

Cigna Drug and Biologic Coverage Policy



Subject Step Therapy – Value and Advantage Prescription Drug Lists (Employer Group Plans)

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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:
Value Prescription Drug Lists**

Antidepressants		
<p><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></p> <p align="center">Complete Plan: Requires THREE Step 1 agents Essential Plan: Requires THREE Step 1 agents Limited Plan: N/A</p>		
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		Celexa® desvenlafaxine ER (Khedezla™) Effexor XR® Fetzima™ Forfivo™XL Khedezla™ Paxil®/Paxil CR® Prozac® Sarafem® Trintellix® Viibryd™ Wellbutrin SR® Zoloft®
Anti-Parkinsonism Drugs		
<p align="center">Complete Plan: Requires ONE Step 1 agent Essential Plan: N/A Limited Plan: N/A</p>		
Step 1 Medications	Step 2 Medications	Step 3 Medications
selegiline		Xadago®
Attention Deficit Hyperactive Disorder (ADHD)		
<p><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></p> <p align="center">Complete Plan: N/A Essential Plan: Requires ONE Step 1 agent AND ONE Step 2 agent Limited Plan: N/A</p>		
Step 1 Medications	Step 2 Medications	Step 3 Medications
amphetamine amphetamine/dextroamphetamine amphetamine-dextroamphetamine ER d-amphetamine dexmethylphenidate methamphetamine methylphenidate		Adderall® Evekeo® Focalin® Ritalin® Zenzedi™
Atypical Antipsychotic Agents		
<p><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></p> <p align="center">Complete Plan: Requires ONE Step 1 agent Essential Plan: Requires ONE Step 1 agent Limited Plan: N/A</p>		
Step 1 Medications	Step 2 Medications	Step 3 Medications
aripiprazole		Clozaril®

clozapine/clozapine ODT olanzapine/olanzapine ODT paliperidone pimozide quetiapine quetiapine ER risperidone risperidone ODT ziprasidone		Fanapt® Invega® Orap® Rexulti® Risperdal®/Risperdal M® Saphris® Seroquel® Seroquel XR® Vraylar™
Beta-Blockers <i>*An exception to the Step Therapy requirement criteria set forth below may be provided if individual has documented inability to take tablet formulations</i> 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 AF Coreg Coreg CR Corgard Dutoprol® Kaspargo Sprinkle* Inderal LA Inderal XL InnoPran XL 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		Fibracor® 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		Fibracor® 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		Belsomra® Lunesta® Rozerem® Silenor® Sonata® ZolpiMist™
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® Celebrex® Daypro® diclofenac epolamine 1.3% topical patch Feldene® Fenortho® Flector® Mobic® Nalfon® Naprosyn®/EC-Naprosyn® Ponstel® Qmiz™ ODT Voltaren®
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®
Overactive Bladder 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
darifenacin ER flavoxate oxybutynin solifenacin succ. tolterodine tolterodine LA trospium		Oxytrol®
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 propionate 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™ Clodan® Diprolene® Impoyz™ Olux®/Olux-E® Temovate® Ultravate® cream, ointment
Topical Inflammatory, High Potency		
<ul style="list-style-type: none"> ApexiCon E® 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 		Diprolene AF® 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) 		Cloderm® Cordran® Dermasorb™ TA Dermatop® Elocon® Luxiq® Synalar® Topicort® 0.05% cream

<ul style="list-style-type: none"> • 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 		
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 • fluocinolone acetonide 0.01% cream, oil, solution • hydrocortisone cream, lotion, ointment 		<p style="text-align: center;"> Ala-Scalp HP® Capex Shampoo® Derma-Smoothe/FS® Dermasorb™ HC Desonate® Desowen® MiCort™ HC Nucort® Pandel® Scalacort DK® Synalar®/ Synalar TS® Texacort® Tridesilon® </p>

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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