovent Diskus / HFA fluticasone/salmeterol (authorized generic for Advair™ Diskus) fluticasone/salmeterol (authorized generic for Airduo™ Respiclick®) Pulmicort Flexhaler Qvar Redihaler Symbicort® Wixela™ Inhub™ (generic for Advair® Diskus)	Spiriva® Respimat 1.25 mcg*
Long Acting Muscarinic Antagonist (LAMA) for COPD		
	Incruse® Ellipta®	Seebri™ Neohaler® Spiriva® Handihaler / Spiriva® Respimat 2.5 mcg Tudorza™ Pressair™
Long-Acting Muscarinic Antagonist (LAMA)/Long-Acting Beta-2 Adrenergic Agonist (LABA)		
	Anoro™ Ellipta™	Bevespi Aerosphere™ Stiolto™ Respimat® Utibron™ Neohaler®
Statins		
Complete Plan: Requires TWO Step 1 agents Essential Plan: Requires TWO Step 1 agents Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
atorvastatin ezetimibe-simvastatin fluvastatin/fluvastatin ER lovastatin pravastatin rosuvastatin simvastatin		Altoprev® Crestor® Ezallor™ Sprinkle Flolipid™ Lescol®/Lescol® XL Lipitor® Livalo® Pravachol® Vytorin® Zocor® Zypitamag™
Tetracycline and Oral Acne Class		
Complete and Essential plans: Tetracycline, Minocycline and Tetracycline, Doxycycline Requires ONE Step 1 medication		

Complete and Essential plans: Tetracycline, Acne, Oral Requires THREE Step 1 medications Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
<u>Tetracycline, Minocycline</u> minocycline minocycline ER		<u>Tetracycline, Minocycline</u> Minocin
<u>Tetracycline, Doxycycline</u> doxycycline hyclate doxycycline monohydrate		<u>Tetracycline, Doxycycline</u> Acticlate Doryx Doryx MPC Doxycycline IR 40 and 80mg Targadox Vibramycin Capsule only
<u>Tetracyclines, Acne, Oral</u> doxycycline hyclate doxycycline monohydrate minocycline minocycline ER		<u>Tetracyclines, Acne, Oral</u> Minolira ER Oracea Solodyn Ximino
Topical Antifungals, Toenail Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
itraconazole terbinafine		Jublia® Kerydin®
Topical Immunomodulator Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
imiquimod 5% cream		Imiquimod 3.75% Zyclara® 2.5%, 3.75%
Topical Inflammatory Complete Plan: Requires THREE Step 1 agents Essential Plan: Requires THREE Step 1 agents Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
Topical Inflammatory, Very High Potency		
<ul style="list-style-type: none"> betamethasone dipropionate, augmented 0.05% gel, ointment, lotion clobetasol proprionate 0.05% cream, foam, ointment, gel, lotion, shampoo, solution, spray diflorasone diacetate 0.05% ointment fluocinonide 0.1% cream halobetasol propionate 0.05% cream, foam, ointment 		Bryhali™ Clobex® Clodan® Diprolene® Impoyz™ Olux®/Olux-E® Lexette® Temovate® Ultravate® cream, ointment Ultravate X® Vanos®
Topical Inflammatory, High Potency		
<ul style="list-style-type: none"> ApexiCon E® 		Diprolene AF®

<ul style="list-style-type: none"> • amcinonide 0.1% cream, lotion, ointment • betamethasone dipropionate 0.05% ointment • betamethasone dipropionate, augmented 0.05% cream • desoximetasone 0.25% spray • desoximetasone 0.05% gel, ointment, cream • diflorasone diacetate 0.05% cream • fluocinonide 0.05% cream, gel, ointment, solution • triamcinolone acetonide 0.5% cream, ointment 		halcinonide 0.1% cream (generic Halog®) Halog® Topicort® 0.05% gel, ointment Topicort® 0.25% cream, ointment, spray
Topical Inflammatory, Medium Potency		
<ul style="list-style-type: none"> • betamethasone dipropionate 0.05% cream, lotion, spray • betamethasone valerate 0.1% cream, foam • clocortolone pivalate 0.1% cream • desoximetasone 0.05% cream • fluocinolone acetonide 0.025% cream, ointment • fluocinonide 0.05% cream (emollient base) • flurandrenolide 0.05% cream, lotion, ointment • fluticasone propionate 0.005% ointment, cream, lotion • hydrocortisone butyrate 0.1% cream, lotion, ointment, solution • hydrocortisone valerate 0.2% cream, ointment • mometasone furoate 0.1% cream, lotion, ointment • prednicarbate 0.1% cream, ointment • triamcinolone acetonide 0.025% cream, lotion, ointment • triamcinolone acetonide 0.05% ointment • triamcinolone acetonide 0.1% cream, lotion, ointment • triamcinolone acetonide 0.147% spray 		Cloderm® Cordran® Cutivate® Dermasorb™ TA Dermatop® Elocon® Kenalog® Locoid®/Locoid Lipocream® Luxiq® Sernivo™ Synalar® Topicort® 0.05% cream
Topical Inflammatory, Low Potency		
<ul style="list-style-type: none"> • alclometasone dipropionate 0.05% cream, ointment • betamethasone valerate 0.1% lotion • desonide 0.05% cream, lotion, ointment 		Ala-Scalp HP® Capex Shampoo® Derma-Smoothe/FS® Dermasorb™ HC Desonate® Desowen®

<ul style="list-style-type: none"> fluocinolone acetonide 0.01% cream, oil, solution hydrocortisone cream, lotion, ointment 		<p>MiCort™ HC Nucort® Pandel® Scalacort DK® Synalar®/Synalar TS® Texacort® Tridesilon® Verdeso®</p>
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General Background

Step Therapy is a prior authorization program that encourages the use of less costly yet effective medications before more costly medications are approved for coverage. Health care providers may be able to choose from several different safe and effective prescription medications to treat an individual's condition. Cost is often the biggest difference. Generic medication, which have the same quality, strength, purity and stability as brand name medications, typically cost less, while brand name medications are usually the most expensive.

Step Therapy medications are grouped into three "steps." Though the Step Therapy requirements vary by condition, in general, an individual is required to try at least one Step 1 medication before a Step 2 medication is eligible for coverage without prior authorization. Likewise, an individual is required to try a Step 2 medication before a Step 3 medication is eligible for coverage without prior authorization.

Drugs included in the Step Therapy program are considered therapeutic alternatives to each other for their respective step therapy group. Therapeutic alternatives (drug protocols with different chemical structures that are the same therapeutic or pharmacological class, and usually can be expected to have similar outcomes and adverse reaction profiles when administered in therapeutically equivalent doses) are determined from FDA approved product information and pharmaceutical compendia sources. Exceptions for indications or uses are noted in the respective clinical criteria above and by specific FDA-approved indication in the table below.

FDA-Approved indications exempt from Step Therapy requirements:

Drug	Exempt FDA-Approved Indication
Vyvanse	Vyvanse is indicated for the treatment of: <ul style="list-style-type: none"> Moderate to Severe Binge Eating Disorder (BED) in adults

Example: Two-Step Process:

The Two Step process is described below. Other Step Therapy types work in a similar fashion:

- Individual tries one or more Step 1 medication. There is no prior authorization required for Step 1 medications.
- If an individual tries one or more Step 1 medications without success, then one or more Step 2 medications would be eligible for coverage without the need for prior authorization.
- If an individual tries both Step 1 and Step 2 medications without success, then Step 3 medications would be eligible for coverage without the need for prior authorization.

Other Program Features:

Additional program features are a part of Step Therapy programs, including an initial "Grace Period", a "first-fill pay and educate" notification process, age exemptions, and a prior authorization option.

- Initial Grace Period – Upon introduction of the Step Therapy program, many plans will incorporate an Initial Grace Period, typically 60 days, during which time the program is not yet active at dispensing pharmacies, but introduction letters are sent to individuals alerting them of the new program.
- First Fill Pay & Educate – To help minimize disruption, the first fill of a medication subject to Step Therapy requirements will be covered without interruption, but will trigger written notification to prescribing health care professionals and individuals, advising that action needs to be taken before the next fill.
- Age Exemptions – For all Step Therapy drug classes EXCEPT Attention Deficit Hyperactivity Disorder (ADHD), individuals under 18 years of age are exempt from the program. The ADHD drug class has no age exemption.

- Prior Authorization – At any time, a health care professional can request prior authorization for coverage for a Step 2 or Step 3 medication if clinically indicated. Prior authorization is not required for Step 1 medications. Prior authorization requests should document evidence of failure, intolerance, or contraindication to a prerequisite medication.

Authorized Generics

From the US Food and Drug Administration:

An “authorized generic drug” is a listed drug as that has been approved by the FDA’s rules (under subsection 505(c)) and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, etc.), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.

A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, doesn't allow anyone else to make and sell the drug. When the patent expires, other drug companies can start selling a generic version of the drug. But, first, they must test the drug and the FDA must approve it.

The FDA’s generic drug approval process does not require the drug sponsor to repeat costly animal and clinical research on ingredients or dosage forms already approved for safety and effectiveness. Generic drugs must establish the following for approval:

- contain the same active ingredients as the innovator drug (inactive ingredients may vary)
- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA’s good manufacturing practice regulations required for innovator products

Coding/Billing Information

Note: Step Therapy is typically covered under pharmacy benefit plans. Medical drug coding and diagnosis codes are generally not required for pharmacy claims submissions; therefore, this section is not in use.

References

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2. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. 2017. Available from Wolters Kluwer Health, Inc. Accessed July 2017.
3. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> Accessed July 2017.
4. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: Vyvanse https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/021977s045,208510s001lbl.pdf Accessed July 2017
5. U.S. Food and Drug Administration. FDA List of Authorized Generic Drugs: How Drugs are Developed and Approved: <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/ucm126389.htm>
6. U.S. Food and Drug Administration. Generic Drugs Questions and Answers: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm>

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