Cigna Drug and Biologic Coverage Policy

Subject **Drugs / Biologics Not Covered Unless Approved Under Medical Necessity Review – Employer Group Plans: Standard Prescription Drug List and Performance Prescription Drug List**

Effective Date 7/15/2020
Next Review Date 1/1/2021
Coverage Policy Number 1601

Table of Contents

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 may adopt a Prescription Drug List that does not cover certain drugs or biologics unless those products are approved based on a medical necessity review. Cigna approves coverage for these drugs or biologics as medically necessary when sufficient information demonstrates that the clinical criteria set forth below are met. Unless otherwise stated, all Covered Alternative Drugs are required prior to the approval of the non-covered drug or biologic.

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

Cigna Standard Prescription Drug List or Performance Prescription Drug List

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
Antimycobacterial agents	**Mycobutin®** (rifabutin)	All of the following: • Documented intolerance to 1 generic formulation of Mycobutin (rifabutin)
Diabetes: Insulins	**Admelog®** (insulin lispro)	All of the following: • Documented contraindication per FDA label, intolerance, or inability to use Humalog® (insulin lispro)
	Apidra® (insulin glulisine)	All of the following: • Documented contraindication per FDA label, intolerance, or inability to use Humalog® (insulin lispro)
	Insulin Lispro	All of the following: • Documented inability to obtain Humalog® (insulin lispro)

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	(authorized generic for Humalog®)	
	Novolog® (insulin aspart) **Fiasp®** (insulin aspart)	All of the following: • Documented contraindication per FDA label, intolerance, or inability to use Humalog® (insulin lispro)
	Novolog Mix 70/30® (70% insulin aspart protamine/30% insulin aspart)	All of the following: • Documented contraindication per FDA label, intolerance, inability to use or not a candidate for Humalog® Mix 75/25
	Novolin 70/30® (70% NPH, human insulin isophane/30% regular human insulin)	All of the following: • Documented contraindication per FDA label, intolerance, or inability to use Humulin® 70/30)
	Novolin N® (insulin, NPH human recombinant isophane)	All of the following: • Documented contraindication per FDA label, intolerance, or inability to use Humulin® N
	Novolin R® (insulin, regular, human recombinant)	All of the following: • Documented contraindication per FDA label, intolerance, or inability to use Humulin R
Diabetes: Non-insulins (extended release metformin)	**Fortamet®** (metformin extended release tablets) **Glumetza®** (metformin extended release tablets) **Metformin ER osmotic tablets** (Fortamet®) **Metformin ER tablets** (Glumetza®)	All of the following: • Documented intolerance to metformin ER (Glucophage® XR)
Diabetes: Test Strips	**AccuChek®** **Freestyle®** **Contour®** All other test strips	All of the following: • Documented inability to use BOTH One Touch Ultra® AND One Touch Verio® due to a physical limitation that makes utilization of the One Touch product not accurate, safe or for other reason not medically appropriate (e.g. manual dexterity, visual impairment, or use of a insulin pump with a dedicated meter)
Renal and Genitourinary Agents	**Gelnique 10% gel** (oxybutynin chloride metered-dose pump, sachet) **Myrbetriq®** (mirabegron)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: darifenacin ER, oxybutynin, tolterodine and trospium

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Toviaz® (fesoterodine) **Vesicare**® (solifenacin)	
	Detrol® **/ Detrol LA**® (tolterodine)	All of the following: • Documented intolerance to 1 generic formulation of Detrol / Detrol LA • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: darifenacin ER oxybutynin and trospium
	Ditropan XL® (oxybutynin)	All of the following: • Documented intolerance to 1 generic formulation of Ditropan XL • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: darifenacin ER, tolterodine and trospium
	Enablex® (darifenacin ER)	All of the following: • Documented intolerance to 1 generic formulation of Enablex • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: oxybutynin, tolterodine and trospium
	Oxytrol® (oxybutynin transdermal system)	All of the following: • Documented inability to use oxybutynin syrup, extended release tablets or tablets
Anti-diuretic and vasopressor hormone agents	**DDAVP**® (desmopressin acetate 0.01% nasal solution)	All of the following: • Documented intolerance to 1 generic formulation of DDAVP nasal solution • Documented inability to use desmopressin tablets
	DDAVP® (0.1 mg, 0.2 mg tablets)	All of the following: • Documented intolerance to 1 generic formulation of DDAVP
	Nocdurna® (desmopressin acetate sublingual tablet)	All of the following: • Individual is 18 years of age or older • Documented nocturnal polyuria confirmed by 24-hour urine collection • Awaking at least 2 times per night to void • All underlying causes of nocturia (including medical or pharmacologic induced) have been ruled out or are being treated and, despite documented treatment and treatment failure, symptoms still persist: [for example] Benign Prostatic Hyperplasia, Overactive Bladder, Postmenopausal Genitourinary Syndrome • No concurrent use of loop diuretics or systemic or inhaled glucocorticoids

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
Anti-infective agents: antifungals	**Diflucan®** (fluconazole 50 mg, 100 mg, 150 mg, 200 mg tablets, 10 mg/ml, 40 mg/ml suspension)	All of the following: • Documented intolerance to 1 generic formulation of Diflucan
	Onmel® (itraconazole 200 mg tablets, 10 mg/ml solution)	All of the following: • Documented intolerance or inability to use itraconazole 100 mg capsules • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for terbinafine tablets
	Sporanox® (itraconazole 100mg capsules, 10 mg/ml solution)	All of the following: • Documented intolerance to 1 generic formulation of Sporanox
	Tolsura (itraconazole 65mg capsules)	Treatment of one of the following fungal infections: • Blastomycosis • Histoplasmosis • Aspergillosis in individuals intolerant or refractory to amphotericin B therapy
Anti-infective agents: antiprotozoals	**Mepron®** (atovaquone 750 mg/ 5 ml oral suspension)	One of the following: • Prevention or treatment of Pneumocystis jiroveci pneumonia (PCP) in adults or individuals 13 years of age and older o Documented intolerance to 1 generic formulation of Mepron AND o Documented intolerance to trimethoprim/sulfamethoxazole (TMP-SMX) • Prevention or treatment of Toxoplasma gondii encephalitis (TE) in adults or adolescents o Documented intolerance to 1 generic formulation of Mepron AND o Documented intolerance to 1 of the following: trimethoprim/sulfamethoxasole (TMP-SMX), pyrimethamine or sulfadiazine
Anti-infective agents: antivirals	**Sitavig®** (acyclovir 50 mg buccal tablet)	All of the following: • Documented diagnosis of recurrent herpes labialis • Documented inability to use acyclovir capsules and tablets
	Zovirax® (acyclovir 200 mg capsules, 400 mg and 800 mg tablets, 200 mg/5 ml suspension)	All of the following: • Documented intolerance to 1 generic formulation of Zovirax
	Valcyte® (valganciclovir 450 mg tablets, 50 mg/ml solution)	All of the following: • Documented intolerance to 1 generic formulation of Valcyte
Anti-infective agents: Penicillins	**Augmentin®** (125 mg amoxicillin /31.25mg clavulanate/5ml suspension, 250 mg amoxicillin / 62.5mg	All of the following: • Documented intolerance to 1 generic formulation of Augmentin

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	clavulanate/5ml suspension, 875 mg amoxicillin/125 mg clavulanate tablets) **Augmentin ES-600®** (600 mg amoxicillin /42.9 mg clavulanate / 5 ml suspension) **Augmentin XR®** (1,000 mg amoxicillin /62.5 mg clavulanate tablets)	
Anti-infective agents: Macrolides	**E.E.S. 200** (erythromycin ethylsuccinate 200 mg/5 ml suspension)	All of the following: • Documented intolerance to 1 generic formulation of E.E.S. 200
	EryPed 400 (erythromycin 400 mg/5 ml suspension)	All of the following: • Documented intolerance to 1 generic formulation of EryPed 400 mg suspension • Documented inability to use or not a candidate for erythromycin ethylsuccinate 400 mg tablets
Anti-infective agents: Vancomycin and Derivatives	**Vancocin®** (Vancomycin 125 mg, 250 mg capsules	All of the following: • Documented intolerance to 1 generic formulation of Vancocin
Dermatologic: Local anesthetics, topical	**Lidocaine** 3% lotion **Lido-K** (lidocaine 3% lotion)	All of the following: • Documented failure / inadequate response or intolerance to both lidocaine 3 % cream and lidocaine 5 % ointment
Dermatologic: Steroidal Anti-inflammatory, Topical	**Anusol-HC®** (hydrocortisone 2.5 % rectal cream) **Anusol-HC®** (hydrocortisone acetate 25 mg rectal suppository) **Cortifoam®** (hydrocortisone acetate 10 % foam) **Proctocort®** (hydrocortisone 1 % cream) **Proctocort®**	All of the following: • Documented failure / inadequate response, intolerance, or not a candidate for ALL of the following o hydrocortisone 1 % or 2.5 % rectal cream o hydrocortisone 100 mg / 60 ml rectal enema o hydrocortisone acetate 25 mg or 30 mg rectal suppository

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	(hydrocortisone 30 mg suppository)	
	Clobex® (clobetasol 0.05 % lotion, liquid spray, shampoo)	All of the following: • Documented failure / inadequate response or intolerance to FIVE dosage forms of clobetasol 0.05 %: lotion, liquid spray, shampoo, solution, ointment, cream, gel, or foam
	Cutivate® (fluticasone 0.05% cream, lotion)	All of the following: • Documented intolerance to 1 generic formulation of Cutivate • Documented failure / inadequate response, contraindication per FDA label, or intolerance to betamethasone, clocortolone, desoximetasone, fluocinonide, flurandrenolide, hydrocortisone, mometasone, prednicarbate, triamcinolone
	Halog (halcinonide 0.1% cream)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, or intolerance to triamcinolone cream, fluocinonide cream, betamethasone cream, halobetasol cream, and clobetasol cream
	Halog (halcinonide 0.1% ointment)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, or intolerance to triamcinolone ointment, fluocinonide ointment, betamethasone ointment, halobetasol ointment, and clobetasol ointment
	Halog (halcinonide 0.1% solution)	All of the following: • Documented failure/inadequate response, contraindication per FDA label, or intolerance to triamcinolone cream/ointment, fluocinonide cream/gel/ointment/solution, betamethasone cream/gel/lotion/ointment, halobetasol cream/ointment, and clobetasol cream/ointment
	Lexette (halobetasol propionate 0.05% foam)	All of the following: • Plaque psoriasis • Age 18 years of age and older • Documented intolerance to 1 generic formulation of Lexette 0.05% foam • Documented failure / inadequate response or intolerance to **FOUR** of the following: o betamethasone dipropionate, augmented 0.05 % (gel, lotion and ointment) o clobetasol propionate 0.05 % (cream, foam, gel, lotion, ointment, shampoo, solution, spray) o diflorasone diacetate 0.05% (ointment) o fluocinonide 0.1% (cream) o halobetasol propionate 0.05 % (cream and ointment)
	Locoid® (hydrocortisone butyrate 0.1 % cream, lipocream, lotion, ointment, solution)	All of the following: • Documented failure / inadequate response or intolerance to hydrocortisone butyrate 0.1 % solution, ointment, cream, and lipid cream
	Kenalog® (triamcinolone acetonide 0.147 mg	All of the following: • Documented intolerance to 1 generic formulation of Kenalog

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	/ gm aerosol solution)	• Documented failure / inadequate response or intolerance to ALL of the following: Triamcinolone acetonide cream, lotion and ointment
	Trianex® (augmented triamcinolone acetonide 0.05 % ointment)	All of the following: • Documented failure / inadequate response or intolerance to ALL of the following: Triamcinolone acetonide cream, lotion and ointment
	Ultravate® (halobetasol propionate 0.05 % lotion) **Ultravate® X** (halobetasol propionate / lactic acid 0.05 % - 10 % cream) **Ultravate® X** (halobetasol propionate / lactic acid 0.05 % - 10 % ointment)	All of the following: • Documented failure / inadequate response or intolerance to FIVE of the following: o halobetasol propionate 0.05 % cream o halobetasol propionate 0.05 % ointment o clobetasol propionate 0.05 % cream o clobetasol propionate 0.05 % lotion o clobetasol propionate 0.05 % ointment o betamethasone dipropionate, augmented 0.05 % ointment o betamethasone dipropionate, augmented 0.05 % lotion
	Verdeso® (desonide 0.05 % foam)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, or intolerance to fluocinolone body oil, fluticasone lotion, and topical hydrocortisone
	Vanos® (fluocinonide 0.1 % cream)	All of the following: • Documented intolerance to 1 generic formulation of Vanos 0.1 % cream • Documented failure / inadequate response or intolerance to fluocinonide 0.05 % solution, ointment, cream, and gel
	Sernivo™ (betamethasone dipropionate 0.05 % emulsion)	All of the following: • Documented failure / inadequate response, intolerance, or not a candidate for FIVE of the following: o betamethasone dipropionate 0.05 % ointment o betamethasone dipropionate 0.05 % cream o betamethasone dipropionate 0.05 % lotion o augmented betamethasone dipropionate 0.05 % gel o betamethasone valerate 0.12 % foam
Dermatologic: Acne Agents, Systemic	**Absorica**® (isotretinoin 10 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg capsules)	All of the following: • Documented intolerance to Claravis™ (isotretinoin 10 mg, 20 mg, 30 mg, and 40 mg capsules), Myorisan™ (isotretinoin 10 mg, 20 mg, and 40 mg capsules), and Zenatane™ (isotretinoin 10 mg, 20 mg, 30 mg, and 40 mg capsules)
Dermatologic: Antineoplastics, Topical	**Aldara**® (imiquimod 5 % cream)	All of the following: • Documented intolerance to 1 generic formulation of Aldara • One of the following: o For actinic keratosis: Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies:

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		▪ 5-fluorouracil cream (fluorouracil 0.5% cream, Fluoroplex 1%, Tolak 4%, Efudex 5%) ▪ 5-fluorouracil solution (2% or 5%) ▪ Picato (ingenol) 0.015% or 0.05% gel o For superficial basal cell carcinoma: Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for topical 5-fluorouracil 5% (cream or solution) o For external genital and perianal warts (*Condylomata acuminata*): Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: ▪ podofilox 0.5% (solution, Condylox gel) ▪ Veregen (sinecatechins) 15% ointment
	Zyclara® (imiquimod 2.5 % cream pump)	All of the following: • Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: o 5-fluorouracil cream (flurouracil 0.5% cream, Fluoroplex 1%, Tolak 4%, Efudex 5%) o 5-fluorouracil solution (2% or 5%) o imiquimod 5% cream o Picato (ingenol) 0.015% or 0.05% gel
	Zyclara® (imiquimod 3.75 % cream pump, and 3.75 % cream)	One of the following: • For actinic keratosis: Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: o 5-fluorouracil cream (flurouracil 0.5% cream, Fluoroplex 1%, Tolak 4%, Efudex 5%) o 5-fluorouracil solution (2% or 5%) o imiquimod 5% cream o Picato (ingenol) 0.015% or 0.05% gel • For external genital and perianal warts (*Condylomata acuminata*): Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: o imiquimod 5% cream o podofilox 0.5% (solution, Condylox gel) o Veregen (sinecatechins) 15% ointment
	Carac® (fluorouracil 0.5 % cream)	All of the following: • Documented intolerance to 1 generic formulation of Carac • Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: o 5-fluorouracil cream (Fluoroplex 1%, Tolak 4%, Efudex 5%) o 5-fluorouracil solution (2% or 5%) o imiquimod 5% cream o Picato (ingenol) 0.015% or 0.05% gel
Dermatologic: Actinic Keratosis, Topical	**Solaraze, Diclofenac 3% topical gel**	All of the following: • Diagnosis of actinic keratoses • Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies:

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
		o 5-fluorouracil cream (fluorouracil 0.5%, Fluoroplex 1%, Tolak 4%, Efudex 5%) o 5-fluorouracil solution (2% or 5%) o Imiquimod 5% cream o Picato (ingenol) 0.015% or 0.05% gel
Dermatologic: Antipsoriatic agents, systemic	**Soriatane**® (acitretin 10 mg, 17.5 mg, 22.5 mg, 25 mg capsules)	One of the following: • Documented diagnosis of severe psoriasis o Documented intolerance to 1 generic formulation of Soriatane o Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: methotrexate or cyclosporine • Documented diagnosis of discoid lupus erythematosus o Documented intolerance to 1 formulation of Soriatane o Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for hydroxychloroquine
Dermatologic: Antipsoriatic agents, topical	**Tazorac**® (tazarotene 0.05% cream, gel)	All of the following: • For plaque psoriasis: Documented intolerance OR not a candidate to 1 generic formulation of Tazorac AND • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for calcipotriene
Dermatologic: Keratolytics	**Bensal HP**® (salicylic acid 3 % ointment) **Salex**® 6% cream kit (salicylic acid 6 % cream) **Salex**® 6% lotion kit (salicylic acid 6 % lotion) **Salex**® 6% shampoo (salicylic acid 6 % shampoo)	All of the following: • Documented inability to use or not a candidate for salicylic acid 6 % cream, salicylic acid 6 % lotion, salicylic acid 6 % gel, and salicylic acid 6 % shampoo
Dermatologic: Topical rosacea agents	**Noritate**® (metronidazole 1 % cream)	All of the following: • Documented failure / inadequate response or inability to use metronidazole 0.75 % cream, metronidazole 0.75 % lotion, metronidazole 0.75 % gel, and metronidazole 1 % gel
Cardiovascular: Antithrombotic Agents	**Yosprala**™ (aspirin delayed release / omeprazole 81 mg – 40 mg tablets and 325 – 40 mg tablets)	All of the following: • Individual is at risk of developing aspirin associated gastric ulcers defined as EITHER of the following o 55 years of age or older o Documented history of gastric ulcers • Individual requires aspirin for secondary prevention of cardiovascular and cerebrovascular events defined as ONE of the following:

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		o Previous ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli o Previous myocardial infarction or unstable angina pectoris o Chronic stable angina pectoris o History of revascularization procedure (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) when there is pre-existing condition for which aspirin is already indicated • Documented intolerance to immediate release (including enteric coated) aspirin
Cardiovascular: Diuretics	**Edecrin®** (ethacrynic acid 25 mg tablets) **ethacrynic acid** (ethacrynic acid 25 mg tablets)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: bumetanide, furosemide, and torsemide
Cardiovascular: Inotropic Agents	**Lanoxin®** (digoxin 125 mcg and 250 mcg tablets)	All of the following: • Documented intolerance to 1 generic formulation of Lanoxin 125 mcg or 250 mcg tablets
	Lanoxin® (digoxin 62.5 mcg and 187.5 mcg tablets)	All of the following: • Documented inability to use or intolerance to one-half or one and one-half tablets of digoxin 125 mcg tablets
Cardiovascular: Vasodilators	**Cardizem** (diltiazem 30 mg, 60 mg, and 120 mg tablets)	All of the following: • Documented intolerance to 1 generic formulation of Cardizem • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following o Verapamil 40 mg, 80 mg, and 120 mg tablets o Diltiazem CD extended release capsules o Diltiazem extended release tablets
	Cardizem CD (diltiazem 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg extended release capsules)	All of the following: • Documented intolerance to 1 generic formulation of Cardizem CD • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following o Verapamil extended release tablets o Verapamil extended release capsules o Diltiazem extended release tablets
	GoNitro™ (nitroglycerin sublingual powder)	All of the following: • Documented intolerance or inability to use nitroglycerin sublingual tablets and nitroglycerin sublingual spray
	Isordil® (isosorbide dinitrate 40 mg tablet)	All of the following: • Documented inability to use two tablets of isosorbide dinitrate 20 mg tablets
	Isordil® Titradose™ (isosorbide dinitrate 5 mg tablet)	All of the following: • Documented intolerance to 1 generic formulation of Isordil Titradose 5 mg tablets

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Cholesterol Lowering	**Antara**® (fenofibrate 30 mg and 90 mg capsules)	All of the following: • Documented intolerance to fenofibrate 43 mg, 67 mg, or 130 mg capsules • Documented failure / inadequate response, intolerance, or not a candidate for fenofibric acid (Trilipix®), fenofibrate (Tricor® / Lofibra®), and gemfibrozil (Lopid®)
	Fenoglide® (fenofibrate 40 mg and 120 mg tablets)	All of the following: • Documented intolerance to fenofibrate 48 mg or 120 mg tablets • Documented failure / inadequate response, intolerance, or not a candidate for fenofibric acid (Trilipix®), fenofibrate (Tricor® / Lofibra®), and gemfibrozil (Lopid®)
Gastrointestinal Agents: Aminosalicylates	**Asacol® HD** (mesalamine)	All of the following: • Documented intolerance or inability to use generic mesalamine • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for FOUR of the following: Apriso™ (mesalamine), Lialda® (mesalamine), Pentasa® (mesalamine), balsalazide, and sulfasalazine
	Colazal® (balsalazide) **Delzicol**® (mesalamine) **Dipentum**® (olsalazine) **Giazo**® (balsalazide)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for FIVE of the following: Apriso™ (mesalamine), Lialda® (mesalamine), Pentasa® (mesalamine), generic mesalamine, balsalazide, and sulfasalazine
	Rowasa™ (mesalamine 4 gm/ 60 ml rectal suspension)	All of the following: • Documented intolerance to 1 generic formulation of Rowasa • Documented failure / inadequate response, intolerance or inability to use Canasa
Gastrointestinal Agents: Anticholinergic combinations	**Librax**® (chlordiazepoxide / clidinium bromide 5 mg – 2.5 mg capsules)	All of the following: • Documented intolerance to 1 generic formulation of Librax • Documented failure / inadequate response, contraindication per FDA label, or intolerance to dicyclomine capsules
Gastrointestinal Agents: Anti-infective combinations	**Omeclamox®-Pak** (amoxicillin / clarithromycin / omeprazole 500 mg – 500 mg – 20 mg)	All of the following: • Documented diagnosis of Helicobacter pylori infection • Documented contraindication per FDA label, intolerance, or not a candidate for 1 generic formulation of Prevpac • Documented inability to obtain amoxicillin 500 mg tablets or capsules, clarithromycin 500 mg tablets, and omeprazole 20 mg tablets or capsules

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Prevpac® (amoxicillin / clarithromycin / lansoprazole 500 mg – 500 mg – 30 mg)	All of the following: • Documented diagnosis of Helicobacter pylori infection • Documented intolerance to 1 generic formulation of Prevpac • Documented inability to obtain amoxicillin 500 mg tablets or capsules, clarithromycin 500 mg tablets, and lansoprazole 30 mg capsules
	Pylera® (bismuth subcitrate / metronidazole / tetracycline 140 mg – 125 mg – 125 mg capsules)	All of the following: • Documented diagnosis of Helicobacter pylori infection • Documented failure, contraindication per FDA label, intolerance, or not a candidate for 1 generic formulation of Prevpac • Documented inability to use or obtain bismuth subsalicylate tablets or suspension, metronidazole tablets, and tetracycline capsules concurrently
Gastrointestinal Agents: Histamine H_2 Antagonists	**Pepcid®** (famotidine 20 mg, 40 mg tablets, and 40 mg / 5 ml suspension)	All of the following: • Documented intolerance to 1 generic formulation of Pepcid • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for TWO of the following: cimetidine (tablet or solution), nizatidine (capsule or solution), or ranitidine (tablet, capsule, or syrup)
Gastrointestinal Agents: Motility Stimulant	**Metozolv® ODT** (metoclopramide 5 mg orally disintegrating tablets)	All of the following: • Documented intolerance to 1 generic formulation of Metozolv ODT • Documented inability to use metoclopramide tablets and solution
Gastrointestinal Agents: 5-HT_3 receptor antagonists	**Lotronex®** (alosetron 0.5 mg and 1 mg tablets)	All of the following: • Documented intolerance to 1 generic formulation of Lotronex • Documented failure / inadequate response, contraindication per FDA lable, intolerance or not a candidate for FOUR of the following: clidinium/ chlordiazepoxide, dicyclomine, hyoscyamine, rifaximin, Viberzi
Hormones: oral corticosteroids	**Dexpak®** (dexamethasone 1.5 mg tablets) **Dxevo 11-Day Dose Pack** (dexamethasone 1.5 mg tablets) **TaperDex 12 Day and 6 Day** (dexamethasone 1.5 mg tablets) **ZonaCort 7 Day and 11 Day** (dexamethasone 1.5 mg tablets)	All of the following: • Documented inability to use dexamethasone 1.5 mg tablets • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for methylprednisolone tablet therapy pack • Documented failure / inadequate response, contraindication per FDA label, or intolerance to hydrocortisone and methylprednisolone tablets

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	ZoDex 6-Day and 12-Day (dexamethasone 1.5 mg tablets)	
	Rayos® (prednisone 1 mg, 2 mg, and 5 mg delayed release tablets)	All of the following: • Documented intolerance or inability to use prednisone 1 mg, 2.5 mg, or 5 mg tablets • Documented failure / inadequate response, contraindication per FDA label, or intolerance to dexamethasone, hydrocortisone, and methylprednisolone tablets
Psychotherapeutic Drugs: Benzodiazepines	**Ativan**® (lorazepam)	All of the following: • Documented intolerance to 1 generic formulation of Ativan • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for TWO of the following: alprazolam, clonazepam, diazepam, oxazepam, temazepam
	Restoril™ (temazepam 7.5 mg, 15 mg. 22.5mg, 30mg capsules)	All of the following: • Documented in tolerance to 1 generic formulation of Restoril • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for TWO of the following: estazolam, eszopiclone, flurazepam, quazepam, triazolam, zaleplon, zolpidem, Doral, Silenor or Rozerem
Psychotherapeutic Drugs: Monoamine oxidase inhibitors	**Mysoline**® (primidone tablets)	All of the following: • Documented intolerance to 1 generic formulation of Mysoline
	Parnate® (tranylcypromine sulfate 10 mg tablets)	All of the following: • Documented intolerance to 1 generic formulation of Parnate • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: Marplan, selegiline (oral formulations only), phenelzine
Psychotherapeutic Drugs: NDRIs	**Aplenzin**® (bupropion hydrobromide 174 mg, 348 mg, and 522 mg extended release tablets)	All of the following: • Documented failure / inadequate response to bupropion XL 150 mg or 300 mg extended release tablets • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: citalopram, desvenlafaxine succinate ER, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine
	Wellbutrin XL® (bupropion 150 mg and 300 mg extended release tablets)	All of the following: • Documented intolerance to 1 generic formulation of Wellbutrin XL • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: citalopram, desvenlafaxine succinate ER, duloxetine,

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
		escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine
Psychotherapeutic Drugs: Atypical Antipsychotics	**Abilify**® (aripiprazole)	All of the following: • Documented intolerance to 1 generic formulation of Abilify
	Fazaclo® (clozapine 12.5 mg, 25 mg, 100 mg, 150 mg, and 200 mg dispersible tablets) **Versacloz**® (clozapine 50 mg / ml suspension)	All of the following: • Documented inability to use or not a candidate for clozapine 25 mg, 50 mg, 100 mg, or 200 mg tablets AND clozapine 12.5 mg, 25 mg, 100 mg, 150 mg, or 200 mg orally disintegrating tablets
	Geodon® (ziprasidone 20 mg, 40 mg, 60 mg, and 80 mg capsules)	All of the following: • Documented intolerance to 1 generic formulation of Geodon
	Zyprexa® (olanzapine 2.5mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20mg tablets)	All of the following: • Documented intolerance to 1 generic formulation of Zyprexa
	Zyprexa Zydis® (olanzapine 5 mg, 10 mg, 15 mg, 20 mg orally disintegrating tablets)	All of the following: • Documented intolerance 1 generic formulation of Zyprexa Zydis
Psychotherapeutic Drugs: SNRIs	**Cymbalta**® (duloxetine delayed release capsules)	All of the following: • Documented intolerance 1 generic formulation of Cymbalta • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: bupropion SR/XL, citalopram, desvenlafaxine succinate ER, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine ER
Psychotherapeutic Drugs: SSRIs	**Lexapro**® (escitalopram tablets)	All of the following: • Documented intolerance to 1 generic formulation of Lexapro • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: bupropion SR/XL, citalopram, desvenlafaxine succinate ER, duloxetine, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine ER
	Pexeva® (paroxetine mesylate 10 mg, 20 mg, 30 mg, and 40 mg tablets)	All of the following: • Documented intolerance to paroxetine hydrochloride 10 mg, 20 mg, 30 mg, or 40 mg tablets • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following:

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
		bupropion SR/XL, citalopram, desvenlafaxine succinate ER, duloxetine, escitalopram, fluoxetine, fluvoxamine, sertraline, venlafaxine ER
Psychotherapeutic Drugs: Tricyclic antidepressants	**Anafranil™** (clomipramine 25 mg, 50 mg and 75 mg capsules)	All of the following: • Documented intolerance to 1 generic formulation of Anafranil • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: amitryptline, amoxapine, bupropion SR/XL, citalopram, desvenlafaxine succinate ER, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, imipramine, nortriptyline, paroxetine, sertraline, venlafaxine ER
	Pamelor™ (nortriptyline 10 mg, 25 mg. 50 mg, and 75 mg capsules)	All of the following: • Documented intolerance to 1 generic formulation of Pamelor • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: amitryptline, amoxapine,bupropion SR/XL, citalopram, clomipramine, desvenlafaxine succinate ER, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, imipramine, paroxetine, sertraline, venlafaxine ER
	Tofranil™ (imipramine 10 mg, 25 mg, and 50 mg tablets)	All of the following: • Used for childhood enuresis in child 6 years and older Documented intolerance to 1 generic formulation of Tofranil
	Tofranil™ (imipramine 10 mg, 25 mg, and 50 mg tablets)	All of the following: • Documented intolerance to 1 generic formulation of Tofranil • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for (e.g., stabilized condition where therapeutic interchange is inappropriate) ONE of the following: amitryptline, amoxapine,bupropion SR/XL, citalopram, clomipramine, desvenlafaxine succinate ER, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, nortriptyline, paroxetine, sertraline, venlafaxine ER
Nonsteroidal Anti-inflammatory Drugs; Topical	**Diclofenac** 1.5% topical solution **Klofensaid II™** (diclofenac 1.5 % topical solution) **Pennsaid** (diclofenac 2 % topical solution)	All of the following: • Documented intolerance or inability to use diclofenac tablets or diclofenac delayed release tablets • Documented failure / inadequate response to diclofenac 1% topical gel or Voltaren® gel • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for THREE oral generic NSAIDs (for example celecoxib, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamate, meloxicam, nabumetone, naproxen, piroxicam, sulindac)
Vitamin D Analogs	**Hectorol®** (doxercalciferol 0.5 mcg capsules)	All of the following: • Documented intolerance to 1 generic formulation of Hectorol

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
		• Documented failure / inadequate response, intolerance, inability to use, or not a candidate for the following: paricalcitol
Asthma and Respiratory: Inhalers, Long Acting Anticholinergics	**Seebri™ Neohaler®** (glycopyrrolate) **Tudorza®** **Pressair®** (aclidinium)	All of the following: • Documented intolerance, failure / inadequate response, contraindication per FDA label, inability to use, or not a candidate for Incruse® Ellipta® (umeclidinium)
	Spiriva® HandiHaler® /Spiriva® Respimat® (tiotropium)	**Spiriva Handihaler and Spiriva Respimat <u>2.5 mcg/actuation</u>:** For COPD - Documented intolerance, failure / inadequate response, contraindication per FDA label, inability to use, or not a candidate for Incruse® Ellipta® (umeclidinium) **Spiriva Respimat <u>1.25 mcg/actuation</u>:** For the add-on treatment of uncontrolled asthma and **ALL** of the following: ▪ Individual is 6 years of age or older ▪ Documented failure/inadequate response, intolerance, contraindication per FDA label, inability to use, or not a candidate for a high-dose inhaled corticosteroid (ICS) <u>AND</u> another controller therapy such as a long-acting beta-agonist (LABA)
Asthma and Respiratory: Inhalers, Long-Acting Beta Agonists	**Striverdi® Respimat®** (olodaterol)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for Arcapta™ Neohaler® (indacaterol) and Serevent Diskus® (salmeterol)
Asthma and Respiratory: Inhalers, Glucocorticoids	**Aerospan™** (flunisolide) **Alvesco®** (ciclesonide) **Armonair™ Respiclick®** (fluticasone propionate) **Arnuity™ Ellipta®** (fluticasone) **Asmanex® / HFA** (mometasone)	All of the following: • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for Flovent® Diskus/HFA (fluticasone), Qvar®/Qvar® Redihaler™ (beclomethasone) AND Pulmicort Flexhaler™ (budesonide)
Asthma and Respiratory: Inhalers, Albuterol	**Proventil®** (albuterol sulfate 108 mcg / act aerosol solution) **Xopenex®**	All of the following: • Documented intolerance or inability to use ProAir® (albuterol sulfate 108 mcg / act aerosol solution), ProAir generic, or ProAir® Respiclick • Documented intolerance or inability to use Ventolin® (albuterol sulfate 108 mcg / act aerosol solution) or its authorized generic

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	(levalbuterol tartrate 45 mcg / act aerosol)	• Documented intolerance or inability to use levalbuterol 45mcg/act aerosol solution (authorized generic for Xopenex® HFA)
	Proair® Digihaler™ (albuterol sulfate 108 mcg / act inhalation powder)	All of the following: • Documented intolerance or inability to use ProAir® (albuterol sulfate 108 mcg / act aerosol solution), ProAir generic, or ProAir® Respiclick • Documented intolerance or inability to use Ventolin® (albuterol sulfate 108 mcg / act aerosol solution) or its authorized generic • Documented intolerance or inability to use levalbuterol 45mcg/act aerosol solution (authorized generic for Xopenex® HFA)
Respiratory, Asthma/COPD: Asthma combinations	**Advair Diskus®** (fluticasone / salmeterol)	All of the following: • Inability to obtain fluticasone/salmeterol (authorized generic for Advair Diskus®) • Documented intolerance or inability to use ALL of the following: o Wixela™ Inhub™ (fluticasone/salmeterol, AB-rated generic for Advair Diskus®) o Advair HFA (fluticasone/salmeterol) o Generic fluticasone/salmeterol aerosol powder (authorized generic for AirDuo™ Respiclick®) • Documented failure/inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for ONE of the following: o Breo® Ellipta (fluticasone/vilanterol) o Dulera (mometasone/formoterol) o Symbicort® (budesonide/formoterol)
	AirDuo™ RespiClick® (fluticasone/ salmeterol)	All of the following: • Inability to obtain fluticasone/salmeterol aerosol powder (authorized generic for AirDuo™ Respiclick®) • Documented intolerance or inability to use BOTH of the following: o fluticasone/salmeterol (authorized generic for Advair Diskus® or Wixela™ Inhub™) o Advair HFA • Documented failure/inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for TWO of the following: o Breo® Ellipta (fluticasone/vilanterol) o Dulera (mometasone/formoterol) o Symbicort® (budesonide/formoterol)
Asthma and Respiratory: Inhaled Beta-Adrenergic and Anticholinergic Combinations	**Bevespi Aerosphere™** (glycopyrrolate / formoterol) **Duaklir® Pressair®** (aclidinium bromide	All of the following: • Documented intolerance, failure / inadequate response, contraindication per FDA label, inability to use, or not a candidate for Anoro Ellipta (umeclidinium / vilanterol)

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	and formoterol fumarate) **Stiolto® Respimat®** (tiotropium / olodaterol) **Utibron™ Neohaler®** (indacaterol / glycopyrrolate)	
Asthma and Respiratory: Leukotriene modifiers	**Zyflo®** (zileuton 600 mg tablets) **Zyflo CR®** (zileuton 600 mg extended release tablets)	All of the following: • Documented intolerance to 1 generic formulation of Zyflo CR • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use or not a candidate for montelukast or zafirlukast
Asthma and Respiratory: Xanthine derivatives	**Elixophyllin** (theophylline 80 mg/15 ml solution)	All of the following: • Documented intolerance to 1 generic formulation of Elixophyllin solution • Inability to use theophylline extended release capsules or tablets

*Refer to General Background

General Background

A patient must document the failure of or intolerance to any Covered Alternative Drug(s) before Cigna will approve coverage for the identified drug. A "Covered Alternative Drug" is a drug or biologic in the same therapeutic class that can be expected to have equivalent clinical efficacy and safety when administered to patients under the conditions specified in the FDA-approved product information (Label). The number of Covered Alternative Drugs may vary by employer group plan and Prescription Drug Lists (e.g. "closed" versus "open" formulary plan designs).

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

Off Label Uses

The American Hospital Formulary Service supports the following off label uses:

- Mepron for the prevention or treatment of Toxoplasma gondii encephalitis (TE) in adults or adolescents
- Soriatane for the treatment of discoid lupus erythematosus (AHFS, 2017)

Fluticasone delivered via swallowed multi-dose inhaler formulation or swallowed budesonide aqueous solution are recommended for treatment of eosinophilic esophagitis by the American College of Gastroenterology guidelines for esophageal eosinophilia and eosinophilic esophagitis. No other topical steroid therapies are mentioned (Dellon, 2013).

References

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4. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.
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6. U.S Food and Drug Administration. Generic Drugs Questions and Answers: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm