



Cigna Drug and Biologic Coverage Policy

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

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INSTRUCTIONS FOR USE

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

Coverage Policy

Employer group plans 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 Value Prescription Drug List or Advantage Prescription Drug List

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
Anti-diuretic and vasopressor hormone agents	DDAVP [®] (desmopressin acetate 0.01% nasal solution)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of DDAVP
	Nocdurna [®] (desmopressin acetate sublingual tablet)	All of the following: <ul style="list-style-type: none"> • Individual is 18 years of age or older • Documented nocturnal polyuria confirmed by 24-hour urine collection

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		<ul style="list-style-type: none"> • Awakening 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
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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Diflucan
	Onmel® (itraconazole 200 mg tablets)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Sporanox
	Tolsura (itraconazole 65mg capsules)	Treatment of one of the following fungal infections: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Prevention or treatment of Pneumocystis jiroveci pneumonia (PCP) in adults or individuals 13 years of age and older <ul style="list-style-type: none"> ○ Documented intolerance to 1 generic formulation of Mepron AND ○ Documented intolerance to trimethoprim/sulfamethoxazole (TMP-SMX) • Prevention or treatment of Toxoplasma gondii encephalitis (TE) in adults or adolescents <ul style="list-style-type: none"> ○ Documented intolerance to 1 generic formulation of Mepron AND ○ Documented intolerance to 1 of the following: trimethoprim/sulfamethoxazole (TMP-SMX), pyrimethamine or sulfadiazine
Anti-infective agents: antivirals	Sitavig® (acyclovir 50 mg buccal tablet)	All of the following: <ul style="list-style-type: none"> • Documented diagnosis of recurrent herpes labialis • Documented inability to use acyclovir capsules and tablets
	Zovirax® (acyclovir 200 mg capsules, 400 mg and 800 mg)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Zovirax

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	tablets, 200 mg/5 ml suspension) Valcyte [®] (valganciclovir 450 mg tablets, 50 mg/ml solution)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Valcyte
Anti-infective agents: Macrolides	E.E.S. 200 (erythromycin ethylsuccinate 200 mg/5 ml suspension)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of E.E.S. 200
	EryPed 400 (erythromycin 400 mg/5 ml suspension)	All of the following: <ul style="list-style-type: none"> • 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: Penicillins	Augmentin [®] (125 mg amoxicillin /31.25mg clavulanate/5ml suspension, 250 mg amoxicillin / 62.5mg 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)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Augmentin
Anti-infective agents: Vancomycin and Derivatives	Vancocin [®] (Vancomycin 125 mg, 250 mg capsules)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Vancocin
Antimycobacterial agents	Mycobutin [®] (rifabutin)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Mycobutin (rifabutin)
Asthma and Respiratory: Inhalers, Albuterol	Proventil [®] (albuterol sulfate 108 mcg / act aerosol solution) and its authorized generic Ventolin [®] (albuterol sulfate 108 mcg / act aerosol solution) and	Both of the following: <ul style="list-style-type: none"> • 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 levalbuterol 45mcg/act aerosol solution (authorized generic for Xopenex HFA)

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	its authorized generic Xopenex® (levalbuterol tartrate 45 mcg / act aerosol) Proair® Digihaler™ (albuterol sulfate 108 mcg / act inhalation powder)	Both of the following: <ul style="list-style-type: none"> • 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 levalbuterol 45mcg/act aerosol solution (authorized generic for Xopenex HFA)
Asthma and Respiratory: Inhalers, Glucocorticoids	Aerospan™ (flunisolide) Alvesco® (ciclesonide) Armonair™ Respiclick® (fluticasone propionate) Arnuity™ Ellipta® (fluticasone) Asmanex® / HFA (mometasone) Pulmicort® Flexhaler™ (budesonide)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for Flovent® Diskus/HFA (fluticasone) AND Qvar®/Qvar® Redihaler™ (beclomethasone)
Asthma and Respiratory: Inhalers, Long Acting Anticholinergics	Seebri™ Neohaler® (glycopyrrolate) Tudorza® Pressair® (aclidinium) Spiriva® /Spiriva®Respimat® (tiotropium)	All of the following: <ul style="list-style-type: none"> • Documented intolerance, failure / inadequate response, contraindication per FDA label, inability to use, or not a candidate for Incruse® Ellipta® (umeclidinium) <p>Spiriva Handihaler and Spiriva Respimat 2.5 mcg/actuation: For COPD - Documented intolerance, failure / inadequate response, contraindication per FDA label, inability to use, or not a candidate for Incruse® Ellipta® (umeclidinium)</p> <p>Spiriva Respimat 1.25 mcg/actuation: For the add-on treatment of uncontrolled asthma and ALL of the following: <ul style="list-style-type: none"> ▪ 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) AND another controller therapy such as a long-acting beta-agonist (LABA) </p>

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Asthma and Respiratory: Inhalers, Long-Acting Beta Agonists	Arcapta™ Neohaler® (indacaterol) Striverdi® Respimat® (olodaterol)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for Serevent Diskus® (salmeterol)
Respiratory, Asthma/COPD: Asthma combinations	Advair Diskus® (fluticasone / salmeterol)	All of the following: <ul style="list-style-type: none"> • Inability to obtain fluticasone/salmeterol (authorized generic for Advair Diskus®) • Documented intolerance or inability to use ALL of the following: <ul style="list-style-type: none"> ○ Wixela™ Inhub™ (fluticasone/salmeterol, AB-rated generic for Advair Diskus®) ○ Advair HFA (fluticasone/salmeterol) ○ 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: <ul style="list-style-type: none"> ○ Breo® Ellipta (fluticasone/vilanterol) ○ Dulera (mometasone/formoterol) ○ Symbicort® (budesonide/formoterol)
	AirDuo™ RespiClick® (fluticasone/ salmeterol)	All of the following: <ul style="list-style-type: none"> • Inability to obtain fluticasone/salmeterol aerosol powder (authorized generic for AirDuo™ Respiclick®) • Documented intolerance or inability to use BOTH of the following: <ul style="list-style-type: none"> ○ fluticasone/salmeterol (authorized generic for Advair Diskus® or Wixela™ Inhub™) ○ Advair HFA • Documented failure/inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for TWO of the following: <ul style="list-style-type: none"> ○ Breo® Ellipta (fluticasone/vilanterol) ○ Dulera (mometasone/formoterol) ○ Symbicort® (budesonide/formoterol)
Asthma and Respiratory: Inhaled Beta-Adrenergic and Anticholinergic Combinations	Bevespi Aerosphere™ (glycopyrrolate / formoterol) Duaklir® Pressair® (aclidinium bromide and formoterol fumarate) Stiolto® Respimat® (tiotropium / olodaterol) Utibron™ Neohaler® (indacaterol / glycopyrrolate)	All of the following: <ul style="list-style-type: none"> • Documented intolerance, failure / inadequate response, contraindication per FDA label, inability to use, or not a candidate for Anoro® Ellipta® (umeclidinium / vilanterol)

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Asthma and Respiratory: Leukotriene modifiers	Zyflo® (zileuton 600 mg tablets) Zyflo CR® (zileuton 600 mg extended release tablets)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Elixophyllin solution • Inability to use theophylline extended release capsules or tablets
Cardiovascular: Antithrombotic Agents	Yospira™ (aspirin delayed release / omeprazole 81 mg – 40 mg tablets and 325 – 40 mg tablets)	All of the following: <ul style="list-style-type: none"> • Individual is at risk of developing aspirin associated gastric ulcers defined as either of the following <ul style="list-style-type: none"> ○ 55 years of age or older ○ Documented history of gastric ulcers • Individual requires aspirin for secondary prevention of cardiovascular and cerebrovascular events defined as one of the following: <ul style="list-style-type: none"> ○ Previous ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli ○ Previous myocardial infarction or unstable angina pectoris ○ Chronic stable angina pectoris ○ 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented inability to use or intolerance to one-half or one and one-half tablets of digoxin 125 mcg tablets
Cardiovascular: Renin Inhibitors	Accupril® (quinapril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Accupril • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, enalapril, fosinopril, lisinopril, ramipril,trandolapril

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	Accuretic® (quinapril / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Accuretic • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril / hydrochlorothiazide, captopril / hydrochlorothiazide, enalapril / hydrochlorothiazide, fosinopril / hydrochlorothiazide, lisinopril / hydrochlorothiazide • Documented inability to use quinapril and hydrochlorothiazide concurrently
	Aceon® (perindopril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Aceon • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, trandolapril
	Altace® (ramipril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Altace • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, trandolapril
	Atacand® (candesartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Atacand • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: irbesartan, losartan, olmesartan, telmisartan, valsartan
	Atacand® HCT (candesartan / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Atacand HCT • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: irbesartan / hydrochlorothiazide, losartan / hydrochlorothiazide, olmesartan / hydrochlorothiazide, telmisartan / hydrochlorothiazide, valsartan / hydrochlorothiazide • Documented inability to use candesartan and hydrochlorothiazide concurrently
	Avapro® (irbesartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Avapro • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan, losartan, olmesartan, telmisartan, valsartan
	Azor® (amlodipine / olmesartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Azor • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: amlodipine / benazepril, amlodipine / telmisartan, amlodipine / valsartan • Documented inability to use olmesartan and amlodipine concurrently

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	Benicar® (olmesartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Benicar • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan, irbesartan, losartan, telmisartan, valsartan
	Benicar HCT® (olmesartan / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Benicar HCT • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan / hydrochlorothiazide, irbesartan / hydrochlorothiazide, losartan / hydrochlorothiazide, telmisartan / hydrochlorothiazide, valsartan / hydrochlorothiazide • Documented inability to use olmesartan and hydrochlorothiazide concurrently
	Cozaar® (losartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Cozaar • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan, irbesartan, olmesartan, telmisartan, valsartan
	Diovan® (valsartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Diovan • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan, irbesartan, losartan, olmesartan, telmisartan
	Diovan HCT® (valsartan / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Diovan HCT • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan / hydrochlorothiazide, irbesartan / hydrochlorothiazide, losartan / hydrochlorothiazide, olmesartan / hydrochlorothiazide, telmisartan / hydrochlorothiazide • Documented inability to use valsartan and hydrochlorothiazide concurrently
	Edarbi (azilsartan)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for FIVE of the following: candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan
	Edarbyclor (azilsartan / chlorthalidone)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for FIVE of the following: candesartan / hydrochlorothiazide, irbesartan / hydrochlorothiazide, losartan / hydrochlorothiazide, olmesartan / hydrochlorothiazide, telmisartan / hydrochlorothiazide, valsartan / hydrochlorothiazide

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	Exforge® (amlodipine / valsartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Exforge • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: amlodipine / benazepril, amlodipine / olmesartan, amlodipine / telmisartan • Documented inability to use valsartan and amlodipine concurrently
	Exforge HCT® (amlodipine / hydrochlorothiazide / valsartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Exforge HCT • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for FOUR of the following: <ul style="list-style-type: none"> ○ generic Azor (amlodipine / olmesartan) and hydrochlorothiazide concurrently ○ generic Benicar HCT (olmesartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Tribenzor (amlodipine / hydrochlorothiazide / valsartan) ○ generic Diovan HCT (valsartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Exforge (amlodipine / valsartan) and hydrochlorothiazide concurrently ○ generic Avalide (irbesartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Atacand HCT (candesartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Accuretic (quinapril / hydrochlorothiazide) and amlodipine concurrently
	Hyzaar® (losartan / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Hyzaar • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan / hydrochlorothiazide, irbesartan / hydrochlorothiazide, olmesartan / hydrochlorothiazide, telmisartan / hydrochlorothiazide, valsartan / hydrochlorothiazide • Documented inability to use losartan and hydrochlorothiazide concurrently
	Lotensin® (benazepril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Lotensin • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril,trandolapril

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	Lotensin HCT® (benazepril / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Lotensin HCT • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: captopril / hydrochlorothiazide, enalapril / hydrochlorothiazide, fosinopril / hydrochlorothiazide, lisinopril / hydrochlorothiazide, quinapril / hydrochlorothiazide • Documented inability to use benazepril and hydrochlorothiazide concurrently
	Lotrel® (amlodipine / benazepril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Lotrel • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: amlodipine / olmesartan, amlodipine / telmisartan, amlodipine / valsartan • Documented inability to use benazepril and amlodipine concurrently
	Mavik® (trandolapril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Mavik • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril
	Micardis® (telmisartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Micardis • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan, irbesartan, losartan, olmesartan, valsartan
	Micardis® HCT (telmisartan / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Micardis HCT • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: candesartan / hydrochlorothiazide, irbesartan / hydrochlorothiazide, losartan / hydrochlorothiazide, olmesartan / hydrochlorothiazide, valsartan / hydrochlorothiazide • Documented inability to use telmisartan and hydrochlorothiazide concurrently
	Prinivil® (lisinopril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Prinivil • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, enalapril, fosinopril, quinapril, ramipril, trandolapril
	Tekturna® (aliskiren)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, intolerance, or not a candidate for FIVE of the following: benazepril, captopril, enalapril, fosinopril, lisinopril, quinapril, ramipril, trandolapril, candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan

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	Tekturna® HCT (aliskiren / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, intolerance, or not a candidate for FIVE of the following: benazepril / hydrochlorothiazide, captopril / hydrochlorothiazide, enalapril / hydrochlorothiazide, fosinopril / hydrochlorothiazide, lisinopril / hydrochlorothiazide, quinapril / hydrochlorothiazide, candesartan / hydrochlorothiazide, irbesartan / hydrochlorothiazide, losartan / hydrochlorothiazide, olmesartan / hydrochlorothiazide, telmisartan / hydrochlorothiazide, valsartan / hydrochlorothiazide
	Tarka® (trandolapril / verapamil)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Tarka • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for amlodipine / benazepril • Documented inability to use trandolapril and verapamil concurrently
	Tribenzor® (amlodipine / hydrochlorothiazide / olmesartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Tribenzor • Documented failure / inadequate response, contraindication per FDA label, intolerance, inability to use, or not a candidate for FOUR of the following: <ul style="list-style-type: none"> ○ generic Azor (amlodipine / olmesartan) and hydrochlorothiazide concurrently ○ generic Benicar HCT (olmesartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Diovan HCT (valsartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Exforge (amlodipine / valsartan) and hydrochlorothiazide concurrently ○ generic Exforge HCT (amlodipine / hydrochlorothiazide / valsartan) ○ generic Avalide (irbesartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Atacand HCT (candesartan / hydrochlorothiazide) and amlodipine concurrently ○ generic Accuretic (quinapril / hydrochlorothiazide) and amlodipine concurrently
	Twynsta® (amlodipine / telmisartan)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Twynsta • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: amlodipine / benazepril, amlodipine / olmesartan, amlodipine / valsartan • Documented inability to use telmisartan and amlodipine concurrently
	Vaseretic® (enalapril / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Vaseretic • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril / hydrochlorothiazide, captopril / hydrochlorothiazide,

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		fosinopril / hydrochlorothiazide, lisinopril / hydrochlorothiazide, quinapril / hydrochlorothiazide <ul style="list-style-type: none"> • Documented inability to use enalapril and hydrochlorothiazide concurrently
	Vasotec® (enalapril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Vasotec • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, fosinopril, lisinopril, quinapril, ramipril, trandolapril
	Zestoretic® (lisinopril / hydrochlorothiazide)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Zestoretic • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril / hydrochlorothiazide, captopril / hydrochlorothiazide, enalapril / hydrochlorothiazide, fosinopril / hydrochlorothiazide, quinapril / hydrochlorothiazide • Documented inability to use lisinopril and hydrochlorothiazide concurrently
	Zestril® (lisinopril)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Zestril • Documented failure / inadequate response, intolerance, or not a candidate for FOUR of the following: benazepril, captopril, enalapril, fosinopril, quinapril, ramipril, trandolapril
Cardiovascular: Vasodilators	Cardizem (diltiazem 30 mg, 60 mg, and 120 mg tablets)	All of the following: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Verapamil 40 mg, 80 mg, and 120 mg tablets ○ Diltiazem CD extended release capsules ○ 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: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ Verapamil extended release tablets ○ Verapamil extended release capsules ○ Diltiazem extended release tablets
	GoNitro™ (nitroglycerin sublingual powder)	All of the following: <ul style="list-style-type: none"> • Documented intolerance or inability to use nitroglycerin sublingual tablets and nitroglycerin sublingual spray
	Isordil® (isosorbide dinitrate 40 mg tablet)	All of the following: <ul style="list-style-type: none"> • Documented inability to use two tablets of isosorbide dinitrate 20 mg tablets
	Isordil® Titradose™ (isosorbide dinitrate 5 mg tablet)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Isordil Titradose 5 mg tablets

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
Cholesterol Lowering	Antara® (fenofibrate 30 mg and 90 mg capsules)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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®)
Dermatologic: Actinic Keratosis, Topical	Solaraze, Diclofenac 3% topical gel	All of the following: <ul style="list-style-type: none"> • Diagnosis of actinic keratosis • Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: <ul style="list-style-type: none"> ○ 5-fluorouracil cream (fluorouracil 0.5%, Fluoroplex 1%, Tolak 4%, Efudex 5%) ○ 5-fluorouracil solution (2% or 5%) ○ Imiquimod 5% cream ○ Picato (ingenol) 0.015% or 0.05% gel
Dermatologic: Steroidal Anti-inflammatory, Topical	Clobex® (clobetasol 0.05 % lotion, liquid spray, shampoo)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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
	Lexette (halobetasol propionate 0.05% foam)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ betamethasone dipropionate, augmented 0.05 % (gel, lotion and ointment) ○ clobetasol propionate 0.05 % (cream, foam, gel, lotion, ointment, shampoo, solution, spray) ○ diflorasone diacetate 0.05% (ointment) ○ fluocinonide 0.1% (cream) ○ halobetasol propionate 0.05 % (cream and ointment)
	Locoid® (hydrocortisone butyrate 0.1 % cream, lipocream, lotion, ointment, solution)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response or intolerance to hydrocortisone butyrate 0.1 % solution, ointment, cream, and lipid cream

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Kenalog® (triamcinolone acetonide 0.147 mg / gm aerosol solution)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Kenalog • 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented failure / inadequate response or intolerance to FIVE of the following: <ul style="list-style-type: none"> ○ halobetasol propionate 0.05 % cream ○ halobetasol propionate 0.05 % ointment ○ clobetasol propionate 0.05 % cream ○ clobetasol propionate 0.05 % lotion ○ clobetasol propionate 0.05 % ointment ○ betamethasone dipropionate, augmented 0.05 % ointment ○ betamethasone dipropionate, augmented 0.05 % lotion
	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® (hydrocortisone 30 mg suppository)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, intolerance, or not a candidate for ALL of the following <ul style="list-style-type: none"> ○ hydrocortisone 1 % or 2.5 % rectal cream ○ hydrocortisone 100 mg / 60 ml rectal enema ○ hydrocortisone acetate 25 mg or 30 mg rectal suppository
Dermatologic: Steroidal Anti-inflammatory, Topical	Verdeso® (desonide 0.05 % foam) Halog	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, or intolerance to fluocinolone body oil, fluticasone lotion, and topical hydrocortisone

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	(halcinonide 0.1% cream)	<ul style="list-style-type: none"> 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)	<p>All of the following:</p> <ul style="list-style-type: none"> 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)	<p>All of the following:</p> <p>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</p>
	Sernivo™ (betamethasone dipropionate 0.05 % emulsion)	<p>All of the following:</p> <ul style="list-style-type: none"> Documented failure / inadequate response, intolerance, or not a candidate for FIVE of the following: <ul style="list-style-type: none"> betamethasone dipropionate 0.05 % ointment betamethasone dipropionate 0.05 % cream betamethasone dipropionate 0.05 % lotion augmented betamethasone dipropionate 0.05 % gel betamethasone valerate 0.12 % foam
	Vanos® (fluocinonide 0.1 % cream)	<p>All of the following:</p> <ul style="list-style-type: none"> 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
Dermatologic: Anti-psoriatics	Dovonex® (calcipotriene 0.005% cream) Sorilux™ (calcipotriene 0.005% foam) Vectical (calcitriol 3 mcg/Gm ointment)	<p>All of the following:</p> <ul style="list-style-type: none"> Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: calcipotriene cream, ointment, solution Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for tazarotene cream
	Enstilar® (calcipotriene 0.005% / betamethasone 0.064% foam) Taclonex® (calcipotriene 0.005% / betamethasone 0.064% ointment and suspension)	<p>All of the following:</p> <ul style="list-style-type: none"> Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ONE of the following: calcipotriene cream, ointment, solution Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for tazarotene cream Inability to use calcipotriene and betamethasone components separately
Dermatologic: Acne Agents, Systemic	Absorica® (isotretinoin 10 mg, 20 mg, 25 mg, 30	<p>All of the following:</p> <ul style="list-style-type: none"> 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

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	mg, 35 mg, and 40 mg capsules)	Zenatane™ (isotretinoin 10 mg, 20 mg, 30 mg, and 40 mg capsules)
Dermatologic: Acne Agents, Topical	Tazorac® (tazarotene 0.05% cream, gel)	All of the following: <ul style="list-style-type: none"> • 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: Antineoplastics, Topical	Aldara® (imiquimod 5 % cream)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Aldara • One of the following: <ul style="list-style-type: none"> ○ For actinic keratosis: Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: <ul style="list-style-type: none"> ▪ 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 ○ 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) ○ For external genital and perianal warts (<i>Condylomata acuminata</i>): Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: <ul style="list-style-type: none"> ▪ podofilox 0.5% (solution, Condylox gel) ▪ Veregen (sinecatechins) 15% ointment
	Zyclara® (imiquimod 2.5 % cream pump)	All of the following: <ul style="list-style-type: none"> • Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: <ul style="list-style-type: none"> ○ 5-fluorouracil cream (fluoracil 0.5% cream, Fluoroplex 1%, Tolak 4%, Efudex 5%) ○ 5-fluorouracil solution (2% or 5%) ○ imiquimod 5% cream ○ Picato (ingenol) 0.015% or 0.05% gel
	Zyclara® (imiquimod 3.75 % cream pump, and 3.75 % cream)	One of the following: <ul style="list-style-type: none"> • For actinic keratosis: Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: <ul style="list-style-type: none"> ○ 5-fluorouracil cream (fluorouracil 0.5% cream, Fluoroplex 1%, Tolak 4%, Efudex 5%) ○ 5-fluorouracil solution (2% or 5%) ○ imiquimod 5% cream ○ Picato (ingenol) 0.015% or 0.05% gel • For external genital and perianal warts (<i>Condylomata acuminata</i>): Documented failure or inadequate response, contraindication per FDA label, intolerance or not a candidate for ALL of the following topical therapies: <ul style="list-style-type: none"> ○ imiquimod 5% cream ○ podofilox 0.5% (solution, Condylox gel) ○ Veregen (sinecatechins) 15% ointment

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Carac® (fluorouracil 0.5 % cream)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ 5-fluorouracil cream (Fluoroplex 1%, Tolak 4%, Efudex 5%) ○ 5-fluorouracil solution (2% or 5%) ○ imiquimod 5% cream ○ 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: <ul style="list-style-type: none"> • Documented diagnosis of severe psoriasis <ul style="list-style-type: none"> ○ Documented intolerance to 1 generic formulation of Soriatane ○ 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 <ul style="list-style-type: none"> ○ Documented intolerance to 1 formulation of Soriatane ○ Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for hydroxychloroquine
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: <ul style="list-style-type: none"> • 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: Local anesthetics, topical	Lidocaine 3% lotion Lido-K (lidocaine 3% lotion)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response or intolerance to use both lidocaine 3 % cream and lidocaine 5 % ointment
Diabetes: Non-insulins (extended release metformin)	Fortamet® (metformin extended release tablets) Glumetza® (metformin extended release tablets) Metformin ER osmotic tablets (Fortamet®)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to metformin ER (Glucophage® XR)

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Metformin ER tablets (Glumetza®)	
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: <ul style="list-style-type: none"> Documented contraindication per FDA label, intolerance, or inability to use Humalog® (insulin lispro)
	Novolog ® (insulin aspart) Fiasp ® (insulin aspart)	All of the following: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Documented contraindication per FDA label, intolerance, or inability to use Humulin® 70/30
	Novolin N ® (insulin, NPH human recombinant isophane)	All of the following: <ul style="list-style-type: none"> Documented contraindication per FDA label, intolerance, or inability to use Humulin® N
	Novolin R ® (insulin, regular, human recombinant)	All of the following: <ul style="list-style-type: none"> Documented contraindication per FDA label, intolerance, or inability to use Humulin® R
Diabetes: Test Strips	AccuCheck ® Contour ® Freestyle ® All other test strips	All of the following: <ul style="list-style-type: none"> 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)
Eye anti-histamines	Alocri ® (nedocromil 2% ophthalmic solution)	All of the following: <ul style="list-style-type: none"> Documented failure / inadequate response, intolerance, or not a candidate for cromolyn ophthalmic solution
	Alomide ® (lodoxamide 0.1% ophthalmic solution)	
	Bepreve ® (bepotastine 0.5% ophthalmic solution) Emadine ® (emedastine 0.05% ophthalmic solution) Lastacaft ® (alcaftadine 0.25% ophthalmic solution)	All of the following: <ul style="list-style-type: none"> Documented failure / inadequate response, intolerance, or not a candidate for ALL of the following: azelastine ophthalmic solution, epinastine ophthalmic solution, AND olopatadine 0.1% or 0.2% ophthalmic solutions

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	Pazeo [®] (olopatadine 0.7% ophthalmic solution)	
	Elestat [®] (epinastine 0.05% ophthalmic solution)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Elestat • Documented failure / inadequate response, intolerance, or not a candidate for ALL of the following: azelastine, and olopatadine 0.1% or 0.2% ophthalmic solution
	Pataday [™] (olopatadine 0.2% ophthalmic solution)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Pataday • Documented failure / inadequate response, intolerance, or not a candidate for ALL of the following: azelastine AND epinastine ophthalmic solutions
	Patanol [®] (olopatadine 0.1% ophthalmic solution)	All of the following: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Patanol • Documented failure / inadequate response, intolerance, or not a candidate for ALL of the following: azelastine AND epinastine ophthalmic solutions
Gastrointestinal Agents: Anticholinergic combinations	Librax [®] (chlordiazepoxide / clidinium bromide 5 mg – 2.5 mg capsules)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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
	Prevpac [®] (amoxicillin / clarithromycin / lansoprazole 500 mg – 500 mg – 30 mg)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 inability to 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: <ul style="list-style-type: none"> • 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

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
		solution), nizatidine (capsule or solution), and ranitidine (tablet, capsule, and syrup)
Gastrointestinal Agents: Anti-inflammatory	Asacol® HD (mesalamine)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for 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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Rowasa • Documented failure / inadequate response, intolerance or inability to use Canasa
	Metozolv® ODT (metoclopramide 5 mg orally disintegrating tablets)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Lotronex • Documented failure / inadequate response, contraindication per FDA label, intolerance or not a candidate for FOUR of the following: clindinium/ chlordiazepoxide, dicyclomine, eluxadolone, hyoscyamine, rifaximin
Hormones: adrenal corticosteroids	Rayos® (prednisone 1 mg, 2 mg, and 5 mg delayed release tablets)	All of the following: <ul style="list-style-type: none"> • 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
	Dexpak® (dexamethasone 1.5 mg tablets) Dxevo 11-Day Dose Pack (dexamethasone 1.5 mg tablets)	All of the following: <ul style="list-style-type: none"> • 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

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	<p>TaperDex 12 Day and 6 Day (dexamethasone 1.5 mg tablets)</p> <p>ZonaCort 7 Day and 11 Day (dexamethasone 1.5 mg tablets)</p> <p>ZoDex 6-Day and 12-Day (dexamethasone 1.5 mg tablets)</p>	<ul style="list-style-type: none"> Documented failure / inadequate response, contraindication per FDA label, or intolerance to hydrocortisone and methylprednisolone tablets
Nonsteroidal Anti-inflammatory Drugs; Topical	<p>Diclofenac 1.5 % topical solution</p> <p>Klofensaid II™ (diclofenac 1.5 % topical solution)</p> <p>Pennsaid (diclofenac 2 % topical solution)</p>	<p>All of the following:</p> <ul style="list-style-type: none"> 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 (ex. celecoxib, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketoprofen, meclofenamate, meloxicam, nabumetone, naproxen, piroxicam, sulindac)
Psychotherapeutic Drugs: Atypical Antipsychotics	<p>Abilify® (aripiprazole)</p> <p>Fazaclo® (clozapine 12.5 mg, 25 mg, 100 mg, 150 mg, and 200 mg dispersible tablets)</p> <p>Versacloz® (clozapine 50 mg / ml suspension)</p> <p>Geodon® (ziprasidone 20 mg, 40 mg, 60 mg, and 80 mg capsules)</p> <p>Zyprexa® (olanzapine 2.5mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20mg tablets)</p> <p>Zyprexa Zydis® (olanzapine 5 mg, 10 mg, 15 mg, 20 mg orally disintegrating tablets)</p>	<p>All of the following:</p> <ul style="list-style-type: none"> Documented intolerance to 1 generic formulation of Abilify <p>All of the following:</p> <ul style="list-style-type: none"> 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 <p>All of the following:</p> <ul style="list-style-type: none"> Documented intolerance to 1 generic formulation of Geodon <p>All of the following:</p> <ul style="list-style-type: none"> Documented intolerance to 1 generic formulation of Zyprexa <p>All of the following:</p> <ul style="list-style-type: none"> Documented intolerance 1 generic formulation of Zyprexa Zydis
Psychotherapeutic Drugs: Benzodiazepines	<p>Ativan® (lorazepam)</p>	<p>All of the following:</p> <ul style="list-style-type: none"> Documented intolerance to 1 generic formulation of Ativan Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Restoril™ (temazepam 7.5 mg, 15 mg, 22.5mg, 30mg capsules)	candidate for TWO of the following: alprazolam, clonazepam, diazepam, oxazepam, temazepam All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Mysoline
	Parnate® (tranylcypromine sulfate 10 mg tablets)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 <p>Note: receipt of samples does not satisfy criteria requirements for coverage</p>
	Wellbutrin XL® (bupropion 150 mg and 300 mg extended release tablets)	All of the following: <ul style="list-style-type: none"> • 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, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine <p>Note: receipt of samples does not satisfy criteria requirements for coverage</p>
Psychotherapeutic Drugs: SNRIs	Cymbalta® (duloxetine delayed release capsules)	All of the following: <ul style="list-style-type: none"> • 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

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	<p>Pristiq® (desvenlafaxine succinate 25 mg, 50 mg, and 100 mg extended release tablets)</p>	<p>ER, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine ER</p> <p>All of the following:</p> <ul style="list-style-type: none"> • Documented intolerance to 1 generic formulation of Pristiq • 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, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine ER <p>Note: receipt of samples does not satisfy criteria requirements for coverage</p>
<p>Psychotherapeutic Drugs: SSRIs</p>	<p>Lexapro® (escitalopram tablets)</p>	<p>All of the following:</p> <ul style="list-style-type: none"> • 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 <p>Note: receipt of samples does not satisfy criteria requirements for coverage</p>
	<p>Pexeva® (paroxetine mesylate 10 mg, 20 mg, 30 mg, and 40 mg tablets)</p>	<p>All of the following:</p> <ul style="list-style-type: none"> • 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: bupropion SR/XL, citalopram, desvenlafaxine succinate ER, duloxetine, escitalopram, fluoxetine, fluvoxamine, sertraline, venlafaxine ER <p>Note: receipt of samples does not satisfy criteria requirements for coverage</p>
<p>Psychotherapeutic Drugs: Tricyclic antidepressants</p>	<p>Anafranil™ (clomipramine 25 mg, 50 mg and 75 mg capsules)</p>	<p>All of the following:</p> <ul style="list-style-type: none"> • 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: amitriptyline, amoxapine, bupropion SR/XL, citalopram, desvenlafaxine succinate ER, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, imipramine, nortriptyline, paroxetine, sertraline, venlafaxine ER

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
	Pamelor™ (nortriptyline 10 mg, 25 mg, 50 mg, and 75 mg capsules)	All of the following: <ul style="list-style-type: none"> • 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: amitriptyline, 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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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: amitriptyline, amoxapine, bupropion SR/XL, citalopram, clomipramine, desvenlafaxine succinate ER, doxepin, duloxetine, escitalopram, fluoxetine, fluvoxamine, nortriptyline, paroxetine, sertraline, venlafaxine ER
Renal and Genitourinary Agents	Gelnique 10% gel (oxybutynin chloride metered-dose pump, sachet) Myrbetriq® (mirabegron) Toviaz® (fesoterodine) Vesicare® (solifenacin)	All of the following: <ul style="list-style-type: none"> • Documented failure / inadequate response, contraindication per FDA label, intolerance, or not a candidate for ALL of the following: darifenacin ER, oxybutynin, tolterodine and trospium
	Detrol® / Detrol LA® (tolterodine)	All of the following: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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:

Therapeutic Category	Drug or Biologic	Clinical Coverage Criteria / Covered Alternative Drug
		<ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> Documented inability to use oxybutynin syrup, extended release tablets or tablets
Rosacea agents: Topical	Noritate (metronidazole 1 % cream)	All of the following: <ul style="list-style-type: none"> Documented failure / inadequate response or inability to use metronidazole 0.75 % cream, metronidazole 0.75 % lotion, metronidazole 0.75 % gel, and metronidazole 1 % gel
Vitamin D analogs	Hectorol® (doxercalciferol 0.5 mcg capsules)	All of the following: <ul style="list-style-type: none"> Documented intolerance to 1 generic formulation of Hectorol Documented failure / inadequate response, intolerance, inability to use, or not a candidate for the following: paricalcitol

*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 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).

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4. Individual Drug Name Entries. Drug Facts and Comparisons. Facts & Comparisons® eAnswers [online]. Available from Wolters Kluwer Health, Inc. Accessed July, 2017.
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6. 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/abbreviatednewdrugapplicationandagenerics/ucm126389.htm>
7. U.S Food and Drug Administration. Generic Drugs Questions and Answers: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100>.

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