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Coverage Policy Number	1602

Drugs/Biologics Not Covered Unless Approved Under Medical Necessity Review

Employer Group Plans: Value, Advantage, or Cigna Total Savings Prescription Drug List

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Related Coverage Resources

INSTRUCTIONS FOR USE

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

Overview

This policy supports employer group plan Prescription Drug Lists that require medical necessity exceptions for non-covered drugs.

Coverage for varies across plans and requires the use of preferred products in addition to the criteria listed below. Refer to the customer's benefit plan document for coverage details.

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

Coverage Policy

Non-covered drugs are considered medically necessary when the following criteria are met: (1) where an A-rated generic is available and (2) for covered alternatives

 Documentation that individual has tried the bioequivalent generic product AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives]
 Page 1 of 33 between the brand and the bioequivalent generic product which, per the prescribing physician, would result in a significant allergy or serious adverse reaction.

- 2. When there is documentation of **ONE** of the following:
 - a. The individual has had inadequate efficacy to the number of covered alternatives according to the table below
 - OR
 - b. The individual has a contraindication according to FDA label, significant intolerance, or is not a candidate* for ALL the covered alternatives according to the table below

*<u>Note</u>: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation)

Employer Group Non-Covered Products and Preferred Covered Alternatives:

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Acne Vulgaris Agents (Topical)	Cabtreo (clindamycin	EFFECTIVE 5/15/2024
	phosphate, adapalene and benzoyl peroxide topical gel)	 Cabtreo is considered medically necessary when the patient meets BOTH of the following (1 and 2): 1. Patient has concomitantly used ALL three of the following products: a. a topical benzoyl peroxide product b. a topical tretinoin-containing or adapalene-containing product c. a topical clindamycin-containing product; AND 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to continue to use the products in criterion [1]
Angiotensin Converting Enzyme (ACE) Inhibitors	Qbrelis (lisinopril oral solution)	Documented inability to swallow lisinopril tablets
Antibiotics (Oral)	Firvanq®	EFFECTIVE 7/1/2024
	(vancomycin oral solution)	 Firvanq is considered medically necessary when there is documentation of ONE of the following: 1. Failure or intolerance to ONE of the following: a. vancomycin capsules b. vancomycin 50 mg/mL oral solution Inability to swallow generic vancomycin capsules AND failure or intolerance to vancomycin 50 mg/mL oral solution
	Vancomycin 25 mg/mL oral	EFFECTIVE 7/1/2024
	solution (generic for Firvanq)	 Vancomycin oral solution is considered medically necessary when there is documentation of ONE of the following: 1. Failure or intolerance to ONE of the following: a. vancomycin capsules b. vancomycin 50 mg/mL oral solution Inability to swallow generic vancomycin capsules AND failure or intolerance to vancomycin 50 mg/mL oral solution

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Likmez™ (metronidazole oral suspension)	 Likmez is considered medically necessary when the individual meets of ONE of the following: 1. Failure, contraindication, or intolerance to metronidazole tablets 2. Inability to swallow tablets
	Solosec [®] (secnidazole oral granules)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to TWO of the following: a. clindamycin capsules b. metronidazole tablets c. tinidazole tablets 2. Treatment of trichomoniasis AND failure, contraindication, or intolerance to ONE of the following: a. metronidazole tablets b. tinidazole tablets 3. Inability to swallow tablets and capsules
Anti-diuretic and vasopressor hormone agents	DDAVP [®] (desmopressin acetate 0.01% nasal solution)	 BOTH of the following: desmopressin nasal solution (generic for DDAVP) desmopressin tablets
Antiepileptics	Primidone 125 mg oral tablet	Documented inability to achieve desired dose with generic primidone 50 mg or 250 mg oral tablets
Antihistamines (Oral)	Karbinal [®] ER (carbinoxamine maleate extended- release oral suspension)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to ALL of the following: a. carbinoxamine b. cetirizine c. clemastine 2.86 mg tablets d. hydroxyzine 2. Inability to swallow tablets and capsules AND failure, contraindication, or intolerance to BOTH of the following: a. carbinoxamine syrup b. hydroxyzine solution
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 BOTH of the following: atovaquone oral suspension (generic for Mepron) trimethoprim/ sulfamethoxazole (TMP-SMX) Prevention or treatment of Toxoplasma gondii encephalitis (TE) in adults or adolescents BOTH of the following: atovaquone oral suspension (generic for Mepron) ONE of the following: atovaquone oral suspension (generic for Mepron) ONE of the following: trimethoprim/sulfamethoxazole (TMP-SMX) pyrimethamine sulfadiazine
Anti-infective agents: antivirals	Sitavig [®] (acyclovir 50 mg buccal tablet)	 BOTH of the following: Documented diagnosis of recurrent herpes labialis Documented inability to use acyclovir capsules and tablets

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Anti-infective agents: Macrolides	EryPed 400 (erythromycin 400 mg/5 ml suspension)	 BOTH of the following: erythromycin suspension (generic for EryPed) erythromycin ethylsuccinate 400 mg tablets
Anti-infective agents: Miscellaneous	Nitrofurantoin 50 mg/5 mL oral suspension	Documentation of failure, contraindication, or intolerance to nitrofurantoin 25 mg/5 mL oral suspension
Anti-infective agents: Topical antibiotics	Mupirocin 2% cream	Documented failure, contraindication, or intolerance to mupirocin 2% ointment
Anti-parasitic agents	Xdemvy™ (lotilaner 0.25% ophthalmic solution)	Xdemvy (lotilaner 0.25% ophthalmic solution)is considered medically necessary for the treatment of Demodex blepharitis.
Anti-Parkinson Agents	Dhivy (carbidopa/levodo pa 25-100 mg oral tablet)	 ALL of the following criteria: 1. Documented diagnosis of ONE of the following: a. Parkinson's disease b. Postencephalitic Parkinsonism c. Symptomatic Parkinsonism 2. Medication is prescribed by, or in consultation with, a neurologist 3. Documented inability to achieve desired dose with carbidopalevodopa tablets (generic for Sinemet)
Asthma and Respiratory: Inhalers, Corticosteroid/ Beta - Agonist Combination Inhalers	Airsupra™ (albuterol and budesonide inhalation aerosol)	 Airsupra is considered medically necessary when the following are met: As-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations. Individual meets ALL of the following criteria: Age 18 years and older Documented diagnosis of asthma Documentation of failure, contraindication, or intolerance to ONE of the following: Dulera (mometasone/ formoterol) budesonide/ formoterol (generic for Symbicort) Documentation of failure, contraindication, or intolerance to one albuterol-containing inhaler (for example, ProAir HFA, Proventil HFA, albuterol HFA, Ventolin HFA) OR levalbuterol-containing inhaler (for example, Xopenex HFA and levalbuterol HFA) taken concomitantly with one single-entity inhaled corticosteroid (Alvesco, ArmonAir Digihaler, Arnuity Ellipta, Asmanex HFA, Pulmicort Flexhaler, Rovar RediHaler)
Asthma and Respiratory: Inhalers, Glucocorticoids	ArmonAir® Digihaler™ (fluticasone)	 ONE of the following: 1. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		 Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: Alvesco[®] (ciclesonide) Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is unable to coordinate breath and actuation with a conventional metered-dose inhaler and documented failure, contraindication, or intolerance to BOTH of the following: Asmanex[®] Twisthaler (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
	Arnuity[™] Ellipta[®] (fluticasone)	 ONE of the following: 1. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: Alvesco[®] (ciclesonide) Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is unable to coordinate breath and actuation with a conventional metered-dose inhaler and documented failure, contraindication, or intolerance to BOTH of the following: Asmanex[®] Twisthaler (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
	Flovent [®] Diskus (fluticasone)	 ONE of the following: 1. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: Alvesco[®] (ciclesonide) Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is unable to coordinate breath and actuation with a conventional metered-dose inhaler and documented failure, contraindication, or intolerance to BOTH of the following: Asmanex[®] Twisthaler (mometasone) Qvar[®] Redihaler[™] (beclomethasone)

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Flovent HFA (fluticasone)	ONE of the following: 1. Individual has eosinophilic esophagitis
		2. Individual is less than 4 years of age
		 Individual is 4 years of age to less than 6 years of age and has a low inspiratory flow rate and is unable to use a dry powder inhaler and documented failure, contraindication, or intolerance to Qvar[®] Redihaler[™] (beclomethasone)
		 4. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)
		 5. Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: a. Alvesco[®] (ciclesonide) b. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) c. Qvar[®] Redihaler[™] (beclomethasone)
		 6. Individual has a low inspiratory flow rate and is unable to use a dry powder inhaler, and documented failure, contraindication, or intolerance to ALL of the following: a. Alvesco[®] (ciclesonide) b. Asmanex[®] HFA (mometasone) c. Qvar[®] Redihaler[™] (beclomethasone)
	Fluticasone propionate Diskus	 ONE of the following: 1. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: Alvesco[®] (ciclesonide) Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is unable to coordinate breath and actuation with a conventional metered-dose inhaler and documented failure, contraindication, or intolerance to BOTH of the following: Asmanex[®] Twisthaler (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
	Fluticasone	ONE of the following:
	propionate HFA	 Individual has eosinophilic esophagitis Individual is less than 4 years of age

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		 Individual is 4 years of age to less than 6 years of age and has a low inspiratory flow rate and is unable to use a dry powder inhaler and documented failure, contraindication, or intolerance to Qvar[®] Redihaler[™] (beclomethasone)
		 4. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: Alvesco[®] (ciclesonide) Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
		 6. Individual has a low inspiratory flow rate and is unable to use a dry powder inhaler, and documented failure, contraindication, or intolerance to ALL of the following: a. Alvesco[®] (ciclesonide) b. Asmanex[®] HFA (mometasone) c. Qvar[®] Redihaler[™] (beclomethasone)
	Pulmicort [®] Flexhaler™ (budesonide)	 ONE of the following: 1. Individual is less than 12 years of age and documented failure, contraindication, or intolerance to BOTH of the following: a. Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) b. Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is 12 years of age, or older, and documented failure, contraindication, or intolerance to ALL of the following: Alvesco[®] (ciclesonide) Asmanex[®] Twisthaler OR Asmanex[®] HFA (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
		 Individual is unable to coordinate breath and actuation with a conventional metered-dose inhaler and documented failure, contraindication, or intolerance to BOTH of the following: Asmanex[®] Twisthaler (mometasone) Qvar[®] Redihaler[™] (beclomethasone)
Asthma and Respiratory: Leukotriene modifiers	Zyflo [®] (zileuton 600 mg tablets)	 BOTH of the following: zileuton extended-release tablet (generic for Zyflo CR) ONE of the following: montelukast zafirlukast
Asthma and Respiratory: Inhalers, Long Acting Anticholinergics	Seebri™ Neohaler® (glycopyrrolate) Tudorza®	 ONE of the following: Incruse[®] Ellipta[®] (umeclidinium) Spiriva (tiotropium)
Antionolinergica	Pressair [®] (aclidinium)	

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Asthma and Respiratory: Inhalers, Long- Acting Beta- Agonists	Serevent [®] Diskus [®] (salmeterol xinafoate inhalation powder)	 ONE of the following: 1. Documented failure, contraindication, or intolerance to Striverdi Respimat (olodaterol inhalation spray) 2. Individual is unable to coordinate breath and actuation with a metered-dose inhaler (MDI) 3. Individual with asthma and is using Serevent Diskus concomitantly with an inhaled corticosteroid or an inhaled corticosteroid-containing product 4. Individual with exercise induced bronchospasm without asthma
Asthma and Respiratory: Xanthine derivatives	Elixophyllin (theophylline 80 mg/15 ml solution)	 BOTH of the following: theophylline solution (generic for Elixophyllin) theophylline extended release capsules or tablets
Bacterial Vaginosis Agents	Cleocin [®] Vaginal Ovules (clindamycin phosphate vaginal suppositories)	 Documentation of ONE of the following: 18 years of age or older AND failure contraindication or intolerance to BOTH of the following: a. clindamycin phosphate 2% vaginal cream b. metronidazole 0.75% vaginal gel OR Vandazole 0.75% vaginal gel Post-menarchal and BOTH of the following: a. Less than 18 years of age b. Documented failure, contraindication or intolerance to ONE of the following: i. clindamycin phosphate 2% vaginal cream ii. metronidazole 0.75% vaginal gel OR Vandazole 0.75% vaginal gel
	Clindesse [™] (clindamycin phosphate vaginal cream)	 Documentation of ONE of the following: 18 years of age or older AND failure contraindication or intolerance to BOTH of the following: a. clindamycin phosphate 2% vaginal cream b. metronidazole 0.75% vaginal gel OR Vandazole 0.75% vaginal gel Post-menarchal and BOTH of the following: a. Less than 18 years of age b. Documented failure, contraindication or intolerance to ONE of the following: i. clindamycin phosphate 2% vaginal cream ii. metronidazole 0.75% vaginal gel OR Vandazole 0.75% vaginal gel
	Nuvessa[®] (metronidazole 1.3% vaginal gel)	 Documentation of ONE of the following: 18 years of age or older AND failure contraindication or intolerance to BOTH of the following: a. clindamycin phosphate 2% vaginal cream b. metronidazole 0.75% vaginal gel OR Vandazole 0.75% vaginal gel

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
oategory		2. Pre-menarchal
		 3. Post-menarchal and BOTH of the following: a. Less than 18 years of age b. Documented failure, contraindication or intolerance to ONE of the following: i. clindamycin phosphate 2% vaginal cream ii. metronidazole 0.75% vaginal gel OR Vandazole 0.75% vaginal gel
	Xaciato™ (clinamycin) 2% vaginal gel	 Xaciato (clinamycin) is considered medically necessary when the following are met: Bacterial Vaginosis. Individual meets ONE of the following criteria: 1. 18 years of age or older AND documented failure contraindication or intolerance to BOTH of the following: A. Generic clindamycin phosphate 2% vaginal cream B. Generic metronidazole 0.75% vaginal gel or Vandazole 0.75% vaginal gel
		 2. Pre-menarchal 3. Post-menarchal and BOTH of the following: A. Less than 18 years of age B. Documented failure, contraindication or intolerance to ONE of the following: i. Generic clindamycin phosphate 2% vaginal cream ii. Generic metronidazole 0.75% vaginal gel or Vandazole 0.75% vaginal gel
Calcium Channel Blockers (CCBs)	Conjupri® (levamlodipine)	 There is documentation of EITHER of the following (A or B): A. Individual is less than 18 years of age and has had an inadequate response, contraindication, or is intolerant to amlodipine B. Individual has had an inadequate response, contraindication, or is intolerant to ALL of the following (i, ii, iii, and iv): Amlodipine Felodipine nifedipine LA nisoldipine
	levamlodipine maleate 2.5 mg oral tablet	 There is documentation of EITHER of the following (A or B): A. Individual is less than 18 years of age and has had an inadequate response, contraindication, or is intolerant to amlodipine B. Individual has had an inadequate response, contraindication, or is intolerant to ALL of the following (i, ii, iii, and iv): amlodipine felodipine nifedipine LA nisoldipine

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	levamlodipine maleate 5 mg oral tablet	 There is documentation of EITHER of the following (A or B): A. Individual is less than 18 years of age and has had an inadequate response, contraindication, or is intolerant to amlodipine B. Individual has had an inadequate response, contraindication, or is intolerant to ALL of the following (i, ii, iii, and iv): Amlodipine Felodipine nifedipine LA nisoldipine
Calcium Channel Blockers (CCBs)/Non- Steroidal Anti- inflammatories (NSAIDs)	Consensi[®] (amlodipine/ celecoxib tablet)	Documented inability to use amlodipine and celecoxib as separate agents
Cardiac Glycosides	digoxin 62.5 mcg oral tablet (A-rated generic Lanoxin)	 EITHER of the following: Documented inability to achieve dose with other generic digoxin products covered on formulary Significant intolerance to at least one generic digoxin formulation
Cardiovascular: Antithrombotic Agents	Yosprala [™] (aspirin delayed release/omeprazol e 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 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: 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: Beta-Blocker Agents	Hemangeol [™] (propranolol hydrochloride 4.28 mg/mL oral solution)	 Documentation of BOTH of the following: Proliferating infantile hemangioma Failure, contraindication or intolerance to propranolol hydrochloride oral solution (20 mg/5mL)
	Inderal XL [®] (propranolol hydrochloride extended-release capsules)	 Documentation of ONE of the following: Failure, contraindication or intolerance to propranolol extended-release capsules There is significant clinical concern such that the individual is unable to use propranolol extended-release capsules

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Kapspargo® (metoprolol succinate extended-release capsules)	Documented inability to swallow metoprolol succinate extended- release tablets
Cardiovascular: Beta-Blocker Combination Products	Dutoprol [™] (metoprolol succinate [extended release] and hydrochlorothiazid e)	Documented inability to take single agents metoprolol succinate and hydrochlorothiazide concurrently
Cardiovascular: Diuretics	Aldactazide® (spironolactone / hydrochlorothiazid e [25 mg / 25 mg] tablets)	The individual has tried spironolactone / hydrochlorothiazide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
	Aldactazide [®] (spironolactone / hydrochlorothiazid e [50 mg / 50 mg] tablets)	 BOTH of the following (A and B): A. Documented inability to achieve dose with other generic spironolactone / hydrochlorothiazide products covered on formulary (for example, spironolactone / hydrochlorothiazide 25 mg / 25 mg tablets) B. Documented inability to use spironolactone and hydrochlorothiazide concurrently as separate agents
	Edecrin [®] (ethacrynic acid 25 mg tablets) ethacrynic acid (ethacrynic acid	 ALL of the following: bumetanide furosemide torsemide
	25 mg tablets) Soaanz [®] (torsemide 20 mg, 40 mg, 60 mg tablets)	 Individual meets the following (1): 1. Treatment of edema associated with heart failure or renal disease. Individual meets ALL of the following criteria (A, B, <u>and</u> C): A. Individual is 18 years of age or older B. EITHER of the following (i <u>or</u> ii): i. Documented inability to achieve dose with other generic torsemide products covered on formulary (for example, torsemide 20 mg tablets) ii. Significant intolerance to at least one generic torsemide formulation (difference in the inactive ingredient[s], dyes, fillers, preservatives) C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to BOTH of the following (i <u>or</u> ii): i. bumetanide tablets ii. furosemide tablets

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Cardiovascular: Other	Multaq (dronedarone 400 mg tablets)	 EITHER of the following: Individual is currently receiving dronedarone (Multaq) TWO of the following: amiodarone disopyramide dofetilide flecainide propafenone quinidine sotalol/AF
Cardiovascular: Renin Inhibitors	Accupril [®] (quinapril)	 BOTH of the following: quinapril (generic for Accupril) FOUR of the following: benazepril captopril enalapril fosinopril lisinopril ramipril trandolapril
	Accuretic [®] (quinapril / hydrochlorothiazid e)	 ALL of the following: quinapril / hydrochlorothiazide (generic for Accuretic) Documented inability to use quinapril and hydrochlorothiazide concurrently THREE of the following: benazepril/hydrochlorothiazide captopril/hydrochlorothiazide fosinopril/hydrochlorothiazide lisinopril/hydrochlorothiazide
	Altace® (ramipril)	 BOTH of the following: ramipril (generic for Altace) FOUR of the following: benazepril captopril enalapril fosinopril lisinopril quinapril trandolapril
	Lotensin [®] (benazepril)	 BOTH of the following: benazepril (generic for Lotensin) FOUR of the following: captopril enalapril fosinopril lisinopril quinapril ramipril trandolapril

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Lotensin HCT [®] (benazepril / hydrochlorothiazid e)	 ALL of the following: benazepril / hydrochlorothiazide (generic for Lotensin HCT) Documented inability to use benazepril and hydrochlorothiazide concurrently THREE of the following: captopril/hydrochlorothiazide enalapril/hydrochlorothiazide fosinopril/hydrochlorothiazide lisinopril/hydrochlorothiazide quinapril/hydrochlorothiazide
	Lotrel [®] (amlodipine / benazepril)	 quinapril/hydrochlorothiazide ALL of the following (A, B, and C): A. The individual has tried amlodipine / benazepril (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. Documented inability to use benazepril and amlodipine as separate agents C. The individual has had an inadequate response, contraindication, or is intolerant to ALL of the following (i, ii, and iii):
	Prinivil® (lisinopril)	 iii. amlodipine/termisartan iii. amlodipine/termisartan BOTH of the following: lisinopril (generic for Prinivil) FOUR of the following: benazepril captopril enalapril fosinopril quinapril trandolapril
	Tarka[®] (trandolapril / verapamil)	 ALL of the following: trandolapril / verapamil (generic for Tarka) Documented inability to use trandolapril and verapamil concurrently amlodipine/benazepril
	Tekturna[®] (aliskiren)	BOTH of the following: aliskiren (generic for Tekturna) FOUR of the following: benazepril candesartan captopril enalapril fosinopril irbesartan lisinopril losartan olmesartan valuapril ramipril telmisartan

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		o trandolapril o valsartan
	Tekturna [®] HCT (aliskiren/ hydrochlorothiazid e)	FIVE of the following: benazepril/hydrochlorothiazide candesartan/hydrochlorothiazide captopril/hydrochlorothiazide enalapril/hydrochlorothiazide fosinopril/hydrochlorothiazide lisinopril/hydrochlorothiazide losartan/hydrochlorothiazide olmesartan/hydrochlorothiazide quinapril/hydrochlorothiazide telmisartan/hydrochlorothiazide valsartan/hydrochlorothiazide
	Vaseretic [®] (enalapril / hydrochlorothiazid e)	 ALL of the following: enalapril / hydrochlorothiazide (generic for Vaseretic) Documented inability to use enalapril and hydrochlorothiazide concurrently THREE of the following: benazepril/hydrochlorothiazide captopril/hydrochlorothiazide fosinopril/hydrochlorothiazide lisinopril/hydrochlorothiazide quinapril/hydrochlorothiazide
	Vasotec [®] (enalapril)	 BOTH of the following (A and B): A. The individual has tried enalapril (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction B. The individual has had an inadequate response, contraindication, or is intolerant to FOUR of the following: benazepril captopril fosinopril ramipril trandolapril
	Zestoretic [®] (lisinopril / hydrochlorothiazid e)	 ALL of the following: lisinopril / hydrochlorothiazide (generic for Zestoretic) Documented inability to use lisinopril and hydrochlorothiazide concurrently THREE of the following: benazepril/hydrochlorothiazide captopril/hydrochlorothiazide enalapril/hydrochlorothiazide

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Zestril [®] (lisinopril)	 fosinopril/hydrochlorothiazide quinapril/hydrochlorothiazide BOTH of the following: lisinopril (generic for Zestril) FOUR of the following: benazepril captopril enalapril fosinopril quinapril ramipril trandolapril
Cardiovascular: Vasodilators	Cardizem CD (diltiazem 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg extended release capsules) GoNitro [™] (nitroglycerin sublingual powder) Isordil [®] Titradose [™] (isosorbide dinitrate 40 mg tablet)	 BOTH of the following: diltiazem ER capsules (generic for Cardizem CD) Diltiazem extended-release 24-hour capsules OR tablets (for example: generic Cardizem LA tablets, generic Dilacor XR capsules, or generic Tiazac capsules) BOTH of the following: nitroglycerin sublingual tablets nitroglycerin sublingual spray Documented inability to use two tablets of isosorbide dinitrate 20 mg tablets
Corticosteroids (Rectal Formulations)	Cortifoam [®] (hydrocortisone acetate) 10% aerosol foam	 ONE of the following: Colocort (hydrocortisone) 100 mg/60 mL rectal enema hydrocortisone 100 mg/60 mL rectal enema
Dermatologic: Anti-acne agents, topical	Avar-E (sodium sulfacetamide 10% and sulfur 5% topical cream)	 Documented failure, contraindication or intolerance to ONE of the following: 1. sodium sulfacetamide 10% / sulfur 2% emollient cream 2. sodium sulfacetamide 10% / sulfur 5% emollient cream
	Avar-E Green (sodium sulfacetamide 10% and sulfur 5% topical cream)	 Documented failure, contraindication or intolerance to ONE of the following: 1. sodium sulfacetamide 10% / sulfur 2% emollient cream 2. sodium sulfacetamide 10% / sulfur 5% emollient cream
Dermatologic: Anti- neoplastics, Topical	Condylox [®] (podofilox) 0.5% topical gel	EFFECTIVE 5/1/2024 Condylox is considered medically necessary when there is documentation of EITHER of the following: 1. Failure, contraindication or intolerance to TWO of the following: A. podofilox 0.5% topical solution B. imiquimod cream (Aldara generic)

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		 C. Veregen 15% ointment [may require prior authorization] 2. For treatment of perianal warts and there is failure, contraindication or intolerance to ONE of the following: A. podofilox 0.5% topical solution B. imiquimod cream (Aldara generic) C. Veregen 15% ointment [may require prior authorization]
Dermatologic: Anti-psoriatic agents, topical	Duobrii [®] (halobetasol propionate 0.01% and tazarotene 0.045% lotion)	 Documented inability to use halobetasol (0.05% cream or ointment) and topical tazarotene 0.1% cream concurrently Topical retinoid products will be approved based on BOTH of the following: Member has a non-cosmetic medical condition (for example, acne vulgaris, psoriasis, precancerous lesion) Member is not requesting topical retinoid products for the treatment of cosmetic purposes (for example, photoaging, wrinkling, hyperpigmentation, sun damage) Under many benefit plans, services are not covered when they are performed solely for the purpose of altering appearance or selfesteem, or to treat psychological symptomatology or psychosocial
Dermatologic: Local anesthetics, topical	Lidocaine 3% lotion	 complaints related to one's appearance. BOTH of the following: lidocaine 3% cream lidocaine 5% ointment
	Lidocan II (lidocaine 5% topical patch)	Documented trial of <u>lidocaine 5% topical patch</u> (generic for Lidoderm) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction.
	Lido-K (lidocaine 3% lotion)	 BOTH of the following: lidocaine 3% cream lidocaine 5% ointment
Dermatologic: Steroidal Anti- inflammatory, Topical	Clobex [®] (clobetasol 0.05%) lotion	 BOTH of the following: clobetasol lotion (generic for Clobex lotion) FOUR dosage forms of clobetasol 0.05%: liquid spray, shampoo, solution, ointment, cream, gel, or foam
	Clobex® (clobetasol 0.05%) liquid spray	 BOTH of the following: clobetasol lotion (generic for Clobex liquid spray) FOUR dosage forms of clobetasol 0.05%: lotion, shampoo, solution, ointment, cream, gel, or foam
	Clobex® (clobetasol 0.05%) shampoo	 BOTH of the following: clobetasol lotion (generic for Clobex shampoo) FOUR dosage forms of clobetasol 0.05%: lotion, liquid spray, solution, ointment, cream, gel, or foam
	Cutivate® (fluticasone 0.05% lotion)	 BOTH of the following: fluticasone (generic for Cutivate) FOUR of the following: betamethasone

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Halog (halcinonide 0.1% cream) Halog (halcinonide 0.1% ointment)	 clocortolone desoximetasone fluocinonide flurandrenolide hydrocortisone mometasone prednicarbate triamcinolone ALL of the following: betamethasone cream clobetasol cream fluocinonide cream halobetasol cream triamcinolone cream ALL of the following: betamethasone cream clobetasol cream fluocinonide cream betanethasone cream
	ontment)	 clobetasol ointment fluocinonide ointment halobetasol ointment triamcinolone ointment
	Halog (halcinonide 0.1% solution)	 ALL of the following: betamethasone cream/gel/lotion/ointment clobetasol cream/ointment fluocinonide cream/gel/ointment/solution halobetasol cream/ointment triamcinolone cream/ointment
	hydrocortisone butyrate 0.1% cream	 FIVE of the following: alclometasone dipropionate 0.05% cream betamethasone dipropionate 0.05% lotion betamethasone valerate 0.05% lotion betamethasone valerate 0.1% cream clocortolone pivalate 0.1% cream desonide 0.05% cream, lotion fluocinolone acetonide 0.025% cream flurandrenolide 0.05% cream fluticasone propionate 0.05% cream hydrocortisone probutate 0.1% cream hydrocortisone valerate 0.2% cream mometasone furoate 0.1% cream, lotion prednicarbate 0.1% cream triamcinolone acetonide 0.025% cream
	Impeklo™ (clobetasol propionate 0.05% lotion)	 ALL of the following clobetasol 0.05% lotion betamethasone diproprionate augmented 0.05% (gel, ointment, or lotion) diflorasone diacetate 0.05% ointment fluocinonide 0.1% cream halobetasol propionate 0.05% (cream or ointment)

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Lexette [®] (halobetasol propionate 0.05% foam) halobetasol propionate 0.05% foam	 FIVE of the following: amcinonide 0.1% ointment betamethasone dipropionate, augmented 0.05% cream, foam, gel, ointment betamethasone dipropionate 0.05% cream, ointment clobetasol propionate 0.05% cream, foam, gel, lotion, ointment, shampoo desoximetasone 0.25% cream, ointment desoximetasone 0.05% gel fluocinonide 0.05% cream, gel, ointment, solution fluocinonide 0.1% cream halobetasol propionate 0.05% cream, ointment triamcinolone acetonide 0.5% ointment
	Kenalog [®] (triamcinolone acetonide 0.147 mg/gm aerosol solution) triamcinolone acetonide 0.147 mg/gm aerosol solution	 FIVE of the following: Amcinonide 0.1% cream, lotion Betamethasone valerate 0.1% Betamethasone valerate 0.12% foam, ointment Desoximetasone 0.05% cream Fluocinolone acetonide 0.025% ointment Fluocinonide-E 0.05% cream Fluticasone propionate 0.005% ointment Hydrocortisone valerate 0.2% ointment Mometasone furoate 0.1% cream, lotion, ointment, solution Prednicarbate 0.1% ointment Triamcinolone acetonide 0.05% cream Triamcinolone acetonide 0.05% cream Triamcinolone acetonide 0.05% cream
	Sernivo [™] (betamethasone dipropionate 0.05% emulsion) Trianex [®]	 ALL of the following: 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
	(triamcinolone acetonide 0.05% ointment) triamcinolone acetonide 0.05% ointment	 FIVE of the following: Amcinonide 0.1% cream, lotion Betamethasone valerate 0.1% Betamethasone valerate 0.12% foam, ointment Desoximetasone 0.05% cream Fluocinolone acetonide 0.025% ointment Fluocinonide-E 0.05% cream Fluticasone propionate 0.005% ointment Hydrocortisone valerate 0.2% ointment Mometasone furoate 0.1% cream, lotion, ointment, solution Prednicarbate 0.1% ointment Triamcinolone acetonide 0.05% cream Triamcinolone acetonide 0.05% cream Triamcinolone acetonide 0.1% ointment

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Ultravate [®] (halobetasol propionate 0.05% lotion)	 FIVE of the following: betamethasone dipropionate, augmented 0.05% ointment betamethasone dipropionate, augmented 0.05% lotion clobetasol propionate 0.05% cream clobetasol propionate 0.05% lotion clobetasol propionate 0.05% ointment halobetasol propionate 0.05% cream halobetasol propionate 0.05% ointment
	Vanos [®] (fluocinonide 0.1% cream)	 BOTH of the following: fluocinonide cream (generic for Vanos) fluocinonide 0.05% solution, ointment, cream, and gel
	Verdeso ® (desonide 0.05% foam)	 ALL of the following: fluocinolone body oil fluticasone lotion topical hydrocortisone
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP- 4) Inhibitors	Zituvio (sitagliptin)	 EFFECTIVE 5/1/2024 <u>Value/Advantage Drug List Plans:</u> Zituvio is considered medically necessary when BOTH of the following are met (1 and 2): ONE of the following (a, b, <u>or</u> c):
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP- 4) Inhibitor/ Sodium Glucose Co- Transporter-2 (SGLT-2) Inhibitors	Qtern (dapagliflozin/ saxagliptin)	EFFECTIVE 7/1/2024 Qtern is considered medically necessary when BOTH of the following are met (1 and 2): 1. Contraindication or intolerance to a metformin-containing product

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		 <u>Note</u>: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis. 2. Contraindication or intolerance to Glyxambi (empagliflozin-linagliptin) [Step Therapy may apply]
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP- 4) Inhibitor/ Sodium Glucose Co- Transporter-2 (SGLT-2) Inhibitors	Steglujan (sitagliptin / ertugliflozin)	 EFFECTIVE 7/1/2024 Steglujan is considered medically necessary when BOTH of the following are met (1 and 2): 1. Contraindication or intolerance to a metformin-containing product Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis. 2. Contraindication or intolerance to Glyxambi (empagliflozin-linagliptin) [Step Therapy may apply]
Diabetes Agents – Insulin (Basal) and Glucagon-Like Peptide-1 (GLP-1) Agonist Combination	Xultophy [®] (insulin degludec/liraglutid e injection)	EFFECTIVE 7/1/2024 Xultophy is considered medically necessary when there is documentation of failure, contraindication or intolerance to Soliqua (insulin glargine and lixisenatide)
Diabetes: Insulins	Novolog Mix 70/30 [®] (70% insulin aspart protamine/30% insulin aspart)	• Humalog [®] Mix 75/25
	Novolin 70/30 [®] (70% NPH, human insulin isophane/30% regular human insulin)	• Humulin [®] 70/30
	Novolin N [®] (insulin, NPH human recombinant isophane)	• Humulin [®] N
	Novolin R[®] (insulin, regular, human recombinant)	Humulin R
Dronabinol Products	Syndros (dronabinol oral solution)	 ONE of the following: 1. Documented inability to swallow dronabinol capsules 2. The individual has tried <u>dronabinol capsules</u> AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Fecal Microbiota Agent (spore)	Vowst™	Fecal microbiota spores, live-brpk capsules (Vowst) is considered medically necessary when the following are met:

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	(fecal microbiota spores, live-brpk capsules)	 Prevention of recurrent Clostridioides difficile Individual is 18 years of age or older
Gastrointestinal Agents: Anti- inflammatory	Asacol [®] HD (mesalamine)	 Documentation of BOTH of the following: 1. The individual has tried <u>mesalamine</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to ALL of the following: a. Apriso[™] (mesalamine) b. balsalazide c. Lialda[®] (mesalamine) d. sulfasalazine
	Colazal[®] (balsalazide)	 Documentation of BOTH of the following: The individual has tried <u>balsalazide</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction Failure, contraindication, or intolerance to ALL of the following: Apriso[™] (mesalamine) Lialda[®] (mesalamine) sulfasalazine
	Delzicol[®] (mesalamine)	 Documentation of BOTH of the following: 1. The individual has tried <u>mesalamine</u> (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction 2. Failure, contraindication, or intolerance to ALL of the following: a. Apriso[™] (mesalamine) b. balsalazide c. Lialda[®] (mesalamine) d. sulfasalazine
	Dipentum [®] (olsalazine)	 Documentation of failure, contraindication, or intolerance to ALL of the following: 1. Apriso™ (mesalamine) 2. balsalazide 3. generic mesalamine 4. Lialda[®] (mesalamine) 5. sulfasalazine
	Pentasa (mesalamine) 250 mg tablet	Individual is unable to achieve the desired dose with generic mesalamine 500 mg tablets .

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Gastrointestinal Agents: Anticholinergic	Donnatal [®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Tablets Donnatal [®] (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Elixir	 BOTH of the following (A and B): A. The individual has had an inadequate response, contraindication, or is intolerant to dicyclomine B. The individual has had an inadequate response or is intolerant to ONE of the following (i, ii, or iii): phenobarbital – belladonna elixir phenobarbital / hyoscyamine / atropine / scopolamine elixir Phenohytro elixir
Gold Compound	Ridaura [®] (auranofin)	The individual has had an inadequate response, contraindication, or is intolerant to FIVE nonsteroidal anti-inflammatory drugs
Gout Medications	Allopurinol 200 mg tablet	Individual is unable to achieve the desired dose with generic allopurinol 100 mg AND 300 mg tablets.
Hyperlipidemia Agents	Niacor (niacin 500 mg tablet) niacin 500 mg tablet	Documentation that individual has tried ONE niacin extended- release tablet product and cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the brand and a covered alternative product which, per the prescribing physician, would
Hormones: oral corticosteroids	Alkindi [®] Sprinkle oral granules (hydrocortisone)	 result in a significant allergy or serious adverse reaction. Individual is 17 years of age or younger Documented diagnosis of adrenocortical insufficiency Attestation that the individual is unable to swallow hydrocortisone tablets (generic for Cortef)
	dexamethasone 1.5 mg tablets Dxevo 11 Day Dose Pack (dexamethasone 1.5 mg tablets) TaperDex 6 Day , 7 Day and 12 Day Pack (dexamethasone 1.5 mg tablets) Baylon	 ALL of the following: dexamethasone 1.5 mg tablets methylprednisolone tablet therapy pack BOTH of the following: hydrocortisone methylprednisolone tablets
	Rayos [®] (prednisone 1 mg, 2 mg, and 5 mg delayed release tablets)	 BOTH of the following: prednisone 1 mg, 2.5 mg, or 5 mg tablets ALL of the following: dexamethasone tablets hydrocortisone tablets methylprednisolone tablets

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Laxative, Osmotic	Kristalose [®] (lactulose packet)	lactulose oral solution
Neurokinin-3 Antagonists	Veozah (fezolinetant tablets)	 Documentation of BOTH of the following: 1. Failure, contraindication or intolerance to least one oral or topical estrogen or an estrogen / progestin combination product
		 2. ONE of the following: a. Failure, contraindication or intolerance to paroxetine 7.5 mg b. Currently receiving a selective serotonin reuptake inhibitor OR a serotonin and norepinephrine reuptake inhibitor
Ophthalmic Anti- Allergics	Alocril [®] (nedocromil 2% ophthalmic solution)	Documented failure, contraindication, or intolerance to cromolyn 4% ophthalmic solution
	Alomide [®] (lodoxamide 0.1% ophthalmic solution)	Documented failure, contraindication, or intolerance to cromolyn 4% ophthalmic solution
Ophthalmic Agent – Mydriatics/ Cycloplegics	Atropine sulfate 1% ophthalmic solution in a single-use dropperette (preservative free) [brand]	 Atropine sulfate 1% ophthalmic solution (preservative free) is considered medically necessary when the individual has documentation of ONE of the following: Intolerance to generic atropine 1% ophthalmic solution Known sensitivity to a preservative (e.g. benzalkonium chloride [BAK])
Ophthalmic – Antibiotic/Corticost eroid Combination Products	Pred-G (Prednisolone acetate 1% and gentamicin sulfate 0.3% ophthalmic suspension)	 Documentation of ONE of the following: Failure, contraindication, or intolerance to tobramycin- dexamethasone ophthalmic suspension Currently receiving Pred-G ointment for the treatment of an active eye infection and will be continuing therapy
Ophthalmic Antibiotics - Quinolones	Ciloxan [®] ointment (ciprofloxacin ophthalmic ointment 0.3%)	 Documentation of ONE of the following: Failure, contraindication, or intolerance to FOUR of the following: ciprofloxacin 0.3% ophthalmic solution gatifloxacin 0.5% ophthalmic solution moxifloxacin 0.5% ophthalmic solution levofloxacin 0.5% ophthalmic solution levofloxacin 0.5% ophthalmic solution e ofloxacin 0.5% ophthalmic solution levofloxacin 0.3% ophthalmic solution levofloxacin 0.3% ophthalmic solution a following: following: following:
		contraindication, or intolerance to moxifloxacin 0.5% ophthalmic solution

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		3. Currently receiving Ciloxan ointment for the treatment of an active eye infection and will be continuing therapy
Ophthalmic – Antibiotics - Aminoglycosides	Tobrex ointment (tobramycin ophthalmic ointment)	 Documentation of ONE of the following: 1. Inability to use tobramycin ophthalmic suspension 2. Currently receiving Tobrex ointment for the treatment of an active eye infection and will be continuing therapy
Ophthalmic Anti- Inflammatory Agents -NSAIDs	Nevanac [®] (nepafenac 0.1%ophthalmic suspension)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to TWO of the following: a. bromfenac ophthalmic b. diclofenac ophthalmic c. ketorolac ophthalmic 2. Individual with a sulfa allergy AND failure, contraindication, or intolerance to BOTH of the following: a. diclofenac ophthalmic b. ketorolac ophthalmic c. ketorolac ophthalmic c. ketorolac ophthalmic
Corticosteroids (fluorometh 0.25% oph	FML Forte [®] (fluorometholone 0.25% ophthalmic suspension)	 Documentation of ONE of the following: Failure, contraindication, or intolerance to THREE of the following: a. dexamethasone ophthalmic b. difluprednate ophthalmic c. fluorometholone ophthalmic d. loteprednol ophthalmic e. prednisolone ophthalmic 2. Elevated intraocular pressure (IOP) or glaucoma following use of another corticosteroid (for example, topical, inhaled, oral, ophthalmic) AND failure, contraindication, or intolerance to ONE of the following: a. difluprednate ophthalmic b. fluorometholone ophthalmic c. loteprednol ophthalmic c. loteprednol ophthalmic
	Maxidex [®] (dexamethasone 0.1% ophthalmic suspension)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to THREE of the following: a. dexamethasone ophthalmic b. difluprednate ophthalmic c. fluorometholone ophthalmic d. loteprednol ophthalmic e. prednisolone ophthalmic 2. Elevated intraocular pressure (IOP) or glaucoma following use of another corticosteroid (for example, topical, inhaled, oral, ophthalmic) AND failure, contraindication, or intolerance to ONE of the following: a. difluprednate ophthalmic b. fluorometholone ophthalmic

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		c. loteprednol ophthalmic
	Pred Mild 0.12% (prednisolone acetate 0.12% ophthalmic suspension)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to THREE of the following: a. dexamethasone ophthalmic b. difluprednate ophthalmic c. fluorometholone ophthalmic d. loteprednol ophthalmic e. prednisolone ophthalmic
		 Elevated intraocular pressure (IOP) or glaucoma following use of another corticosteroid (for example, topical, inhaled, oral, ophthalmic) AND failure, contraindication, or intolerance to ONE of the following: a. difluprednate ophthalmic b. fluorometholone ophthalmic c. loteprednol ophthalmic
Ophthalmic Drugs for Glaucoma - Alpha-Adrenergic Agonist	Alphagan P 0.1% (brimonidine 0.1% ophthalmic solution)	 Documented intolerance to ONE of the following: 1. brimonidine ophthalmic solution 0.15% 2. brimonidine ophthalmic solution 0.2%
	lopidine[®] 0.5% (apraclonidine 0.5% ophthalmic solution)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to ONE of the following: a. brimonidine ophthalmic solution 0.15% b. brimonidine ophthalmic solution 0.2% 2. Individual is undergoing argon laser trabeculoplasty, argon laser iridotomy or Nd:YAG posterior capsulotomy
Ophthalmic Drugs for Glaucoma - Beta-Adrenergic Blocker	Betimol[®] 0.25% (timolol hemihydrates 0.25% ophthalmic solution)	 Documented failure, contraindication, or intolerance to ALL of the following: 1. betaxolol ophthalmic solution 2. carteolol ophthalmic solution 3. levobunolol ophthalmic solution 4. timolol maleate ophthalmic solution
	Betimol[®] 0.5% (timolol hemihydrates 0.5% ophthalmic solution)	 Documented failure, contraindication, or intolerance to ALL of the following: 1. betaxolol ophthalmic solution 2. carteolol ophthalmic solution 3. levobunolol ophthalmic solution 4. timolol maleate ophthalmic solution
	Timoptic 0.25% Ocudose (timolol maleate 0.25% ophthalmic solution)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to ALL of the following: a. betaxolol ophthalmic solution b. carteolol opthalmic solution c. levobunolol ophthalmic solution d. timolol maleate ophthalmic solution

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		 Individual has a known sensitivity to a preservative OR use of a preservative-free topical medication is advisable
Phosphate Binders	Fosrenol (lanthanum carbonate oral powder packet)	 Documentation of ONE of the following: 1. Failure, contraindication, or intolerance to BOTH of the following: a. sevelamer hydrochloride tablet b. sevelamer carbonate tablet or powder packet 2. Inability to swallow tablets AND failure, contraindication, or intolerance to sevelamer carbonate tablet or powder packet
Potassium Sparing Diuretics	Carospir (spironolactone oral suspension)	Documented inability to swallow spironolactone tablets
Potassium Supplement	Pokonza™ (potassium chloride powder for solution)	Documented inability to use ONE other oral potassium chloride product (for example, potassium chloride powder for oral solution, potassium chloride oral solution)
Psychotherapeutic Drugs: Antidepressants - Other	Auvelity [™] (dextromethorpha n and bupropion extended-release tablet)	 Dextromethorphan and bupropion extended-release tablet (Auvelity) is considered medically necessary for the treatment of Major Depressive Disorder (MDD) when the individual meets ALL of the following criteria: 1. 18 years of age or older 2. ONE of the following (A or B): A. Individual is currently receiving Auvelity B. Documentation that the individual has had an inadequate response, contraindication, or intolerance to at least TWO different antidepressants, each from a different pharmacologic class (see <u>Appendix</u> for examples)
Psychotherapeutic Drugs: Atypical Antipsychotics	Versacloz [®] (clozapine 50 mg/ml suspension)	 BOTH of the following: clozapine 25 mg, 50 mg, 100 mg, or 200 mg tablets clozapine 12.5 mg, 25 mg, 100 mg, 150 mg, or 200 mg orally disintegrating tablets
Psychotherapeutic Drugs: Benzodiazepines	Ativan® (lorazepam)	 BOTH of the following: lorazepam (generic for Ativan) TWO of the following: alprazolam clonazepam diazepam oxazepam temazepam
Psychotherapeutic Drugs: Monoamine oxidase inhibitors	Parnate [®] (tranylcypromine sulfate 10 mg tablets)	 BOTH of the following: tranylcypromine (generic for Parnate) ONE of the following: Marplan selegiline (oral formulations only) phenelzine

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
Psychotherapeutic Drugs: SNRIs	Cymbalta [®] (duloxetine) delayed release capsules Desvenlafaxine	 BOTH of the following: duloxetine (generic for Cymbalta) ONE of the following: citalopram desvenlafaxine succinate ER escitalopram fluoxetine fluvoxamine paroxetine sertraline venlafaxine ER Documentation of ONE of the following:
	ER	 Failure, contraindication or intolerance to TWO of the following: a. desvenlafaxine succinate extended-release b. duloxetine capsules c. venlafaxine extended-release capsules or tablets Currently receiving Desvenlafaxine ER
	Drizalma Sprinkle™ (duloxetine) delayed release capsules	 Individual meets ONE of the following (1, 2, 3, <u>or</u> 4): 1. Treatment of Chronic Musculoskeletal Pain. Individual meets ALL of the following criteria (A, B, <u>and</u> C): A. Individual is 18 years of age or older B. There is documentation the individual is intolerant to or has an inability to swallow duloxetine capsules (Cymbalta generic) C. There is documentation the individual has had an inadequate response, contraindication, is intolerant to, or has an inability to use naproxen 125 mg/5 mL oral suspension
		 2. Treatment of Diabetic Peripheral Neuropathic Pain (DPNP). Individual meets ALL of the following criteria (A, B, and C): A. Individual is 18 years of age or older B. There is documentation the individual is intolerant to or has an inability to swallow duloxetine capsules (Cymbalta generic) C. There is documentation the individual has had an inadequate response, contraindication, or is intolerant to BOTH of the following (i and ii): i. gabapentin 250 mg/5 mL oral solution ii. pregabalin 20 mg/mL oral solution
		 3. Treatment of Generalized Anxiety Disorder (GAD). Individual meets BOTH of the following (A and B): A. Individual is 7 years of age or older B. There is documentation the individual is intolerant to or has an inability to swallow duloxetine capsules (Cymbalta generic)
		 4. Treatment of Major Depressive Disorder (MDD). Individual meets BOTH of the following (A and B): A. Individual is 18 years of age or older

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Venlafaxine besylate extended-release 112.5 mg tablets	 B. There is documentation the individual is intolerant to or has an inability to swallow duloxetine capsules (Cymbalta generic) Documentation of ONE of the following (1 or 2): 1. Individual has had an inadequate response, contraindication, or is intolerant to TWO of the following: a. desvenlafaxine succinate ER tablets (generic for Pristiq) b. duloxetine capsules c. venlafaxine ER capsules d. venlafaxine ER tablets e. venlafaxine immediate-release (IR) tablets
Psychotherapeutic Drugs: SSRIs	Lexapro [®] (escitalopram) tablets	 BOTH of the following: escitalopram (generic for Lexapro) ONE of the following: citalopram fluoxetine fluvoxamine paroxetine sertraline
	Pexeva® (paroxetine mesylate) 10 mg, 20 mg, 30 mg, and 40 mg tablets	 ONE of the following: Individual is currently taking Pexeva Individual has suicidal ideation BOTH of the following: paroxetine hydrochloride 10 mg, 20 mg, 30 mg, or 40 mg tablets ONE of the following: citalopram escitalopram fluoxetine fluvoxamine sertraline
Psychotherapeutic Drugs: Tricyclic antidepressants	Anafranil™ (clomipramine 25 mg, 50 mg and 75 mg capsules)	BOTH of the following: • clomipramine (generic for Anafranil) • ONE of the following: • amitriptyline • amoxapine • bupropion SR/XL • citalopram • desvenlafaxine succinate ER • doxepin • duloxetine • fluoxetine • fluoxetine • fluoxetine • fluoxetine • secitalopram • fluoxetine • secitalopram

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Pamelor™ (nortriptyline 10 mg, 25 mg. 50 mg, and 75 mg capsules)	BOTH of the following: • nortriptyline (generic for Pamelor) • ONE of the following: • amitriptyline • amoxapine • bupropion SR/XL • citalopram • clomipramine • desvenlafaxine succinate ER • doxepin • duloxetine • escitalopram • fluoxetine • fluoxamine • imipramine • paroxetine • sertraline
Renal and Genitourinary Agents	Detrol [®] (tolterodine)	 venlafaxine ER BOTH of the following: tolterodine (generic for Detrol) ALL of the following: darifenacin ER oxybutynin/ oxybutynin ER solifenacin trospium / trospium ER
	Detrol LA® (tolterodine)	 BOTH of the following: tolterodine ER (generic for Detrol LA) ALL of the following: darifenacin ER oxybutynin/ oxybutynin ER solifenacin trospium / trospium ER
	Ditropan XL [®] (oxybutynin)	 BOTH of the following: oxybutynin ER (generic for Ditropan XL) ALL of the following: darifenacin ER solifenacin tolterodine / tolterodine ER trospium / trospium ER
	Gelnique 10% gel (oxybutynin chloride metered- dose pump, sachet)	 ALL of the following: darifenacin ER oxybutynin / oxybutynin ER solifenacin tolterodine / tolterodine ER trospium / trospium ER
	Gemtesa® (vibegron)	 Gemtesa (vibegron) is considered medically when the individual meets ONE of the following: 1. 66 years of age or older 2. 65 years of age or younger AND there is failure, contraindication, or intolerance to TWO of the following: a. darifenacin ER b. oxybutynin / oxybutynin ER c. solifenacin

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
		d. tolterodine / tolterodine ERe. trospium / trospium ER
	Myrbetriq [®] (mirabegron extended-release tablet)	 Myrbetriq (mirabegron) extended-release tablet is considered medically when the individual meets ONE of the following: 1. 66 years of age or older 2. 18 to 65 years of age AND there is failure, contraindication, or intolerance to TWO of the following: a. darifenacin ER b. oxybutynin / oxybutynin ER c. solifenacin d. tolterodine / tolterodine ER e. trospium / trospium ER 3. Less than 18 years of age AND there is failure, contraindication, or intolerance to rule and there is failure, contraindication, or intolerance to oxybutynin syrup, extended release tablets or tablets
	Myrbetriq [®] (mirabegron 8 mg/mL granules for oral suspension)	 Myrbetriq 8 mg/mL granules for oral suspension are considered medically necessary when ALL of the following are met: 1. Treatment of Neurogenic Detrusor Overactivity (NDO) 2. ONE of the following: a. 3 years of age to 5 years of age b. 6 years of age or older AND documented failure, contraindication, or intolerance to oxybutynin syrup, extended-release tablets or tablets
	oxybutynin chloride 2.5mg tablet	Oxybutynin chloride 2.5mg tablet is considered medically necessary when there is documentation of ALL of the following: Intolerance to oxybutynin 5mg tablet Intolerance to oxybutynin 5mg/5ml solution/syrup Failure, contraindication, or intolerance to THREE of the following: A. darifenacin ER Solifenacin tolterodine / tolterodine ER trospium / trospium ER
	Oxytrol [®] (oxybutynin transdermal system) Toviaz [®]	oxybutynin syrup, extended release tablets or tablets ALL of the following:
	(fesoterodine)	 darifenacin ER oxybutynin / oxybutynin ER solifenacin tolterodine / tolterodine ER trospium / trospium ER
	Vesicare® (solifenacin) tablets	 BOTH of the following: solifenacin (generic for Vesicare) ALL of the following: darifenacin ER

Therapeutic Category	Drug or Biologic	Preferred Covered Alternatives Criteria
	Vesicare LS™ (solfenacin succ.) 5 mg / 5 mL oral suspension	 oxybutynin / oxybutynin ER tolterodine / tolterodine ER trospium / trospium ER ONE of the following: Individual is 4 years of age or younger Individual is 5 years of age or older AND ALL of the following: darifenacin ER oxybutynin / oxybutynin ER solifenacin tolterodine / tolterodine ER trospium / trospium ER
Topical Dermatological Drugs - Miscellaneous	Synera (lidocaine and tetracaine patch)	Documented failure, contraindication, or intolerance to BOTH of the following: 1. lidocaine and prilocaine cream 2. lidocaine cream
Vertigo Agents	Meclizine 50 mg	Documented failure, contraindication or intolerance to meclizine 25 mg

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Any other exception is considered not medically necessary.

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

Appendix

Atypical Agents
Bupropion (Aplenzin, Forfivo XL, Wellbutrin, Wellbutrin SR, Wellbutrin XL)
Mirtazapine (Remeron, Remeron SolTab)
Serotonin Modulators
Nefazodone
Trazodone
Vilazodone (Viibryd)
Vortioxetine (Trintellix)
Serotonin-Norepinephrine Reuptake Inhibitors [SNRIs] include the following:
Desvenlafaxine (Khedezla)
Desvenlafaxine succinate (Pristiq)
Duloxetine (Cymbalta)
Levomilnacipran (Fetzima)
Venlafaxine (Effexor XR)
Selective Serotonin Reuptake Inhibitors [SSRIs] include the following:
Citalopram (Celexa)
Escitalopram (Lexapro)
Fluoxetine (Prozac)
Fluvoxamine
Paroxetine hydrochloride (Paxil, Paxil CR)
Paroxetine mesylate (Brisdelle, Pexeva)
Sertraline (Zoloft)
Tricyclic Antidepressants [TCAs] include the following:
Amitriptyline (Elavil)
Amoxapine
Clomipramine (Anafranil)
Desipramine (Norpramin)
Doxepin (Silenor)
Imipramine (Tofranil, Tofranil-PM)
Nortriptyline (Pamelor)
Protriptyline
Trimipramine (Sumontil)

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
- 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. Individual Drug Name Entries. Drug Facts and Comparisons. Facts & Comparisons[®] eAnswers [online]. Available from Wolters Kluwer Health, Inc. Accessed July, 2017.
- 5. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: http://www.accessdata.fda.gov/scripts/cder/drugsatfda/.
- 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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