Effective Date **9/15/2024**
Coverage Policy Number **1601**

Drugs/Biologics Not Covered Unless Approved Under Medical Necessity Review
Employer Group Plans: Standard, Performance, or Legacy 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 plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

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

1. 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] 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

   Note: *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 Plans:

Therapeutic Category	Product	Criteria
Acne Vulgaris Agents (Topical)	**Cabtreo** (clindamycin 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®** (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 2. Inability to swallow generic vancomycin capsules AND failure or intolerance to vancomycin 50 mg/mL oral solution
	Vancomycin 25 mg/mL oral 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 2. Inability to swallow generic vancomycin capsules AND failure or intolerance to vancomycin 50 mg/mL oral solution

Therapeutic Category	Product	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)	**Standard/Performance Drug List Plans:** 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: 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
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

Therapeutic Category	Product	Criteria
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/levodopa 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 carbidopa-levodopa tablets (generic for Sinemet)
Antiseizure Medications - Buccal	**Libervant** (diazepam buccal film strips)	**Libervant** is considered medically necessary when **ONE** of the following is met: **1.** Patient has tried diazepam rectal gel (generic Diastat) Note: If the patient has tried a benzodiazepine nasal spray (e.g., Valtoco or Nayzilam), this would satisfy the requirement for approval. **2.** Patient's caregiver is unable to administer diazepam rectal gel (generic Diastat)
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) 2. 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) 3. 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: a. Asmanex® Twisthaler (mometasone) b. 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)

Therapeutic Category	Product	Criteria
		2. 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) 3. 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: a. Asmanex® Twisthaler (mometasone) b. 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) 2. 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) 3. 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: a. Asmanex® Twisthaler (mometasone) b. Qvar® Redihaler™ (beclomethasone)
	Flovent HFA (fluticasone)	**ONE** of the following: 1. Individual has eosinophilic esophagitis 2. Individual is less than 4 years of age 3. 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)

Therapeutic Category	Product	Criteria
		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) 2. 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) 3. 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: a. Asmanex® Twisthaler (mometasone) b. Qvar® Redihaler™ (beclomethasone)
	Fluticasone propionate HFA	**ONE** of the following: 1. Individual has eosinophilic esophagitis 2. Individual is less than 4 years of age 3. 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)

Therapeutic Category	Product	Criteria
		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)
	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) 2. 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) 3. 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: a. Asmanex® Twisthaler (mometasone) b. 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® Pressair®** (aclidinium)	**ONE** of the following: • Incruse® Ellipta® (umeclidinium) • Spiriva (tiotropium)
Asthma and Respiratory: Inhalers, Long-	**Serevent® Diskus®**	**<u>Standard/Performance Drug List Plans:</u>** **ONE** of the following: 1. Documented failure, contraindication, or intolerance to Striverdi Respimat (olodaterol inhalation spray)

Therapeutic Category	Product	Criteria
Acting Beta-Agonists	(salmeterol xinafoate inhalation powder)	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: 1. 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 2. 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: 1. 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 2. 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: 1. 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 2. Pre-menarchal 3. Post-menarchal and **BOTH** of the following: a. Less than 18 years of age

Therapeutic Category	Product	Criteria
		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): i. Amlodipine ii. Felodipine iii. nifedipine LA iv. 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): i. amlodipine ii. felodipine iii. nifedipine LA iv. nisoldipine

Therapeutic Category	Product	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): i. Amlodipine ii. Felodipine iii. nifedipine LA iv. 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/omeprazole 81 mg – 40 mg tablets and 325 – 40 mg tablets)	**ALL** of the following: • Individual is at risk of developing aspirin associated gastric ulcers defined as **EITHER** of the following o 55 years of age or older o Documented history of gastric ulcers • Individual requires aspirin for secondary prevention of cardiovascular and cerebrovascular events defined as **ONE** of the following: o Previous ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli o Previous myocardial infarction or unstable angina pectoris o Chronic stable angina pectoris o History of revascularization procedure (coronary artery bypass graft or percutaneous transluminal coronary angioplasty) when there is pre-existing condition for which aspirin is already indicated • Documented intolerance to immediate release (including enteric coated) aspirin
Cardiovascular: Beta-Blocker Agents	**Hemangeol™** (propranolol hydrochloride 4.28 mg/mL oral solution)	Documentation of **BOTH** of the following: 1. Proliferating infantile hemangioma 2. Failure, contraindication or intolerance to propranolol hydrochloride oral solution (20 mg/5mL)
	Inderal XL® (propranolol hydrochloride	Documentation of **ONE** of the following: 1. Failure, contraindication or intolerance to propranolol extended-release capsules

Therapeutic Category	Product	Criteria
	extended-release capsules)	2. There is significant clinical concern such that the individual is unable to use propranolol extended-release capsules
	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 hydrochlorothiazide)	Documented inability to take single agents metoprolol succinate and hydrochlorothiazide concurrently
Cardiovascular: Diuretics	**Aldactazide®** (spironolactone / hydrochlorothiazide [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 / hydrochlorothiazide [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 25 mg tablets)	**ALL** of the following: • bumetanide • furosemide • torsemide
	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, and C): A. Individual is 18 years of age or older B. **EITHER** of the following (i or 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 or ii): i. bumetanide tablets ii. furosemide tablets

Therapeutic Category	Product	Criteria
Cardiovascular: Renin Inhibitors	**Lotrel®** (amlodipine / benazepril)	**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): i. amlodipine/olmesartan ii. amlodipine/telmisartan iii. amlodipine/valsartan
	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: i. benazepril ii. captopril iii. fosinopril iv. lisinopril v. quinapril vi. ramipril vii. trandolapril
Cardiovascular: Vasodilators	**Cardizem CD** (diltiazem 120 mg, 180 mg, 240 mg, 300 mg, and 360 mg extended release capsules)	**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)
	GoNitro™ (nitroglycerin sublingual powder)	**BOTH** of the following: • nitroglycerin sublingual tablets • nitroglycerin sublingual spray
	Isordil® Titradose™ (isosorbide dinitrate 40 mg tablet)	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

Therapeutic Category	Product	Criteria
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	**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) 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: o Member has a non-cosmetic medical condition (for example, acne vulgaris, psoriasis, precancerous lesion) o 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 self-esteem, or to treat psychological symptomatology or psychosocial complaints related to one's appearance.*
Dermatologic: Local anesthetics, topical	**Lidocaine** 3% lotion	**BOTH** of the following: • lidocaine 3% cream • lidocaine 5% ointment
	Lidocan II (lidocaine 5% topical patch)	Documented trial of **lidocaine 5% topical patch** (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.

Therapeutic Category	Product	Criteria
	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
		  ○ clocortolone
		  ○ desoximetasone
		  ○ fluocinonide
		  ○ flurandrenolide
		  ○ hydrocortisone
		  ○ mometasone
		  ○ prednicarbate
		  ○ triamcinolone

	Halog (halcinonide 0.1% cream)	**ALL** of the following: • betamethasone cream • clobetasol cream • fluocinonide cream • halobetasol cream • triamcinolone cream
	Halog (halcinonide 0.1% ointment)	**ALL** of the following: • betamethasone ointment • 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

Therapeutic Category	Product	Criteria
	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)
	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% ointment • Triamcinolone acetonide 0.5% cream • Triamcinolone acetonide 0.1% ointment
	Sernivo™ (betamethasone dipropionate 0.05% emulsion)	**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

Therapeutic Category	Product	Criteria
	Trianex® (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% ointment • Triamcinolone acetonide 0.5% cream • Triamcinolone acetonide 0.1% ointment
	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)	**Zituvio is considered medically necessary when BOTH of the following are met (1 <u>and</u> 2):** 1. **ONE** of the following (a, b, <u>or</u> c): a. Intolerance to a metformin-containing product b. The patient is initiating dual (combination) therapy with Zituvio and metformin c. The patient has a contraindication to metformin <u>Note</u>: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis. 2. Contraindication or intolerance to Januvia (sitagliptin) [Step Therapy may apply]
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/ Sodium Glucose Co-Transporter-2	**Qtern** (dapagliflozin/ saxagliptin)	**<u>Standard / Performance Drug List Plans:</u>** **Qtern is considered medically necessary when BOTH of the following are met (1 <u>and</u> 2):** 1. Contraindication or intolerance to a metformin-containing product

Therapeutic Category	Product	Criteria
(SGLT-2) Inhibitors		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 - Dipeptidyl Peptidase-4 (DPP-4) Inhibitor/ Sodium Glucose Co-Transporter-2 (SGLT-2) Inhibitors	**Steglujan** (sitagliptin / ertugliflozin)	**Standard / Performance Drug List Plans:** **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)	**Basaglar** (insulin glargine)	**Standard/Performance Drug List Plans:** **Basaglar** is considered medically necessary when the patient has tried **BOTH** of the following; 1. insulin glargine-yfgn (Semglee-yfgn authorized generic) 2. Semglee-yfgn (insulin glargine)
	Basaglar Tempo Pen (insulin glargine)	**Standard/Performance Drug List Plans:** **Basaglar Tempo Pen** is considered medically necessary when **ALL** of the following are met (1, 2 and 3): 1. Patient will use or is using Basaglar Tempo Pen with the Tempo Smart Button; AND 2. Patient has tried a basal insulin pen; AND 3. Patient was unable to adhere to a regimen using a standard basal insulin pen, according to the prescriber
	Insulin glargine, Insulin glargine SoloStar 100 units/mL	**Standard/Performance Drug List Plans:** **Insulin glargine, Insulin glargine SoloStar** 100 units/mL is considered medically necessary when the patient has tried **BOTH** of the following: 1. insulin glargine-yfgn (Semglee-yfgn authorized generic) 2. Semglee-yfgn (insulin glargine) **Legacy Drug List Plans:** **Insulin glargine, Insulin glargine SoloStar** 100 units/mL is considered medically necessary when the patient has tried **BOTH** of the following: 1. Basaglar (insulin glargine) 2. Rezvoglar (insulin glargine-AGLR)
	insulin glargine-yfgn 100 units/mL (Semglee-yfgn authorized generic)	**Legacy Drug List Plans:** **Insulin glargine-yfgn 100 units/mL** (Semglee-yfgn authorized generic) is considered medically necessary when the patient has tried **BOTH** of the following: 1. Basaglar (insulin glargine) 2. Rezvoglar (insulin glargine-AGLR)

Therapeutic Category	Product	Criteria
	Insulin Glargine Max Solostar U-300 300 units/mL (Toujeo Max Solostar authorized generic)	**Standard/Performance Drug List Plans:** **Insulin Glargine Max Solostar U-300 300 units/mL** (Toujeo Max Solostar authorized generic) is considered medically necessary when **ONE** of the following is met (1, 2, 3 or 4): 1. Type 2 Diabetes, (initial user) OR taking Insulin glargine U300 < 100 Units/injection (all others taking < 100 units/injection) AND the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec);AND b. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine) 2. Type 2 Diabetes, Continuation of Therapy with Insulin glargine U300 ≥ 100 units per injection (and all others taking ≥ 100 units/injection) AND the patient has tried Tresiba U-200 Note: A patient who has previously tried Tresiba U-100 is not required to try Tresiba U-200. 3. Type 1 Diabetes (initial user) AND the patient meets **BOTH** of the following (a and b) a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine) 4. Type 1 Diabetes, Continuation of Therapy with Insulin glargine U300 and the patient meets **ONE** of the following (a or b): a. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine); OR b. Patient is currently receiving an Insulin glargine U300 dose of ≥ 100 units per injection **Legacy Drug List Plans:** **Insulin Glargine Max Solostar U-300 300 units/mL (Toujeo Max Solostar authorized generic)** is considered medically necessary when **ONE** of the following is met (1, 2, 3 or 4): 1. Type 2 Diabetes, (initial user) OR taking Insulin glargine U300 < 100 Units/injection (all others taking < 100 units/injection) AND the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR) 2. Type 2 Diabetes, Continuation of Therapy with Insulin glargine U300 ≥ 100 units per injection (and all others taking ≥ 100 units/injection AND the patient has tried Tresiba U-200

Therapeutic Category	Product	Criteria
		Note: A patient who has previously tried Tresiba U-100 is not required to try Tresiba U-200. 3. Type 1 Diabetes (initial user) AND the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR) 4. Type 1 Diabetes, Continuation of Therapy with Insulin glargine U300 and the patient meets **ONE** of the following (a or b): a. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR); OR b. Patient is currently receiving an Insulin glargine U300 dose of ≥ 100 units per injection
	Lantus, **Lantus SoloStar** (insulin glargine U-100)	**Standard/Performance Drug List Plans:** **Lantus, Lantus SoloStar** (insulin glargine U-100) is considered medically necessary when the patient has tried **BOTH** of the following: 1. insulin glargine-yfgn (Semglee-yfgn authorized generic) 2. Semglee-yfgn (insulin glargine) **Legacy Drug List Plans:** **Lantus, Lantus SoloStar** (insulin glargine U-100) is considered medically necessary when the patient has tried **BOTH** of the following: 1. Basaglar (insulin glargine) 2. Rezvoglar (insulin glargine-AGLR)
	Levemir (insulin detemir U-100)	**Standard/Performance Drug List Plans:** **Levemir** (insulin detemir U-100) is considered medically necessary when **ONE** of the following is met (1 or 2): 1. Patient has Type 2 diabetes (Initial user OR a Patient Currently Receiving Levemir) OR Type 1 Diabetes (Initial user) and meets **ONE** of the following (a, b, or c): a. Patient meets **BOTH** of the following (i and ii): i. Patient has tried Tresiba (insulin degludec); AND ii. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine); OR b. Patients < 6 years of age AND has tried Tresiba (insulin degludec): OR c. Patient is pregnant 2. Patient has Type 1 diabetes AND is currently taking Levemir **Legacy Drug List Plans:** **Levemir** (insulin detemir U-100) is considered medically necessary when **ONE** of the following is met (1 or 2):

Therapeutic Category	Product	Criteria
		1. Patient has Type 2 diabetes (Initial user OR a patient Currently Receiving Levemir) OR Type 1 Diabetes (Initial user) and meets **ONE** of the following (a, b, or c): a. Patient meets **BOTH** of the following (i and ii): i. Patient has tried Tresiba (insulin degludec); AND ii. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR); OR b. Patients < 6 years of age AND has tried Tresiba (insulin degludec): OR c. Patient is pregnant 2. Patient has Type 1 diabetes AND is currently taking Levemir
	Rezvoglar (insulin glargine-AGLR subcutaneous injection)	**Standard/Performance Drug List Plans:** **Rezvoglar** (insulin glargine-AGLR subcutaneous injection) is considered medically necessary when the patient has tried **BOTH** of the following: 1. insulin glargine-yfgn (Semglee-yfgn authorized generic) 2. Semglee-yfgn (insulin glargine)
	Semglee-yfgn (insulin glargine U-100)	**Legacy Drug List Plans:** **Semglee-yfgn** (insulin glargine U-100) is considered medically necessary when the patient has tried **BOTH** of the following: 1. Basaglar (insulin glargine) 2. Rezvoglar (insulin glargine-AGLR)
	Toujeo SoloStar, Toujeo Max SoloStar (insulin glargine U-300)	**Standard/Performance Drug List Plans:** **Toujeo SoloStar, Toujeo Max SoloStar** (insulin glargine U-300) considered medically necessary when **ONE** of the following is met (1, 2, 3 or 4): 1. Type 2 Diabetes, (initial user) OR taking Toujeo < 100 Units/ injection (all others taking < 100 units/injection) and the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine) 2. Type 2 Diabetes, Continuation of Therapy with Toujeo ≥ 100 units per injection (and all others taking ≥ 100 units/injection) AND the patient has tried Tresiba U-200 Note: A patient who has previously tried Tresiba U-100 is not required to try Tresiba U-200. 3. Type 1 Diabetes (initial user) AND the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine)

Therapeutic Category	Product	Criteria
		4. Type 1 Diabetes, Continuation of Therapy with Toujeo and the patient meets **ONE** of the following (a or b): a. Patient has tried insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine); OR b. Patient is currently receiving a Toujeo dose of ≥ 100 units per injection **Legacy Drug List Plans:** **Toujeo SoloStar, Toujeo Max SoloStar** (insulin glargine U-300) considered medically necessary when **ONE** of the following is met (1, 2, 3 or 4): 1. Type 2 Diabetes, (initial user) OR taking Toujeo < 100 Units/ injection (all others taking < 100 units/injection) AND the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR) 2. Type 2 Diabetes, Continuation of Therapy with Toujeo or ≥ 100 units per injection (and all others taking ≥ 100 units/injection) AND the patient has tried Tresiba U-200 Note: A patient who has previously tried Tresiba U-100 is not required to try Tresiba U-200. 3. Type 1 Diabetes (initial user) AND the patient meets **BOTH** of the following (a and b): a. Patient has tried Tresiba (insulin degludec); AND b. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR) 4. Type 1 Diabetes, Continuation of Therapy with Toujeo and the patient meets **ONE** of the following (a or b): A. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR); OR B. Patient is currently receiving a Toujeo dose of ≥ 100 units per injection
Diabetes Agents – Insulin (Basal) and Glucagon-Like Peptide-1 (GLP-1) Agonist Combination	**Xultophy®** (insulin degludec/liraglutide injection)	**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%	• Humulin® 70/30

Therapeutic Category	Product	Criteria
	regular human insulin)	
	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 **dronabinol capsules** 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)	**Fecal microbiota spores, live-brpk capsules (Vowst) is considered medically necessary when the following are met:** 1. Prevention of recurrent Clostridioides difficile 2. Individual is 18 years of age or older
Gastrointestinal Agents: Aminosalicylates	**Asacol® HD** (mesalamine)	**Standard/Performance Drug List Plans:** Documentation of **BOTH** of the following: 1. The individual has tried **mesalamine** (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)	**Standard/Performance Drug List Plans:** Documentation of **BOTH** of the following: 1. The individual has tried **balsalazide** (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. Lialda® (mesalamine) c. sulfasalazine
	Delzicol® (mesalamine)	**Standard/Performance Drug List Plans:** Documentation of **BOTH** of the following: 1. The individual has tried **mesalamine** (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

Therapeutic Category	Product	Criteria
		2. Failure, contraindication, or intolerance to **ALL** of the following: a. Apriso™ (mesalamine) b. balsalazide c. Lialda® (mesalamine) d. sulfasalazine
	Dipentum® (olsalazine)	**Standard/Performance Drug List Plans:** 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	**Standard/Performance Drug List Plans:** Individual is unable to achieve the desired dose with generic **mesalamine 500 mg tablets**.
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): i. phenobarbital – belladonna elixir ii. phenobarbital / hyoscyamine / atropine / scopolamine elixir iii. 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 result in a significant allergy or serious adverse reaction.

Therapeutic Category	Product	Criteria
Hormones: oral corticosteroids	**Alkindi® Sprinkle oral granules** (hydrocortisone)	• 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)
		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

Laxative, Osmotic	**Kristalose®** (lactulose) packet) **lactulose packet**	• lactulose oral 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:** 1. Intolerance to generic atropine 1% ophthalmic solution 2. Known sensitivity to a preservative (e.g., benzalkonium chloride [BAK])
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 – Antibiotic/Corticosteroid Combination Products	**Pred-G** (Prednisolone acetate 1% and gentamicin sulfate 0.3% ophthalmic suspension)	Documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to tobramycin-dexamethasone ophthalmic suspension 2. Currently receiving Pred-G ointment for the treatment of an active eye infection and will be continuing therapy

Therapeutic Category	Product	Criteria
Ophthalmic Antibiotics - Quinolones	**Ciloxan® ointment** (ciprofloxacin ophthalmic ointment 0.3%)	Documentation of **ONE** of the following: 1. Failure, contraindication, or intolerance to **FOUR** of the following: a. ciprofloxacin 0.3% ophthalmic solution b. gatifloxacin 0.5% ophthalmic solution c. moxifloxacin 0.5% ophthalmic solution d. levofloxacin 0.5% ophthalmic solution e. ofloxacin 0.3% ophthalmic solution 2. Individual is allergic to benzalkonium chloride **AND** failure, contraindication, or intolerance to moxifloxacin 0.5% ophthalmic solution 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 solution 2. Individual with a sulfa allergy **AND** failure, contraindication, or intolerance to **BOTH** of the following: a. diclofenac ophthalmic b. ketorolac ophthalmic 3. Less than 18 years of age **AND** failure, contraindication, or intolerance to ketorolac ophthalmic
Ophthalmic Corticosteroids	**FML Forte®** (fluorometholone 0.25% 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 c. loteprednol ophthalmic

Therapeutic Category	Product	Criteria
	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 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 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
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%
	Iopidine® 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 opthalmic solution 3. levobunolol ophthalmic solution 4. timolol maleate ophthalmic solution

Therapeutic Category	Product	Criteria
	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 opthalmic 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 2. 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™** (dextromethorphan 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 Appendix 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

Therapeutic Category	Product	Criteria
Psychotherapeutic Drugs: Benzodiazepines	**Ativan®** (lorazepam)	**BOTH** of the following: • lorazepam (generic for Ativan) • **TWO** of the following: o alprazolam o clonazepam o diazepam o oxazepam o temazepam
Psychotherapeutic Drugs: Monoamine oxidase inhibitors	**Parnate®** (tranylcypromine sulfate 10 mg tablets)	**BOTH** of the following: • tranylcypromine (generic for Parnate) • **ONE** of the following: o Marplan o selegiline (oral formulations only) o phenelzine
Psychotherapeutic Drugs: SNRIs	**Cymbalta®** (duloxetine) delayed release capsules	**BOTH** of the following: • duloxetine (generic for Cymbalta) • **ONE** of the following: o citalopram o desvenlafaxine succinate ER o escitalopram o fluoxetine o fluvoxamine o paroxetine o sertraline o venlafaxine ER
	Desvenlafaxine ER	Documentation of **ONE** of the following: 1. Failure, contraindication or intolerance to **TWO** of the following: a. desvenlafaxine succinate extended-release b. duloxetine capsules c. venlafaxine extended-release capsules or tablets 2. Currently receiving Desvenlafaxine ER
	Drizalma Sprinkle™ (duloxetine) delayed release capsules	Individual meets **ONE** of the following (1, 2, 3, or 4): **1. Treatment of Chronic Musculoskeletal Pain.** 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, 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

Therapeutic Category	Product	Criteria
		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 B. There is documentation the individual is intolerant to or has an inability to swallow duloxetine capsules (Cymbalta generic)
	Venlafaxine besylate extended-release 112.5 mg tablets	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 2. Individual is currently taking venlafaxine besylate ER
Psychotherapeutic Drugs: SSRIs	**Lexapro®** (escitalopram) tablets	**BOTH** of the following: • escitalopram (generic for Lexapro) • **ONE** of the following: o citalopram o fluoxetine o fluvoxamine o paroxetine o sertraline

Therapeutic Category	Product	Criteria

	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
		  ○ escitalopram
		  ○ fluoxetine
		  ○ fluvoxamine
		  ○ imipramine
		  ○ nortriptyline
		  ○ paroxetine
		  ○ sertraline
		  ○ venlafaxine ER

	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
		  ○ fluvoxamine
		  ○ imipramine
		  ○ paroxetine
		  ○ sertraline
		  ○ venlafaxine ER

	Detrol® (tolterodine)	**BOTH** of the following: • tolterodine (generic for Detrol)

Therapeutic Category	Product	Criteria

Renal and Genitourinary Agents		• **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
		  d. tolterodine / tolterodine ER
		  e. trospium / trospium ER

	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

Therapeutic Category	Product	Criteria
	oxybutynin chloride 2.5mg tablet	**Oxybutynin chloride 2.5mg tablet is considered medically necessary when there is documentation of ALL of the following:** 1. Intolerance to oxybutynin 5mg tablet 2. Intolerance to oxybutynin 5mg/5ml solution/syrup 3. Failure, contraindication, or intolerance to **THREE** of the following: A. darifenacin ER B. solifenacin C. tolterodine / tolterodine ER D. trospium / trospium ER
	Oxytrol® (oxybutynin transdermal system)	• oxybutynin syrup, extended release tablets or tablets
	Toviaz® (fesoterodine)	**ALL** of the following: • 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: o darifenacin ER o oxybutynin / oxybutynin ER o tolterodine / tolterodine ER o trospium / trospium ER
	Vesicare LS™ (solfenacin succ.) 5 mg / 5 mL oral suspension	**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: o darifenacin ER o oxybutynin / oxybutynin ER o solifenacin o tolterodine / tolterodine ER o 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 or biologic in the same therapeutic class that can be expected to have equivalent clinical efficacy and safety when administered to patients under the conditions specified in the FDA-approved product information (Label). The number of Covered Alternative Drugs may vary by employer group plan and Prescription Drug Lists (e.g., “closed” versus “open” formulary plan designs).

Authorized Generics:
From the US Food and Drug Administration:

> An “authorized generic drug” is a listed drug as that has been approved by the FDA’s rules (under subsection 505(c)) and is marketed, sold, or distributed directly or indirectly to retail class of trade with either labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, etc.), product code, labeler code, trade name, or trade mark that differs from that of the listed drug.
>
> A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-name drugs. Not every brand-name drug has a generic drug. When new drugs are first made they have drug patents. Most drug patents are protected for 20 years. The patent, which protects the company that made the drug first, does not 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 adolescent

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

References

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