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Coverage Policy Number 1803

Step Therapy – Legacy 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.

Overview

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

Coverage Policy

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
<ul style="list-style-type: none"> • Claravis • Isotretinoin (generic for Absorica) • Myorisan • Zenatane 		<ul style="list-style-type: none"> • Absorica LD
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
<ul style="list-style-type: none"> • balsalazide • mesalamine (oral) 		<ul style="list-style-type: none"> • Apriso • Asacol HD 800MG • Colazal • Delzicol • Dipentum • Lialda • Pentasa
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
<ul style="list-style-type: none"> • benazepril (generic lotensin) • benazepril/HCTZ (generic Lotensin HCT) • candesartan (generic Atacand) • candesartan/HCTZ (generic Atacand HCT) • captopril (generic Capoten) • captopril/HCTZ (generic Capozide) • enalapril (generic Vasotec) • enalapril/HCTZ (generic Vaseretic) • eprosartan (generic Teveten) 		<ul style="list-style-type: none"> • Accupril • Accuretic • Altace • Avalide • Avapro • Benicar • Benicar HCT • Cozaar • Diovan • Diovan HCT • Hyzaar

<ul style="list-style-type: none"> • fosinopril (generic Monopril) • fosinopril/HCTZ (generic Monopril HCT) • irbesartan (generic Avapro) • irbesartan/HCTZ (generic Avalide) • lisinopril (generic Prinivil/Zestril) • lisinopril/HCTZ (generic Zesteretic) • losartan (generic Cozaar) • losartan/hctz (generic Hyzaar) • moexipril • moexipril/HCTZ • olmesartan (generic Benicar) • olmesartan/HCTZ (generic Benicar HCT) • perindopril • quinapril (generic Accupril) • quinapril/hctz (generic Accuretic) • ramipril (generic Altace) • telmisartan (generic Micardis) • telmisartan/hctz (generic Micardis HCT) • trandolapril (generic Mavik) • valsartan (generic Diovan) tablets • valsartan/hctz (generic Diovan HCT) 		<ul style="list-style-type: none"> • Lotensin • Lotensin HCT • Micardis • Micardis HCT • Prinivil • valsartan oral solution • Vaseretic • Zestoretic • Zestril
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Antidepressants

Complete Plan: Requires THREE Step 1 agents unless specified below

Essential Plan: Requires THREE Step 1 agents unless specified below

Limited Plan: N/A

Step 1 Medications	Step 2 Medications	Step 3 Medications
<ul style="list-style-type: none"> • bupropion (Wellbutrin/Wellbutrin SR/Wellbutrin XL) • citalopram (generic Celexa) • desvenlafaxine succ ER (generic Pristiq) • duloxetine (generic Cymbalta and Irenka) • escitalopram (generic Lexapro) • fluoxetine (generic Prozac/Prozac Weekly/Sarafem) • fluvoxamine • paroxetine (generic Paxil/Paxil CR) • sertraline (generic Zoloft) • vilazodone (generic Viibryd) 		<ul style="list-style-type: none"> • Drizalma Sprinkle • Fetzima • Prozac Weekly • Sarafem • Trintellix (Requires ONE Step 1 agent) – Effective until 3/31/2024

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.

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
<ul style="list-style-type: none"> • selegiline 		<ul style="list-style-type: none"> • Xadago

Attention Deficit Hyperactive Disorder (ADHD)

Complete Plan: N/A

Essential Plan: Requires ONE Step 1 agent and ONE Step 2 agent unless specified below

Limited Plan: N/A

Step 1 Medications	Step 2 Medications	Step 3 Medications
<ul style="list-style-type: none"> • amphetamine sulfate (generic Evekeo) • amphetamine/dextroamphetamine (generic Adderall) • amphetamine/dextroamphetamine ER (generic Adderall XR) • d-amphetamine (generic Dexedrine/Dexrostat) • dexmethylphenidate (generic Focalin) • dexmethylphenidate er (generic Focalin XR) • dextroamphetamine (generic for Zenzedi) • methamphetamine (generic Desoxyn) • methylphenidate (generic Ritalin) • methylphenidate CD/ER/LA/SA (generic Ritalin LA/Concerta) 	<ul style="list-style-type: none"> • Vyvanse Capsules [Covered when there is a documented diagnosis of binge-eating disorder (BED) without step therapy requirements.] • Mydayis 	<ul style="list-style-type: none"> • Adderall • Adderall XR • Adhansia XR • Aptensio XR • Azstarys (Requires ONE Step 1 Medication) • Concerta • Evekeo • Focalin • Focalin XR • Jornay PM • Ritalin • Ritalin LA • Zenzedi

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.

Atypical Antipsychotic Agents

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
<ul style="list-style-type: none"> • aripiprazole (generic Abilify) • clozapine (generic Clozaril) • clozapine ODT (generic Fazaclo) • lurasidone (generic Latuda) • olanzapine/olanzapine ODT (generic Zyprexa/Zyprexa Zydis) • paliperidone (generic Invega) • pimozide • quetiapine (generic Seroquel) • quetiapine ER (generic Seroquel XR) • risperidone (generic Risperdal/Risperdal M) • risperidone ODT • ziprasidone (generic Geodon) 		<ul style="list-style-type: none"> • Abilify • Caplyta • Fanapt • Invega • Lybalvi • Rexulti • Risperdal/Risperdal M – Effective until 6/30/2024 • Saphris • Secuado Patch • Seroquel • Seroquel XR • Vraylar

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.

Diabetes Care

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
<ul style="list-style-type: none"> • metformin (greater than or equal to 1,500 mg per day) 		<ul style="list-style-type: none"> • Farxiga • Glyxambi • Janumet

		<ul style="list-style-type: none"> • Janumet XR • Januvia • Jardiance • Qtern • Steglujan • Synjardy • Synjardy XR • Trijardy XR • Xigduo XR
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Note: The metformin step requirement criteria applies to new starts only.

An exception to Step Therapy criteria will be provided when BOTH of the following are met:

- Documented ONE of the following
 - Unable to achieve goal HbA1C despite of metformin or metformin-containing regimen (meglitides, sulfonylureas, or thiazolidinediones) at greater than or equal to 1,500 mg per day
 - Intolerance to metformin 1,500 mg per day despite appropriate dose titration duration (for example, period of 8-12 weeks)
 - Contraindication to metformin (for example, acute/chronic metabolic acidosis, severe renal dysfunction)
 - Individual is using agent for a non-diabetic FDA-approved indication
 - For Farxiga or Jardiance, the individual has heart failure with reduced ejection fraction
 - For Jardiance, the individual has heart failure with preserved ejection fraction
 - For Farxiga, the individual has chronic kidney disease
 - For Farxiga or Jardiance, the individual has atherosclerotic cardiovascular disease or, according to the prescriber, the patient has at least two risk factors for cardiovascular disease
 - Initial dual metformin combination therapy is clinically appropriate for elevated HbA1C (for example; greater than 1.5% above goal)
 - Initial dual metformin combination therapy is clinically appropriate in an individual with co-morbid conditions (such as ASCVD, heart failure, or CKD)
- Individual will continue maximally tolerated metformin therapy unless contraindicated, intolerant, or otherwise not a candidate

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
<ul style="list-style-type: none"> • fenofibrate: 120mg, 150mg, 160mg • fenofibrate micronized: 130mg, 134mg, 200mg • fenofibrate nanocrystallized: 145mg • fenofibric acid 105mg • fenofibric acid DR 135mg 		<ul style="list-style-type: none"> • Fibracor 105 Mg Tablet • Lipofen 150 Mg Capsule • Tricor 145 Mg Tablet • Trilipix DR 135 Mg Capsule • Triglide

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
<ul style="list-style-type: none"> • fenofibrate : 40mg, 50mg, 54mg • fenofibrate micronized: 43mg, 67mg • fenofibrate nanocrystallized: 48mg • fenofibric acid 35mg • fenofibric acid DR 45mg 		<ul style="list-style-type: none"> • Fibracor 35 Mg Tablet • Lipofen 50 Mg Capsule • Tricor 48 Mg Tablet • Trilipix DR 45 Mg Capsule

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
<ul style="list-style-type: none"> doxepin (generic Silenor) eszopiclone (generic Lunesta) ramelteon (generic Rozerem) zaleplon (generic Sonata) zolpidem (generic Ambien and Intermezzo) zolpidem er (generic Ambien CR) 		<ul style="list-style-type: none"> Dayvigo Sonata
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
<ul style="list-style-type: none"> azelastine/fluticasone 137-50 mcg nasal spray (generic Dymista) flunisolide (generic Nasarel) fluticasone mometasone (generic Nasonex) 		<ul style="list-style-type: none"> Beconase AQ Dymista Nasonex Omnaris QNASL Xhance Zetonna
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
<ul style="list-style-type: none"> celecoxib (generic Celebrex) diclofenac (generic Voltaren/Voltaren-XR) diclofenac/misoprostol (generic Arthrotec) etodolac (generic Lodine/Lodine XL) fenoprofen calcium 600mg flurbiprofen (generic Ansaid) ibuprofen (generic Motrin) indomethacin (generic Indocin/Indocin SR) ketoprofen (generic Oruvail) 50mg, 75mg meclofenamate sodium mefenamic acid meloxicam (generic Mobic) nabumetone naproxen tablets (generic Naprosyn/EC-Naprosyn/Anaprox) oxaprozin (generic Daypro) piroxicam (generic Feldene) sulindac (generic Clinoril) tolmetin (generic Tolectin/Tolectin DS) 		<ul style="list-style-type: none"> Anaprox DS Arthrotec 50 Arthrotec 75 Celebrex Daypro EC-Naprosyn Feldene Lodine Mobic Nalfon 600mg Naprosyn tablets Qmiiiz ODT Voltaren Voltaren XR

Non-Steroidal Topical 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
<ul style="list-style-type: none"> pimecrolimus cream (generic for Elidel cream) tacrolimus ointment (generic for Protopic) prescription topical corticosteroid 		<ul style="list-style-type: none"> Eucrisa
An exception to Step Therapy criteria will be provided when the following is met: <ul style="list-style-type: none"> Individual is less than 2 years of age 		
Osteoporosis 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
<ul style="list-style-type: none"> alendronate (generic Fosamax) ibandronate (generic Boniva) risedronate (generic Actonel and Atelvia) 		<ul style="list-style-type: none"> Actonel Atelvia Binosto Boniva Fosamax Fosamax Plus D
Overactive Bladder Complete Plan: Requires TWO Step 1 agent Essential Plan: Requires TWO Step 1 agent Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
<ul style="list-style-type: none"> darifenacin ER (generic Enablex) fesoterodine (generic Toviaz) flavoxate (generic Urispas) oxybutynin (generic Ditropan/Ditropan XL) solifenacin (generic Vesicare) tolterodine (generic Detrol) tolterodine LA (generic Detrol LA) trospium 		<ul style="list-style-type: none"> Detrol Detrol LA Ditropan XL Enablex Gelnique Gemtesa Myrbetriq tablet and oral suspension Oxytrol Vesicare, Vesicare LS
Proton Pump Inhibitors (PPI) 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
<ul style="list-style-type: none"> dexlansoprazole (generic for Dexilant) esomeprazole (generic Nexium) esomeprazole strontium lansoprazole (generic Prevacid) omeprazole (generic Prilosec) pantoprazole (generic Protonix) rabeprazole (generic Aciphex) 		<ul style="list-style-type: none"> Aciphex Prevacid caps Protonix
Respiratory		
Step 1 Medications	Step 2 Medications	Step 3 Medications

Inhaled Corticosteroid (ICS) Complete Plan: Requires ONE Step 2 agent Essential Plan: Requires ONE Step 2 agent Limited Plan: N/A		
	<ul style="list-style-type: none"> • Alvesco • Asmanex • QVAR 	<ul style="list-style-type: none"> • ArmonAir DigiHaler • Arnuity Ellipta
Inhaled Corticosteroid (ICS) with Long-Acting Beta Agonist (LABA) Complete Plan: Requires ONE Step 1 or ONE Step 2 agent unless specified below Essential Plan: Requires ONE Step 1 or ONE Step 2 agent unless specified below Limited Plan: N/A		
<ul style="list-style-type: none"> • budesonide-formoterol (generic Symbicort) • Wixela Inhub/fluticasone-salmeterol (Generic Advair Diskus) 	<ul style="list-style-type: none"> • Advair HFA • Breo Ellipta • Dulera 	<ul style="list-style-type: none"> • Advair Diskus • AirDuo RespiClick • AirDuo DigiHaler (requires ONLY Wixela Inhub/fluticasone-salmeterol (Generic Advair Diskus) • Symbicort
Long-Acting Beta Agonist (LABA) Complete Plan: Requires ONE Step 2 agent Essential Plan: Requires ONE Step 2 agent Limited Plan: N/A		
	<ul style="list-style-type: none"> • Striverdi Respimat 	<ul style="list-style-type: none"> • Serevent Diskus
Long Acting Muscarinic Antagonist (LAMA) Complete Plan: Requires ONE Step 2 agent Essential Plan: Requires ONE Step 2 agent Limited Plan: N/A		
	<ul style="list-style-type: none"> • Incruse Ellipta • Spiriva • Spiriva Respimat 	<ul style="list-style-type: none"> • Seebri Neohaler • Tudorza Pressair
Statins Complete Plan: Requires TWO Step 1 agents unless specified below Essential Plan: Requires TWO Step 1 agents unless specified below Limited Plan: N/A		
Step 1 Medications	Step 2 Medications	Step 3 Medications
<ul style="list-style-type: none"> • atorvastatin (generic Lipitor) • ezetimibe-simvastatin (generic Vytorin) • fluvastatin/ fluvastatin ER (generic Lescol/Lescol XL) • lovastatin • pitavastatin (generic for Livalo) • pravastatin (generic Pravachol) • rosuvastatin calcium (generic Crestor) • simvastatin (generic Zocor) 		<ul style="list-style-type: none"> • Altoprev • Atorvaliq* • Ezallor Sprinkle* • FloLipid* • Vytorin • Zypitamag
<p>*An exception to the Step Therapy requirement criteria may be provided if individual has documented inability to take tablet and capsule formulations</p>		
Tetracycline and Oral Acne Class Complete and Essential plans: 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
<p align="center"><u>Tetracycline, Doxycycline</u></p> <ul style="list-style-type: none"> doxycycline 		<p align="center"><u>Tetracycline, Doxycycline</u></p> <ul style="list-style-type: none"> Acticlate
<p align="center"><u>Tetracyclines, Acne, Oral</u></p> <ul style="list-style-type: none"> doxycycline minocycline minocycline ER tablets 		<p align="center"><u>Tetracyclines, Acne, Oral</u></p> <ul style="list-style-type: none"> Minolira ER Ximino Minocycline ER 105 mg, 135 mg tablets (generic for Minolira ER)

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 fluocinonide 0.1% cream halobetasol propionate 0.05% cream, ointment 		<ul style="list-style-type: none"> Bryhali 0.01% Lotion Clodan 0.05% Kit Diprolene 0.05% Ointment Temovate 0.05% Cream, Ointment Ultravate 0.05% Cream, Ointment
Topical Inflammatory, High Potency		
<ul style="list-style-type: none"> amcinonide 0.1% cream, lotion, ointment betamethasone dipropionate 0.05% ointment betamethasone dipropionate, augmented 0.05% cream desoximetasone 0.05% gel, ointment desoximetasone 0.25% cream, ointment, spray fluocinonide 0.05% cream, gel, ointment, solution triamcinolone acetonide 0.5% cream, ointment 		<ul style="list-style-type: none"> Halog 0.1% Solution 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 		<ul style="list-style-type: none"> Cloderm 0.1% Cream, Cream Pump Dermasorb TA Dermatop Elocon Luxiq 0.12% Foam Synalar 0.025% Cream, Cream Kit, Ointment, Ointment Kit

<ul style="list-style-type: none"> • fluocinonide 0.05% cream (emollient base) • 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 0.1% cream, lotion, ointment 		<ul style="list-style-type: none"> • Topicort 0.05% Cream
Topical Inflammatory, Low Potency		
<ul style="list-style-type: none"> • alclometasone dipropionate 0.05% cream and ointment • betamethasone valerate 0.1% lotion • desonide 0.05% cream, lotion, ointment, gel • fluocinolone acetonide 0.01% cream, oil, solution • hydrocortisone cream, lotion, ointment 		<ul style="list-style-type: none"> • Ala-Scalp 2% Lotion • Capex Shampoo • Derma-Smoothe-FS Body Oil, Scalp Oil • Dermasorb HC • Desonate 0.05% Gel • Nucort Lotion • Scalacort Dk 2% Kit • Synalar 0.01% Solution • Synalar Ts 0.01% Kit • Texacort 2.5% Solution

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2. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. Available from Wolters Kluwer Health, Inc.
3. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>
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
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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