

Cigna Drug and Biologic Coverage Policy



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Subject **Step Therapy**

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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

This coverage policy applies for Employer Group Benefit Plans with a step therapy program not distinguished by the formulary used.

Cigna covers drugs with Step Therapy requirements, in accordance with benefit plan specifications, as medically necessary when there has been a 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 may or may not require Step Therapy. If the physician determines the treatment plan should begin with a Step 2 medication that requires Step Therapy, a request for authorization will need to be submitted and approved.
- **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.)

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.

Angiotensin Converting Enzyme Inhibitors / Angiotensin Receptor Blockers (ACE / ARB) Requires TWO Step 1 medications		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
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®) fosinopril (generic Monopril®) fosinopril / HCTZ (generic Monopril HCT®) irbesartan (generic Avapro®) irbesartan / HCTZ (generic Avalide®) lisinopril (generic Prinivil® / Zestril®) lisinopril / HCTZ (generic Prinzide® / Zestoretic®) losartan (generic Cozaar®) losartan / HCTZ (generic Hyzaar®) moexipril (generic Univasc®) moexipril / HCTZ (generic Uniretic®) olmesartan (generic Benicar®) olmesartan / HCTZ (generic Benicar HCT®) perindopril (generic Aceon®) quinapril (generic Accupril®) quinapril / HCTZ (generic Accuretic®) ramipril (generic Altace®) telmisartan (generic Micardis®) telmisartan / HCTZ (generic Micardis HCT®) trandolapril (generic Mavik®) valsartan (generic Diovan®) valsartan / HCTZ (generic Diovan HCT®)		Accupril® Accuretic® Aceon® 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® Prinzide® / Zestoretic® Uniretic® Univasc® Vaseretic® Vasotec®
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> Requires ONE Step 1 and ONE Step 2 medication		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
Amphetamine (generic Evekeo®)	Vyvanse® Capsule	Adderall® Adderall XR® Adhansia XR™

amphetamine / dextroamphetamine (generic Adderall®) amphetamine-dextroamphetamine ER (generic Adderall XR®) d-amphetamine (generic Dexedrine® / Dextrostat) dexmethylphenidate (generic Focalin®) dexmethylphenidate ER (generic Focalin XR®) methamphetamine (generic Desoxyn®) methylphenidate (generic Ritalin®) methylphenidate CD / ER / LA /SA (generic Ritalin LA® / Metadate CD® / Metadate ER® / Concerta®)		Aptensio XR™ Concerta® Desoxyn® Dexedrine® Evekeo® Focalin® Focalin XR® Jornay 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)*

Requires ONE Step 1 medication

Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
aripiprazole (generic Abilify®) clozapine (generic Clozaril®) clozapine ODT (generic Fazaclo®) olanzapine / olanzapine ODT (generic Zyprexa® / Zyprexa Zydis®) paliperidone (generic Invega®) pimozide (generic Orap®) quetiapine (generic Seroquel®) quetiapine ER (generic Seroquel XR®) risperidone (generic Risperdal®) risperidone ODT (generic Risperdal M®) ziprasidone (generic Geodon®)		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*

Requires TWO Step 1 medications

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® *Kapsargo Sprinkle™ Lopressor Lopressor HCT® *Sotylize

		Tenormin® Tenoretic® Toprol XL® Ziac®
Bone Resorption Inhibitors Requires ONE Step 1 medication		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
alendronate (generic Fosamax®) ibandronate (generic Boniva®) risedronate (generic Actonel® and Atelvia®)		Actonel® Atelvia® Binosto™ Boniva® Fosamax® Fosamax Plus D®
Hypnotics Requires ONE Step 1 medication		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
eszopiclone (generic Lunesta®) ramelteon (generic Rozerem®) zaleplon (generic Sonata®) zolpidem (generic Ambien® and Intermezzo®) zolpidem ER (generic Ambien CR®)		Ambien® Ambien CR® Belsomra® Edluar® Intermezzo® Lunesta® Rozerem® Silenor® Sonata® ZolpiMist™
Long Acting Narcotics <i>Step Therapy may apply for certain benefit plans.</i>		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
Long Acting Narcotics – Non-Abuse Deterrent Formulation Requires ONE Step 1 and ONE Step 2 medication		
hydromorphone ER (generic Exalgo™) methadone HCL (generic Dolophine®) morphine Sulfate ER (generic Kadian® and MS Contin®) oxycodone HCL ER (generic OxyContin®) oxymorphone HCL ER (generic Opana® ER)	Embeda® Hysingla® ER Xtampza™ ER	Exalgo™ Kadian® MS Contin® Nucynta ER® Opana® ER OxyContin® Xartemis® XR Zohydro® ER
Long Acting Narcotics - Abuse Deterrent Formulation Requires ONE Step 2 medication		
	Embeda® Hysingla® ER Xtampza™ ER	Arymo ER™ Morphabond ER™ OxyContin®
Nasal Steroids Requires TWO Step 1 medications		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
budesonide (generic Rhinocort Aqua®) flunisolide (generic Nasarel®) fluticasone (generic Flonase®) mometasone (generic Nasonex®)		Beconase AQ® Dymista™ Nasonex® Omnanis® QNASL™ Veramyst® Xhance™

		Zetonna™
Non-Steroidal Anti-Inflammatory Drugs (NSAID) Requires TWO Step 1 medications		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
celecoxib (generic Celebrex®) diclofenac (generic Voltaren®/ Voltaren-XR® / Cataflam®) Diclofenac / misoprostol (generic Arthrotec®) etodolac (generic Lodine® / Lodine XL®) fenoprofen calcium (generic Nalfon®) flurbiprofen (generic Ansaid®) ibuprofen (generic Motrin®) indomethacin (generic Indocin®/ Indocin SR®) ketoprofen (generic Oruvail®) meclofenamate sodium (generic Meclomen) mefenamic acid (generic Ponstel®) meloxicam (generic Mobic®) nabumetone (generic Relafen®) naproxen (generic Naprosyn®/ EC-Naprosyn® / Anaprox®) oxaprozin (generic Daypro®) piroxicam (generic Feldene®) sulindac (generic Clinoril®) tolmetin (generic Tolectin®/ Tolectin DS®)		Anaprox® Arthrotec® Cambia® Cataflam® Celebrex® Clinoril® Daypro® diclofenac 1.5% topical solution diclofenac epolamine 1.3% topical patch Duexis® Feldene® Fenortho® Flector® Klofensaid II™ 1.5% topical solution Lodine® / Lodine XL® Mobic® Nalfon® Naprelan® Naprosyn® / EC-Naprosyn® Pennsaid® Ponstel® Qmiiiz™ ODT Tivorbex™ Vimovo® Vivlodex™ Voltaren® / Voltaren-XR® Voltaren® Gel Zipsor® Zorvolex®
Urinary Tract Antispasmodic Agents Requires ONE Step 1 and ONE Step 2 medication		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
darifenacin ER (generic Enablex®) flavoxate (generic Urispas®) oxybutynin (generic Ditropan®/ Ditropan XL®) solifenacin succ. (Vesicare®) tolterodine (generic Detrol®) tolterodine LA (generic Detrol LA®) trospium (generic Sanctura®/ Sanctura XR®)	Toviaz®	Detrol® / Detrol LA® Ditropan XL® Enablex® Gelnique® Myrbetriq™ Oxytrol® Vesicare®
Proton Pump Inhibitors (PPI) Requires ONE Step 1 and ONE Step 2 medication		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
esomeprazole (generic Nexium®) esomeprazole strontium lansoprazole (generic Prevacid®) omeprazole (generic Prilosec®) pantoprazole (generic Protonix®) rabeprazole (generic Aciphex®)	Dexilant®	Aciphex® Nexium® omeprazole / sodium bicarbonate (generic Zegerid) Prevacid® Prilosec® Protonix®

		Zegerid®
Respiratory Medications		
Step 1 Medications*	Step 2 Medications*	Step 3 Medications*
Inhaled Corticosteroid (ICS) Requires ONE Step 2 medication		
	Asmanex® / HFA Flovent® Diskus / HFA Pulmicort Flexhaler™ Qvar® / Qvar® Redihaler™	Aerospan® Alvesco® ArmonAir™ Respiclick® Arnuity™ Ellipta®
Inhaled Corticosteroid (ICS) with Long-Acting Beta Agonist (LABA) Requires ONE Step 2 medication		
	Advair® HFA Breo® Ellipta® Dulera® fluticasone/salmeterol (authorized generic for Airduo™ Respiclick®) fluticasone/salmeterol (authorized generic for Advair™ Diskus) Symbicort® Wixela™ Inhub™ (generic for Advair® Diskus)	Advair® Diskus AirDuo™ Respiclick®
Long-Acting Beta Agonist (LABA) Requires ONE Step 2 medication		
	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> Requires ONE Step 2 medication		
	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 Requires ONE Step 2 medication		
	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) Requires ONE Step 2 medication		
	Anoro™ Ellipta™	Bevespi Aerosphere™ Stiolto™ Respimat®

		Utibron™ Neohaler®
<p align="center">Selective Serotonin / Serotonin Norepinephrine Reuptake Inhibitors (SSRI / SNRI) <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> Requires TWO Step 1 medications</p>		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
bupropion (generic Wellbutrin®) bupropion SR (generic Wellbutrin SR®) bupropion XL (generic Wellbutrin XL®) citalopram (generic Celexa®) desvenlafaxine succ ER (generic Pristiq®) duloxetine (generic Cymbalta® and Irenka™) escitalopram (generic Lexapro®) fluoxetine (generic Prozac® / Sarafem® / Rapiflux®) fluoxetine weekly (generic Prozac Weekly®) fluvoxamine (generic Luvox®) paroxetine (generic Paxil®) paroxetine extended-release (generic Paxil CR®) sertraline (generic Zoloft®) venlafaxine (generic Effexor®) venlafaxine ER (generic Effexor XR®)		Aplenzin® Brintellix / Trintellix® Celexa® Cymbalta® Desvenlafaxine Extended Release Drizalma™ Effexor XR® Fetzima™ Forfivo™XL Irenka™ Khedezla™ Lexapro® Paxil®/ Paxil CR® Pexeva® Pristiq® Prozac® Prozac Weekly® Sarafem® Viibryd™ Wellbutrin SR® Wellbutrin XL® Zoloft®
<p align="center">Statins Requires TWO Step 1 medications</p>		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
atorvastatin (generic Lipitor®) ezetimibe / simvastatin (generic Vytorin®) fluvastatin (generic Lescol®) fluvastatin ER (generic Lescol® XL) lovastatin (generic Mevacor®) pravastatin (generic Pravachol®) rosuvastatin (generic Crestor®) simvastatin (generic Zocor®)		Altoprev® Crestor® Ezallor™ Sprinkle Folipid™ Lescol® / Lescol® XL Lipitor® Livalo® Pravachol® Vytorin® Zocor® Zypitamag™
<p align="center">Tetracycline and Oral Acne Class <u>Tetracycline, Minocycline and Tetracycline, Doxycycline Requires ONE Step 1 medication</u> <u>Tetracycline, Acne, Oral Requires TWO Step 1 medications</u></p>		
<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 ER
Topical Inflammatory		
Step 1 Medications*	Step 2 Medications**	Step 3 Medications***
Very High Potency Requires TWO Step 1 medications		
<ul style="list-style-type: none"> betamethasone dipropionate, augmented 0.05% gel, ointment, lotion (generic Diprolene AF®) clobetasol propionate 0.05% cream, foam, ointment, gel, lotion, shampoo, solution, spray (generic Clobex® / Clodan™ / Olux®/Olux-E® / Temovate®) diflorasone diacetate 0.05% ointment (generic Psorcon®) fluocinonide 0.1% cream (generic Vanos®) halobetasol propionate 0.05% cream, foam, ointment (generic Lexette® / Ultravate® / Ultravate X®) 		Bryhali™ Clobex® Clodan™ Diprolene® Impoyz™ Olux® / Olux-E® Lexette® Temovate® Ultravate® / Ultravate X® Vanos®
High Potency Requires TWO Step 1 medications		
<ul style="list-style-type: none"> ApexiCon E® (generic Psorcon®) amcinonide 0.1% cream, lotion, ointment betamethasone dipropionate 0.05% ointment (generic Diprolene®) betamethasone dipropionate, augmented 0.05% cream (generic Diprolene AF®) desoximetasone 0.25% spray (generic Topicort®) desoximetasone 0.05% gel, ointment, cream (generic Topicort®) diflorasone diacetate 0.05% cream (generic Psorcon®) fluocinonide 0.05% cream, gel, ointment, solution (generic Lidex) triamcinolone acetonide 0.5% cream, ointment (generic Kenalog®) 		Diprolene AF® halcinonide cream 0.1% (generic Halog®) Halog® Topicort® 0.05% gel, ointment Topicort® 0.25% cream, ointment, spray
Medium Potency Requires TWO Step 1 medications		

<ul style="list-style-type: none"> • betamethasone dipropionate 0.05% cream, lotion, spray (generic Diprosone® and Sernivo™) • betamethasone valerate 0.1% cream, foam (generic Valisone and Luxiq®) • clocortolone pivalate 0.1% cream (generic Cloderm®) • desoximetasone 0.05% cream (generic Topicort®) • fluocinolone acetonide 0.025% cream, ointment (generic Synalar®) • fluocinonide 0.05% cream (emollient base) (generic Lidex-E) • flurandrenolide 0.05% cream, lotion, ointment (generic Cordran®) • fluticasone propionate 0.005% ointment, cream, lotion (generic Cutivate®) • hydrocortisone butyrate 0.1% cream, lotion, ointment, solution (generic Locoid®) • hydrocortisone valerate 0.2% cream, ointment (generic Westcort®) • mometasone furoate 0.1% cream, lotion, ointment (generic Elocon®) • prednicarbate 0.1% cream, ointment (generic Dermatop®) • triamcinolone acetonide 0.025% cream, lotion, ointment (generic Kenalog®) • triamcinolone acetonide 0.05% ointment (generic Trianex) • triamcinolone acetonide 0.1% cream, lotion, ointment (generic Kenalog® and Dermasorb™ TA) • triamcinolone acetonide 0.147% spray (generic Kenalog®) 		<p>Cloderm® Cordran® Cutivate® Dermasorb™ TA Dermatop® Diprosone® Elocon® Kenalog® Spray Locoid® Luxiq® Sernivo™ Spray Synalar® 0.025% cream, ointment Topicort® 0.05% cream</p>
Low Potency Requires TWO Step 1 medications		
<ul style="list-style-type: none"> • alclometasone dipropionate 0.05% cream, ointment (generic Aclovate®) • betamethasone valerate 0.1% lotion (generic Valisone) • desonide 0.05% cream, lotion, ointment (generic Desowen® and Tridesilon®) 		<p>Ala-Scalp® Capex Shampoo® Derma-Smoother / FS® Dermasorb™ HC Desonate® Desowen® MiCort™ HC Nucort® Pandel®</p>

<ul style="list-style-type: none"> • fluocinolone acetonide 0.01% cream, oil, solution (generic Derma-Smoothe / FS[®] and Synalar[®] / Synalar TS[®]) • hydrocortisone cream, lotion, ointment (generic for Ala-Scalp[®] and MiCort[™] HC and Nucort[®] and Pandel[®] and Texacort[®]) 		Scalacort DK [®] Synalar TS [®] 0.01% solution Texacort [®] Tridesilon [®] Verdeso [®]
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*Step 1 medications are typically generics but may vary based on benefit plan.

**Step 2 medications are typically Preferred Brand medications but may vary based on benefit plan.

***Step 3 medications are typically Non-Preferred Brand medications but may vary based on benefit plan.

Emerging Drug Therapy

Step 1 Medications*	Step 2 Medications** Requires ONE Step 1 Medication
<u>Diagnosis of postherpetic neuralgia:</u> gabapentin (generic Neurontin [®]) pregabalin (generic for Lyrica [®]) <u>Diagnosis of restless leg syndrome:</u> pramipexole (generic Mirapex [®]) ropinirole (generic Requip [®] / Requip [®] XL)	Horizant [®] Lyrica [®] (pregabalin)
itraconazole	Jublia [®]
terbinafine	Kerydin [®]
itraconazole	Onmel [®]
prednisone	Rayos [®]
minocycline / minocycline ER	Minolira [®] Solodyn [®] Ximino [™] ER
latanoprost (generic Xalatan [®]) Travatan Z [®]	Zioptan [®]
ondansetron oral (generic Zofran [®])	Zuplenz [®]
imiquimod 5% cream	Imiquimod 3.75% Zyclara [®] 2.5%, 3.75%
Claravis [™] Myorisan [™] Zenatane [™]	Absorica [®]
balsalazide mesalamine Pentasa [®]	Apriso [®] Asacol [®] HD Colazal [®] Delzicol [®] Dipentum [®] Giazo [®] Lialda [®]

*Step 1 medications are typically generics but may vary based on benefit plan.

** Step 2 medications in Emerging Drug Therapy are typically Non-Preferred Brand medications but may vary based on benefit plan.

General Background

Step Therapy, a prior authorization program, creates a sequence of “steps” in the choice of medications. The program is designed to encourage the use of generic or preferred therapeutic alternatives with the same indications for use, before moving to non-preferred alternatives, unless prior authorization for coverage under

the benefit plan is obtained. Criteria for authorization include failure, intolerance, or contraindication to the prerequisite agents.

Medications to treat several common medical conditions are included in the Step Therapy program.

These include:

- Angiotensin Converting Enzyme (ACE) Inhibitors / and Angiotensin Receptor Blockers (ARB) to treat hypertension
- HMG-CoA-Reductase inhibitors (“statins”) to treat hypercholesteremia,
- Proton Pump Inhibitors (PPI) to treat gastric acid conditions
- Urinary Tract Antispasmodics
- Hypnotics (non-benzodiazepine)
- Inhaled Nasal Steroids
- Serotonin Selective / Serotonin Norepinephrine Receptor Inhibitors (SSRI / SNRI) to treat depression
- Topical Corticosteroids / Immunomodulators
- Atypical Antipsychotic Agents
- Non-Steroidal Anti-inflammatory Drugs (NSAID)
- Attention Deficit Hyperactivity Disorder (ADHD) Stimulants
- Respiratory Medications
- Long Acting Narcotics
- Bone Resorption Inhibitors
- Emerging Drug Therapy [new Food and Drug Administration (FDA) approvals with generic or preferred brand therapeutic alternatives]

Other Program Features:

Additional program features are a part of Step Therapy programs, including a “first-fill pay and educate” notification process, age exemptions, and a prior authorization option.

- 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. FDA List of Authorized Generic Drugs: How Drugs are Developed and Approved: <http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/ucm126389.htm>
5. 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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