

Drug Coverage Policy

Effective Date......11/01/2024 Coverage Policy Number...... 1602

Drugs Requiring Medical Necessity Review for Employer Plans

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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 quidelines. In certain markets, delegated vendor quidelines may be used to support medical necessity and other coverage determinations.

Medical Necessity Criteria

Employer Plan Prescription Drug List does not cover certain drugs unless those products are approved based upon a medical necessity review. Coverage criteria are listed for these drugs **in the below table.**

All products are approved for a duration of up to 12 months unless otherwise noted.

Any other exception is considered not medically necessary.

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Therapeutic Category	Product	Criteria
Acne Vulgaris Agents (Topical)	Cabtreo™ (clindamycin phosphate, adapalene, and benzoyl peroxide topical gel)	Cabtreo is considered medically necessary when BOTH of the following are met: 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]
Actinic Keratosis Agents (Topical)	Carac® (fluorouracil 0.5% cream)	Carac is considered medically necessary when there is documentation that the patient has tried ONE of the following products: 1. Fluoroplex cream 2. fluorouracil 2% solution 3. fluorouracil 5% solution 4. fluorouracil 5% cream (generic Efudex)
	imiquimod 3.75% cream (generic for Zyclara cream)	Imiquimod 3.75% cream is considered medically necessary when there is documentation that the patient has tried imiquimod 5% cream (generic Aldara)
	imiquimod 3.75% cream pump (generic for Zyclara cream pump)	Imiquimod 3.75% cream pump is considered medically necessary when there is documentation that the patient has tried imiquimod 5% cream (generic Aldara)
	Klisyri® (tirbanibulin 1% ointment)	Klisyri is considered medically necessary when there is documentation that the patient has tried ONE of the following products: 1. diclofenac 3% gel, 2. a fluorouracil-containing product (e.g., fluorouracil cream, Carac, fluorouracil topical solution), 3. an imiquimod-containing product (e.g., imiquimod 5% cream, Zyclara)
	Zyclara® 2.5% cream pump (imiquimod 2.5% cream pump)	Zyclara 2.5% cream pump is considered medically necessary when there is documentation that the patient has tried imiquimod 5% cream (generic Aldara)

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cutegory	Zyclara® 3.75% cream (imiquimod 3.75% cream)	Zyclara 3.75% cream is considered medically necessary when there is documentation that the patient has tried imiquimod 5% cream (generic Aldara)
	Zyclara® 3.75% cream pump (imiquimod 3.75% cream pump)	Zyclara 3.75% cream pump is considered medically necessary when there is documentation that patient has tried imiquimod 5% cream (generic Aldara)
Angiotensin Converting Enzyme (ACE) Inhibitors	Qbrelis ® (lisinopril oral solution)	Qbrelis is considered medically necessary when ONE of the following is met: 1. Patient has tried lisinopril tablets 2. Patient is unable to swallow or has difficulty swallowing tablets
Angiotensin Receptor Blockers	valsartan oral solution (previously Prexxartan)	Value/Advantage/Total Savings Drug List Plans: Valsartan oral solution is considered medically necessary when there is documentation of ONE of the following: 1. Patient has tried valsartan tablets 2. Patient is unable to or has difficulty swallowing oral tablets.
Angiotensin Receptor Blockers (ARBs) and Combination Products	Edarbi® (azilsartan medoxomil tablets)	Effective 1/1/2025 Edarbi is considered medically necessary when there is documentation of ONE of the following: 1. Patient has tried FIVE of the following: a. candesartan (generic Atacand) b. eprosartan c. irbesartan (generic Avapro) d. losartan (generic Cozaar) e. olmesartan (generic Benicar) f. telmisartan (generic Micardis) g. valsartan (generic Diovan) 2. Patient was recently hospitalized (and discharged within 30 days) for a cardiovascular event (e.g., myocardial infarction [MI], hypertensive emergency) AND has already been started and stabilized on Edarbi
	Edarbyclor® (azilsartan medoxomil/ chlorthalidone tablets)	EFFECTIVE 1/1/2025 Edarbyclor is considered medically necessary when there is documentation of ONE of the following:

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		 Patient has tried FIVE of the following formulary angiotensin receptor blocker/diuretic combination products: a. candesartan-hydrochlorothiazide (generic Atacand HCT) b. irbesartan-hydrochlorothiazide (generic Avalide) c. losartan-hydrochlorothiazide (generic Hyzaar) d. telmisartan-hydrochlorothiazide (generic Micardis HCT) e. valsartan-hydrochlorothiazide (generic Diovan HCT) f. olmesartan-hydrochlorothiazide (generic Benicar HCT) Patient has tried chlorthalidone AND FIVE of the following angiotensin receptor blockers (ARBs): a. candesartan (generic Atacand) b. eprosartan c. irbesartan (generic Avapro d. losartan (generic Cozaar) e. olmesartan (generic Benicar) f. telmisartan (generic Micardis) g. valsartan (generic Diovan)
Antibiotics (Oral)	Firvanq® (vancomycin hydrochloride for oral solution)	Firvanq is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE of the following:
	Likmez® (metronidazole oral suspension)	 Likmez is considered medically necessary when ONE of the following is met: 1. Patient has tried metronidazole tablets 2. Patient is unable to swallow or has difficulty swallowing tablets
	nitrofurantoin 50 mg/5 mL oral suspension	Documentation of failure, contraindication, or intolerance to nitrofurantoin 25 mg/5 mL oral suspension
	Solosec® (secnidazole oral granules)	Standard/Performance/Value/Advantage/ Total Savings Drug List Plans: Solosec is considered medically necessary when ONE of the following is met: 1. Patient has tried TWO of the following:

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		 a. clindamycin capsules b. metronidazole tablets c. tinidazole tablets 2. Treatment of trichomoniasis AND patient has tried ONE of the following: a. metronidazole tablets b. tinidazole tablets 3. Patient is unable to swallow or has difficulty swallowing tablets or capsules
	vancomycin 25 mg/mL oral solution (generic for Firvanq)	Vancomycin 25 mg/mL oral solution is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE of the following:
Antibiotics (Topical)	Mupirocin 2% cream	Documented failure, contraindication, or intolerance to mupirocin 2% ointment
Antidepressants – Other	Aplenzin® (bupropion hydrobromide extended-release tablets)	Aplenzin is considered medically necessary when the patient has tried ONE bupropion hydrochloride extended-release tablets product (Wellbutrin XL, generics)
	Auvelity® (dextromethorphan HBr and bupropion HCl extended-release tablet)	Auvelity is considered medically necessary when ONE of the following is met: 1. Patient has tried at least two different antidepressants, one of which is bupropion and one additional antidepressant Note: Examples of antidepressants include selective serotonin reuptake inhibitors (SSRIs), serotonin-norepinephrine reuptake inhibitors (SNRIs), tricyclic antidepressants (TCAs), mirtazapine, etc. 2. Patient has suicidal ideation 3. Patient is currently taking or has taken Auvelity at any time in the past
	bupropion hydrochloride 450 mg extended- release tablets	Bupropion HCl 450 mg ER tablet is considered medically necessary when ONE of the following is met: 1. Patient has tried bupropion hydrochloride XL 150 mg and/or 300 mg tablets (Wellbutrin XL, generics)

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		2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use the bupropion hydrochloride XL 150 mg and/or 300 mg tablets (Wellbutrin XL, generics).
	Forfivo XL® (bupropion hydrochloride extended-release tablets)	 Forfivo XL is considered medically necessary when ONE the following is met: 1. Patient has tried bupropion hydrochloride XL 150 mg and/or 300 mg tablets (Wellbutrin XL, generics) 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use the bupropion hydrochloride XL 150 mg and/or 300 mg tablets (Wellbutrin XL, generics)
Antiemetics - Serotonin (5- HT3) Receptor Antagonists (Oral)	ondansetron 16 mg ODT	Ondansetron 16mg ODT is considered medically necessary when the patient is unable to obtain ondansetron ODT 4 mg AND ondansetron ODT 8 mg
Antiemetics - Serotonin (5- HT3) Receptor Antagonists (Injectable)	Posfrea™ (palonosetron intravenous injection)	Posfrea is considered medically necessary when the patient has tried and cannot take generic palonosetron injection.
Antiemetic Agents - Substance P/Neurokinin-1 (NK1) receptor antagonists (Injectable)	Focinvez™ (fosaprepitant injection)	 Focinvez is considered medically necessary when ONE of the following is met: 1. Patient has tried generic fosaprepitant dimeglumine injection (IV) (generic for Emend for injection) 2. Patient has hypersensitivity to polysorbate 80 3. Patient has already started Focinvez IV to complete all cycles in the current course of chemotherapy.
Antihistamines (Oral) - First- generation	carbinoxamine maleate extended- release oral suspension 4mg/5mL [authorized generic of Karbinal ER]	Carbinoxamine maleate ER oral suspension is considered medically necessary when ONE of the following is met: 1. Patient has tried FIVE oral antihistamines (e.g., clemastine, diphenhydramine, chlorpheniramine, carbinoxamine [generic], hydroxyzine, cetirizine, loratadine). Note: OTC products would count toward meeting the requirement. 2. Patient is unable to swallow or has difficulty swallowing solid dosage forms, AND has tried at least two oral liquid antihistamines (e.g., carbinoxamine solution [generic],

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Therapeutic Category	Product	Criteria
		diphenhydramine solution, hydroxyzine solution or syrup, clemastine syrup, cetirizine solution, or loratadine solution or syrup). Note: OTC products would count toward meeting the requirement.
	Karbinal® ER (carbinoxamine maleate extended-release oral suspension)	 Karbinal ER is considered medically necessary when ONE of the following is met: 1. Patient has tried FIVE oral antihistamines (e.g., clemastine, diphenhydramine, chlorpheniramine, carbinoxamine [generic], hydroxyzine, cetirizine, loratadine). Note: OTC products would count toward meeting the requirement. 2. Patient is unable to swallow or has difficulty swallowing solid dosage forms AND has tried at least two oral liquid antihistamines (e.g., carbinoxamine solution [generic], diphenhydramine solution, hydroxyzine solution or syrup, clemastine syrup, cetirizine solution, or loratadine solution or syrup). Note: OTC products would count toward meeting the requirement.
Antiparasitic Agents	Xdemvy™ (lotilaner 0.25% ophthalmic solution)	Xdemvy is considered medically necessary for the treatment of Demodex blepharitis.
Antiparkinson Agents	Dhivy (carbidopa/levodopa 25-100 mg oral tablet)	 ALL of the following criteria: Documented diagnosis of ONE of the following: a. Parkinson's disease b. Postencephalitic Parkinsonism c. Symptomatic Parkinsonism Medication is prescribed by, or in consultation with, a neurologist Documented inability to achieve desired dose with carbidopa-levodopa tablets (generic for Sinemet)
Antipsychotics (Oral)	Fanapt® (iloperidone tablets)	Fanapt is considered medically necessary when ALL of the following are met: 1. Patient has tried TWO oral antipsychotics (e.g., risperidone tablets/orally disintegrating tablets [ODT][generic Risperdal], olanzapine tablets/ODT [generic Zyprexa/Zydis], quetiapine tablets [generic Seroquel], quetiapine extended-release tablets [generic Seroquel XR], aripiprazole tablets [generic Abilify], paliperidone ER tablets [generic Invega], ziprasidone capsules [generic

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		Geodon], Latuda tablets, Rexulti tablets, Vraylar capsules, asenapine sublingual tablets [generic Saphris], Caplyta). 2. Patient is currently taking Fanapt. 3. Patient has taken Fanapt at any time in the past.
	Versacloz® (clozapine, USP oral suspension)	Versacloz is considered medically necessary when the patient has tried clozapine tablets OR clozapine orally disintegrating tablets
Antiseizure Medications	Primidone 125 mg oral tablet	Primidone 125 mg tablet is considered medically necessary when the patient's prescribed dose cannot be obtained with generic primidone 50 mg or 250 mg oral tablets
Antiseizure Medications - Buccal	Libervant™ (diazepam buccal film)	 Libervant is considered medically necessary when ONE of the following is met: 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. Patient's caregiver is unable to administer diazepam rectal gel (generic Diastat)
Antivirals (Oral)	Sitavig® (acyclovir buccal tablet)	Sitavig is considered medically necessary when the patient has tried TWO of the following: 1. acyclovir capsules or tablets 2. famciclovir tablets 3. valacyclovir tablets 4. Denavir 1% cream 5. Xerese 5%/1% cream 6. acyclovir 5% cream
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)

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		 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) 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)	 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:

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Therapeutic Category	Product	Criteria
Category	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) 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)
	Fluticasone propionate Diskus	 b. Asmanex® HFA (mometasone) c. Qvar® Redihaler™ (beclomethasone) ONE of the following: 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: a. Alvesco® (ciclesonide) b. Asmanex® Twisthaler OR Asmanex® HFA (mometasone) c. 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: a. Asmanex® Twisthaler (mometasone) b. Qvar® Redihaler™ (beclomethasone)

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Therapeutic Category	Product	Criteria
Category	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) 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) 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) 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)

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Asthma and Respiratory: Inhalers, Long- Acting Beta- Agonists	Serevent® Diskus® (salmeterol xinafoate inhalation powder)	 Standard/Performance/Value/Advantage/ Total Savings Drug List Plans: ONE of the following: Documented failure, contraindication, or intolerance to Striverdi Respimat (olodaterol inhalation spray) Individual is unable to coordinate breath and actuation with a metered-dose inhaler (MDI) Individual with asthma and is using Serevent Diskus concomitantly with an inhaled corticosteroid or an inhaled corticosteroid-containing product Individual with exercise induced bronchospasm without asthma
Bacterial Vaginosis Agents	Sis Ovules (clindamycin phosphate vaginal suppositories) 1. 18 years of age contraindication following: a. clindamycream b. metronic Vandazo 2. Post-menarchal a. Less tha b. Docume intolerar i. co	contraindication or intolerance to BOTH of the following: a. clindamycin phosphate 2% vaginal
	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®	Documentation of ONE of the following:

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	(metronidazole 1.3% vaginal gel)	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 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™ (clindamycin 2% vaginal gel)	Xaciato 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 or Vandazole 0.75% vaginal gel
Beta-Blocker and Beta- Blocker Combination Products	Hemangeol® (propranolol hydrochloride 4.28 mg/mL oral solution)	 Hemangeol is considered medically necessary when there is documentation of BOTH of the following: 1. Treatment of Proliferating infantile hemangioma 2. Patient has tried to propranolol hydrochloride oral solution (20 mg/5mL) [NOT Hemangeol].

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Therapeutic Category	Product	Criteria
	Inderal® XL (propranolol hydrochloride extended- release capsules)	 Inderal XL is considered medically necessary when there is documentation of ONE of the following: 1. Patient has tried propranolol extended-release capsules 2. According to the prescriber, there is significant clinical concern such that the patient is unable to use generic propranolol extended-release capsules
	Innopran XL® (propranolol hydrochloride extended- release capsules)	 Innopran XL is considered medically necessary when there is documentation of ONE of the following: 1. Patient has tried propranolol extended-release capsules 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use generic propranolol extended-release capsules.
	Kapspargo Sprinkle® (metoprolol succinate extended-release capsules)	 Kapspargo Sprinkle is considered medically necessary when there is documentation of ONE of the following: 1. Patient has tried metoprolol succinate extended-release tablets 2. Patient requires a dosage form which can be opened and sprinkled for alternative administration (e.g., for patients unable to swallow capsules, for nasogastric tube administration)
Bowel Evacuants – Low Volume – Polyethylene Glycol (PEG)- based Preparations	Suflave™ (polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride for oral solution)	Suflave is considered medically necessary when the following is met: Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is NOT required. 1. Patient has tried ONE of the following (a or b): a. PEG3350/Ascorbic Acid powder pack (generic Moviprep); OR b. Sod Sul-Potass Sul-Magnesium sol prep kit (generic Suprep) Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is required. 1. Patient has tried ONE of the following (a or b):

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Therapeutic Category	Product	Criteria
		 a. PEG3350/Ascorbic Acid powder pack (generic Moviprep); OR b. Sod Sul-Potass Sul-Magnesium sol prep kit (generic Suprep) 2. Patient meets BOTH of the following (a and b): a. The requested non-formulary drug is being prescribed for bowel preparation as part of a colorectal cancer screening procedure in a patient between the ages of 45 years and 75 years old; AND b. Other formulary alternative(s) would not be as medically appropriate for the patient as the requested non-formulary drug.
Bowel Evacuants –	Clenpiq® (sodium picosulfate,	EFFECTIVE 1/1/2025
Low Volume – Sodium Picosulfate-	magnesium oxide. anhydrous citric acid oral solution)	Clenpiq is considered medically necessary when the following is met:
based Preparations		Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is NOT required. 1. Patient meets ONE of the following (a or b): a. Patient has tried ONE of the following (i or ii): i. PEG3350/Ascorbic Acid powder pack (generic Moviprep); OR ii. Sod Sul-Potass Sul-Magnesium sol prep kit (generic Suprep); OR b. Patient is < 12 years of age
		Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is
		1. Patient meets ONE of the following (a or b): a. Patient has tried ONE of the following (i or ii): i. PEG3350/Ascorbic Acid powder pack (generic Moviprep); OR ii. Sod Sul-Potass Sul-Magnesium sol prep kit (generic Suprep); OR b. Patient is < 12 years of age. 2. Patient meets BOTH of the following (a and b): a. The requested non-formulary drug is being prescribed for bowel preparation as part of a colorectal cancer screening procedure in a patient between the ages of 45 years and 75 years old; AND b. Other formulary alternative(s) would not be as medically appropriate for the

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Therapeutic Category	Product	Criteria
		patient as the requested non-formulary drug.
Bowel Evacuants – Low Volume – Sodium Sulfate- based Preparations	Sutab® (sodium sulfate, magnesium sulfate, and potassium chloride tablets)	Sutab is considered medically necessary when the following is met: Compliance with the Affordable Care Act, HRSA Guidelines, and PHS Act section 2713 is NOT required. 1. Patient has tried ONE of the following (a or b):
Calcium Channel Blockers (CCBs)	Conjupri® (levamlodipine)	There is documentation of EITHER of the following (A <u>or</u> 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
	Katerzia®	Katerzia is considered medically necessary when there is documentation of ONE of the following:

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23323917	(amlodipine oral suspension)	 Patient has tried amlodipine tablets Patient is unable to swallow or has difficulty swallowing amlodipine tablets AND has tried Norliqva oral solution [may require prior authorization]
	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
	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
	Norliqva® (amlodipine oral solution)	Norliqva is considered medically necessary when there is documentation of ONE of the following: 1. Patient has tried amlodipine tablets 2. Patient is unable to swallow or has difficulty swallowing amlodipine tablets
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

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Therapeutic Category	Product	Criteria
Cardiovascular: Antithrombotic Agents	Yosprala™ (aspirin delayed release/omeprazole 81 mg - 40 mg tablets and 325 - 40 mg tablets)	ALL of the following: 1. Individual is at risk of developing aspirin associated gastric ulcers defined as EITHER of the following a. 55 years of age or older b. Documented history of gastric ulcers 2. Individual requires aspirin for secondary prevention of cardiovascular and cerebrovascular events defined as ONE of the following: a. Previous ischemic stroke or transient ischemia of the brain due to fibrin platelet emboli b. Previous myocardial infarction or unstable angina pectoris c. Chronic stable angina pectoris d. 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 3. Documented intolerance to immediate release (including enteric coated) aspirin
Cardiovascular: Renin Inhibitors	Tekturna® HCT (aliskiren/ hydrochlorothiazide tablets)	Value/Advantage/Total Savings Drug List Plans: Tekturna HCT is considered medically necessary when the patient has tried single agents aliskiren AND hydrochlorothiazide concurrently.
Cardiovascular: Vasodilators	Isordil [®] Titradose [™] (isosorbide dinitrate 40 mg tablet)	Documented inability to use two tablets of isosorbide dinitrate 20 mg tablets
Contraceptives	Estratest® F.S. (esterified estrogens & methyltestosterone 1.25mg/2.50mg tablets)	Estratest F.S. is considered medically necessary when the patient has tried TWO equivalent strength products [Covaryx, EEMT DS 1.25 mg - 2.5 mg, and Esterified Estrogens and Methyltestosterone FS] AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the Estratest FS and the equivalent strength products which, per the prescriber, would result in a significant allergy or serious adverse reaction. Note: A non-covered product is being requested. The patient should use the preferred equivalent strength products.

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Therapeutic Category	Product	Criteria
Corticosteroids (Oral)	Alkindi Sprinkle (hydrocortisone oral granules)	Alkindi Sprinkle is considered medically when ONE of the following is met: 1. Patient has tried and cannot take hydrocortisone tablets. 2. Patient cannot swallow or has difficulty swallowing hydrocortisone tablets 3. Patient's dose cannot be obtained using whole hydrocortisone tablets.
	dexamethasone 1.5 mg tablets Dose Pack	 Dexamethasone 1.5 mg tablets dose pack is considered medically necessary when ONE of the following is met: 1. Patient has tried dexamethasone 1.5 mg tablets (not packed as dose packs). 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use dexamethasone 1.5 mg tablets (not packed as dose packs).
	Dxevo™ 11-Day Dose Pack (dexamethasone 1.5 mg tablets)	 Dxevo 11-Day Dose Pack is considered medically necessary when ONE of the following is met: 1. Patient has tried dexamethasone 1.5 mg tablets (not packed as dose packs). 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use dexamethasone 1.5 mg tablets (not packed as dose packs).
	TaperDex [™] 6-Day, 7-Day, and 12-Day Pack (dexamethasone 1.5 mg tablets)	 TaperDex 6-Day, 7-Day, and 12-Day Pack is considered medically necessary when ONE of the following is met: 1. Patient has tried dexamethasone 1.5 mg tablets (not packed as dose packs). 2. According to the prescriber, there is a significant clinical concern such that the patient is unable to use dexamethasone 1.5 mg tablets (not packed as dose packs).
Corticosteroids (Rectal Formulations)	Cortifoam® (hydrocortisone acetate 10% rectal foam)	Cortifoam is considered medically necessary when ONE of following is met: 1. Patient has tried budesonide foam (generic Uceris foam) 2. Patient is unable to retain a corticosteroid enema AND has tried budesonide foam
Corticosteroids (Topical)	Halog® Ointment (halcinonide 0.1% ointment)	Halog Ointment is considered medically necessary when the patient has tried FIVE of the following: 1. amcinonide 0.1% ointment

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Therapeutic Category	Product	Criteria
		 betamethasone dipropionate 0.05% ointment desoximetasone 0.25% cream OR ointment desoximetasone 0.05% gel diflorasone diacetate 0.05% cream OR emollient cream(Apexicon E) fluocinonide 0.05% cream OR gel OR ointment OR solution triamcinolone acetonide 0.5% ointment
	Halog® Solution (halcinonide 0.1% solution)	 Halog Solution is considered medically necessary when the patient has tried FIVE of the following: amcinonide 0.1% ointment betamethasone dipropionate 0.05% ointment desoximetasone 0.25% cream OR ointment desoximetasone 0.05% gel diflorasone diacetate 0.05% cream OR emollient cream (Apexicon E) fluocinonide 0.05% cream OR gel OR ointment OR solution triamcinolone acetonide 0.5% ointment
	Kenalog® Spray (triamcinolone acetonide 0.147 mg/gm topical aerosol)	 Kenalog Spray is considered medically necessary when the patient has tried FIVE of the following: amcinonide 0.1% cream OR lotion betamethasone valerate 0.1% lotion betamethasone valerate 0.12% foam desoximetasone 0.05% cream OR gel OR ointment fluocinonide 0.05% cream OR gel OR ointment OR solution Fluocinonide-E 0.05% cream fluticasone propionate 0.005% ointment hydrocortisone valerate 0.2% ointment mometasone furoate 0.1% cream OR ointment OR solution triamcinolone acetonide 0.1% ointment OR cream triamcinolone acetonide 0.5% cream OR ointment
	Sernivo® (betamethasone dipropionate 0.05% spray)	Sernivo is considered medically necessary when the patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with FIVE unique, generic prescription-strength topical corticosteroid products. Note: Examples of topical steroid products include: desoximetasone, triamcinolone, betamethasone, clobetasol, fluocinonide, mometasone, halcinonide.

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Therapeutic Category	Product	Criteria
		NOTE: The five products must be chemically unique.
	triamcinolone acetonide 0.147 mg/gm topical aerosol solution (generic Kenalog Spray)	Triamcinolone topical aerosol solution is considered medically necessary when the patient has tried FIVE of the following: 1. amcinonide 0.1% cream OR lotion 2. betamethasone valerate 0.1% lotion 3. betamethasone valerate 0.12% foam 4. desoximetasone 0.05% cream OR gel OR ointment 5. fluocinonide 0.05% cream OR gel OR ointment OR solution 6. fluocinonide-E 0.05% cream 7. fluticasone propionate 0.005% ointment 8. hydrocortisone valerate 0.2% ointment 9. mometasone furoate 0.1% cream OR ointment OR solution 10. triamcinolone acetonide 0.1% ointment OR cream 11. triamcinolone acetonide 0.5% cream OR ointment
	triamcinolone acetonide 0.05% ointment	Triamcinolone 0.05% ointment is considered medically necessary when the patient has tried FIVE of the following: 1. amcinonide 0.1% cream OR lotion 2. betamethasone valerate 0.1% cream OR lotion OR ointment 3. betamethasone valerate 0.12% foam 4. desoximetasone 0.05% cream OR ointment 5. fluocinonide 0.05% cream OR gel OR ointment OR solution 6. fluocinonide-E 0.05% cream 7. fluticasone propionate 0.005% ointment 8. hydrocortisone valerate 0.2% ointment OR cream 9. mometasone furoate 0.1% cream OR ointment OR solution 10. prednicarbate 0.1% ointment OR cream 11. triamcinolone acetonide 0.025% ointment 12. triamcinolone acetonide 0.1% ointment OR cream OR lotion 13. triamcinolone acetonide 0.5% cream OR ointment
	Verdeso [™] (desonide 0.05% foam)	Verdeso is considered medically necessary when the patient has tried and, according to the prescriber, has experienced inadequate efficacy OR

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Therapeutic Category	Product	Criteria
		significant intolerance with FIVE unique, generic prescription-strength topical corticosteroid products. <u>Note</u> : Examples of topical steroid products include: desonide, alclometasone dipropionate, betamethasone valerate, fluocinolone acetonide, triamcinolone, flurandrenolide, hydrocortisone butyrate. <u>NOTE</u> : The five products must be chemically unique (for example, a trial of desoximetasone 0.05% and 0.25% would NOT fulfill the requirement).
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:

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Therapeutic Category	Product	Criteria
dategory		 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 self-esteem, or to treat psychological symptomatology or psychosocial complaints related to one's appearance.
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-4) Inhibitors	Tradjenta® (linagliptin tablets)	Tradjenta is considered medically necessary when ONE of the following is met (1 or 2): 1. Patient meets BOTH of the following (a and b): a. ONE of the following (i, ii, or iii): i. Patient has tried a metformincontaining product ii. Patient is initiating dual (combination) therapy with Tradjenta and metformin iii. The patient has a contraindication to metformin Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis. b. Patient has tried BOTH of the following (i and ii): i. saxagliptin (generic Onglyza) ii. Januvia (sitagliptin) 2. Patients with a history of heart failure (HF) or renal impairment AND has tried Januvia
	Zituvio (sitagliptin)	Standard/Performance/Value/Advantage Drug List Plans: Zituvio is considered medically necessary when BOTH of the following are met (1 and 2): 1. ONE of the following (a, b, or c): a. Intolerance to a metformin-containing product b. The patient is initiating dual (combination) therapy with Zituvio and metformin

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Therapeutic	Product	Criteria
Diabetes Agents - Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Combination Products	Jentadueto® (linagliptin/metformin HCl tablets)	c. The patient has a contraindication to metformin Note: 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] Total Savings Drug List Plans: Zituvio is considered medically necessary when BOTH of the following are met (1 and 2): 1. ONE of the following (a, b, or 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 Note: Examples of contraindications to metformin include acute or chronic metabolic acidosis, including diabetic ketoacidosis. 2. Contraindication or intolerance to Tradjenta (linagliptin) EFFECTIVE 1/1/2025 Jentadueto is considered medically necessary when ONE of the following is met (1 or 2): 1. Patient meets BOTH of the following (a and b): a. Patient has tried a metformin-containing product b. Patient has tried BOTH of the following metformin-DPP-4 inhibitor combination products(i or ii): i. Janumet OR Janumet XR ii. saxagliptin plus metformin extended-release tablets (generic Kombiglyze XR). Note: Janumet and Janumet XR would count as one alternative. 2. Patients with a history of heart failure (HF) or renal impairment AND has tried Janumet OR Janumet XR
	Jentadueto® XR (linagliptin/metformin HCl extended-release tablets)	EFFECTIVE 1/1/2025 Jentadueto XR is considered medically necessary when ONE of the following is met (1 or 2):

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Therapeutic	Product	Criteria
Category	sitagliptin and metformin tablets (generic for Janumet)	1. Patient meets BOTH of the following (a and b): a. Patient has tried a metformin-containing product b. Patient has tried BOTH of the following metformin-DPP-4 inhibitor combination products(i or ii): i. Janumet OR Janumet XR ii. saxagliptin plus metformin extended-release tablets (generic Kombiglyze XR) Note: Janumet and Janumet XR would count as one alternative. 2. Patients with a history of heart failure (HF) or renal impairment AND has tried Janumet or Janumet XR. Standard/Performance/Value/Advantage/Legacy Drug List Plans: Sitagliptin and metformin tablets is considered medically necessary when the patient has tried Janumet EFFECTIVE THROUGH 12/31/2024 Total Savings Drug List Plans: Sitagliptin and metformin tablets is considered medically necessary when ONE of the following is met: 1. Patient has tried Jentadueto OR Jentadueto XR. Note: Jentadueto and Jentadueto XR would count as one alternative. 2. Patients with a history of heart failure (HF) or renal impairment: Patient has tried metformin (Glucophage, Glucophage ER, generics). Note: A brand product and its generic or authorized generic would count as one alternative. EFFECTIVE 1/1/2025 Total Savings Drug List Plans: Sitagliptin and metformin tablets is considered medically necessary when the patient has tried Janumet
Diabetes Agents - Dipeptidyl	Qtern (dapagliflozin/	Standard/Performance/Value/Advantage/ Total Savings Drug List Plans:
Peptidase-4 (DPP-4) Inhibitor/ Sodium Glucose	saxagliptin)	 Qtern is considered medically necessary when BOTH of the following are met (1 and 2): 1. Contraindication or intolerance to a metformin-containing product

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Therapeutic Category	Product	Criteria
Co-Transporter- 2 (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]
	Steglujan (sitagliptin/ertugliflozin)	Standard/Performance/Value/Advantage/ Total Savings Drug List Plans: Steglujan is considered medically necessary when BOTH of the following are met (1 and 2): 1. Contraindication or intolerance to a metformincontaining 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) Value/Advantage/Total Savings/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:

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Therapeutic Category	Product	Criteria
		Basaglar (insulin glargine) Rezvoglar (insulin glargine-AGLR)
	insulin glargine SoloStar® 300	EFFECTIVE 12/1/2024
	Units/mL (U-300) (Toujeo Solostar authorized generic)	 Standard/Performance Drug List Plans: Insulin Glargine Solostar U-300 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 U-300 < 100 Units/injection (all others taking < 100 units/injection) AND the patient meets BOTH of the following (a and b):
		Value/Advantage/Total Savings/Legacy Drug List Plans: Insulin Glargine Solostar U-300 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 U-300 < 100 Units/injection (all others taking < 100 units/injection) AND the patient meets BOTH of the following (a and b):

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Therapeutic Category	Product	Criteria
Category		 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 U-300 ≥ 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 Insulin glargine U-300 and patient meets ONE of the following (a or b): a. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine) OR Rezvoglar (insulin glargine-AGLR); OR b. Patient is currently receiving an Insulin glargine U-300 dose of ≥ 100 units per injection
	insulin glargine Max SoloStar® 300 Units/mL (U-300) (Toujeo Max Solostar authorized generic)	 Standard/Performance Drug List Plans: Insulin Glargine Max SoloStar U-300 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 U-300 < 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 U-300 ≥ 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)

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Therapeutic Category	Product	Criteria
		 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 U-300 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 U-300 dose of ≥ 100 units per injection
		 Value/Advantage/Total Savings/Legacy Drug List Plans: Insulin Glargine Max SoloStar U-300 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 U-300 < 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 U-300 ≥ 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 Insulin glargine U-300 and the patient meets ONE of the following (a or b): a. Patient has tried Basaglar (insulin glargine) OR Rezvoglar (insulin glargine) OR Rezvog

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Therapeutic Category	Product	Criteria
,		 b. Patient is currently receiving an Insulin glargine U-300 dose of ≥ 100 units per injection
	insulin glargine-yfgn 100 units/mL (Semglee- yfgn authorized generic)	Value/Advantage/Total Savings/Legacy Drug List Plans: Insulin glargine-yfgn 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)
	Lantus®, Lantus® SoloStar® (insulin glargine U-100)	Standard/Performance Drug List Plans: Lantus, Lantus SoloStar 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) Value/Advantage/Total Savings/Legacy Drug List Plans: Lantus, Lantus SoloStar 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 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 Value/Advantage/Total Savings/Legacy Drug
		<u>List Plans:</u>

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Therapeutic Category	Product	Criteria
		Levemir 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 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 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-yfgn U- 100)	Value/Advantage/Total Savings/Legacy Drug List Plans: Semglee-yfgn 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 is considered medically necessary when ONE of the following is met (1, 2, 3 or 4): 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):

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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 insulin glargine-yfgn (Semglee-yfgn authorized generic) OR Semglee-yfgn (insulin glargine) 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
		 Value/Advantage/Total Savings/Legacy Drug List Plans: Toujeo SoloStar, Toujeo Max SoloStar is considered medically necessary when ONE of the following is met (1, 2, 3 or 4): 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):

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Therapeutic Category	Product	Criteria
Category		 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 Agents - Insulin (Human)	Novolin® 70/30 (70% NPH, Human Insulin Isophane Suspension and 30% Regular Human Insulin injection)	Novolin 70/30 is considered medically necessary when the patient has tried Humulin 70/30 vials or Humulin 70/30 KwikPens
	Novolin® N (NPH, Human Insulin Isophane Suspension injection)	Novolin N is considered medically necessary when the patient has tried Humulin N vials or Humulin N KwikPens
	Novolin® R (Regular Human Insulin injection)	Novolin R is considered medically necessary when the patient has tried Humulin R U-100 vials
Diabetes Agents - Insulin (Rapid- Acting and Other)	Novolog® Mix 70/30 (70% insulin aspart protamine suspension and 30% insulin aspart)	Novolog Mix 70/30 is considered medically necessary when the patient has tried Humalog Mix 75/25
Direct Muscle Relaxants – Baclofen Agents	baclofen 15 mg tablets	 Baclofen 15 mg tablet is considered medically necessary when ONE of the following is met: 1. Patient has tried generic baclofen 5 mg, 10 mg, or 20 mg tablets 2. According to the prescriber, there is significant clinical concern such that the patient is unable to use generic baclofen 5 mg, 10 mg, or 20 mg tablets
Dronabinol Products	Syndros (dronabinol oral solution)	 ONE of the following: Documented inability to swallow dronabinol capsules 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

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Therapeutic Category	Product	Criteria
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/Value/Advantage/ Total Savings 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/Value/Advantage/ Total Savings 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/Value/Advantage/ Total Savings 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

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Therapeutic Category	Product	Criteria
	Dipentum® (olsalazine)	Standard/Performance/Value/Advantage/ Total Savings 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/Value/Advantage/ Total Savings 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) 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
	Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) Tablets	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
Glucocorticoids	Rayos® (prednisone delayed release tablets)	Rayos is considered medically necessary if the patient has tried prednisone immediate-release tablets AND had inadequate efficacy with the product, according to the prescriber; OR the patient experienced adverse events severe enough to warrant discontinuation of the product.
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	Allopurinol 200 mg tablet is considered medically necessary when, according to the

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Therapeutic Category	Product	Criteria
		prescriber, there is a significant clinical concern such that the patient is unable to use the allopurinol 100 mg or 300 mg tablet.
Hyperlipidemia Agents	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.
	Niacor (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.
Immunosuppres sant Agents	Myhibbin™ (mycophenolate mofetil oral suspension)	Myhibbin is considered medically necessary when the patient has tried mycophenolate mofetil powder for oral suspension (generic for Cellcept powder for oral suspension), AND cannot take due to a formulation difference in the inactive ingredient(s) [for example, difference in dyes, fillers, preservatives] between the Myhibbin and mycophenolate mofetil powder for oral suspension (generic for Cellcept powder for oral suspension) which, per the prescriber, would result in a significant allergy or serious adverse reaction.
Inflammatory Conditions	Sovuna™ (hydroxychloroquine 200 mg tablets)	 Sovuna is considered medically necessary when BOTH of the following are met: 1. Patient has tried generic hydroxychloroquine 200 mg tablets 2. According to the prescriber, there is significant clinical concern such that the patient is unable to use generic hydroxychloroquine tablets
Isotretinoin Products	Absorica LD® (isotretinoin capsules)	Absorica LD is considered medically necessary when the patient has tried THREE of the following: 1. Accutane 2. Amnesteem 3. Claravis 4. isotretinoin capsules (Absorica [not LD]) 5. Zenatane

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Therapeutic Category	Product	Criteria
Laxative, Osmotic	Kristalose® (lactulose packet)	Kristalose is considered medically necessary when the patient has tried lactulose oral solution
	lactulose packet	Standard/Performance/Legacy Drug List Plans: Lactulose packet is considered medically necessary when the patient has tried lactulose oral solution
Leukotriene Pathway Inhibitors	Zyflo ® (zileuton 600 mg tablets)	Zyflo is considered medically necessary when the patient has tried ONE of the following: 1. montelukast 2. zafirlukast
Loop diuretics	Edecrin® (ethacrynic acid 25 mg tablets)	Edecrin is considered medically necessary when the patient has tried ALL of the following: 1. bumetanide 2. furosemide 3. torsemide
	ethacrynic acid 25 mg tablets	Ethacrynic acid is considered medically necessary when the patient has tried ALL of the following: 1. bumetanide 2. furosemide 3. torsemide
	Furoscix® (furosemide subcutaneous injection by on-body infusor)	 Furoscix is considered medically necessary when the following are met: 1. For the treatment of congestion due to fluid overload in a patient ≥ 18 years of age with chronic heart failure. 2. Patient has tried at least one loop diuretic or the patient is currently taking a loop diuretic. Note: Examples of loop diuretics include furosemide, bumetanide, torsemide.
	Soaanz® (torsemide tablets)	Soaanz is considered medically necessary when the patient has tried ALL of the following: 1. bumetanide 2. furosemide 3. torsemide
Migraine – Ergotamine Agents	dihydroergotamine mesylate nasal spray (generic Migranal)	dihydroergotamine mesylate nasal spray is considered medically necessary when there is documentation of failure, contraindication, or intolerance to sumatriptan nasal spray (generic for Imitrex nasal spray)

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Therapeutic Category	Product	Criteria
	Migranal® (dihydroergotamine	EFFECTIVE 1/1/2025
	mesylate nasal spray)	Migranal is considered medically necessary when the patient has tried the bioequivalent generic product, dihydroergotamine mesylate nasal spray [requires prior authorization], AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] which would result, per the prescriber, in a significant allergy or serious adverse reaction.
	Trudhesa™	EFFECTIVE 1/1/2025
	(dihydroergotamine mesylate nasal spray)	Trudhesa is considered medically necessary when BOTH of the following are met: 1. Patient has tried dihydroergotamine mesylate nasal spray [requires prior authorization]; AND 2. Patient meets ONE of the following: a. Patient has tried sumatriptan nasal spray (generic for Imitrex nasal spray) b. Patient has already experienced inadequate efficacy or a contraindication with triptan products.
Neurokinin-3	Veozah	Value/Advantage/Total Savings Drug List
Antagonists	(fezolinetant tablets)	Plans: 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
Nitroglycerin Sublingual (SL) Products	GoNitro™ (nitroglycerin sublingual powder)	GoNitro is considered medically necessary when the patient has tried BOTH of the following: 1. nitroglycerin sublingual tablets 2. nitroglycerin translingual spray
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

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Therapeutic Category	Product	Criteria
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 – Antibiotic/Cortic osteroid 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: 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

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Therapeutic Category	Product	Criteria
,		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
	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:

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Therapeutic Category	Product	Criteria
J		a. difluprednate ophthalmicb. fluorometholone ophthalmicc. loteprednol ophthalmic
Ophthalmic Drugs for Glaucoma - Alpha-	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%
Adrenergic Agonist	Iopidine® 1% (apraclonidine 1% ophthalmic solution)	Iopidine 1% is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE of the following: a. brimonidine 0.1% ophthalmic solution (generic Alphagan P 0.1%) b. brimonidine 0.15% ophthalmic solution (generic Alphagan P 0.15%) c. brimonidine 0.2% ophthalmic solution 2. Patient 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 ophthalmic 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
Oral Agents for Rosacea	doxycycline monohydrate IR 40 mg capsule	Doxycycline monohydrate IR 40 mg capsule is considered medically necessary when the following criteria are met: 1. Rosacea. Patient meets BOTH of the following:

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Therapeutic Category	Product	Criteria
		a. Failure, contraindication, or intolerance to TWO of the following: i. a topical metronidazole-containing product ii. a topical azelaic acid-containing product iii. topical ivermectin b. ONE of the following: i. Patient has as tried, and according to the prescriber, has experienced inadequate efficacy with one other generic, oral doxycycline product after a 4 week duration with the product ii. Patient as tried, and according to the prescriber, has experienced a significant intolerance with one other generic, oral doxycycline product.
Overactive Bladder Agents (Oral and Topical)	Gelnique®10% gel (oxybutynin chloride)	Gelnique 10% gel is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE of the following: a. oxybutynin tablets OR oxybutynin extended-release tablets b. oxybutynin syrup 2. Patient cannot swallow or has difficulty swallowing tablets or capsules
	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)	Oxytrol is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE of the following: a. oxybutynin tablets OR oxybutynin extended-release tablets b. oxybutynin syrup

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Therapeutic Category	Product	Criteria
		Patient cannot swallow or has difficulty swallowing tablets or capsules
	Vesicare LS® (solifenacin succinate 5mg/5mL oral suspension)	 Vesicare LS is considered medically necessary when ONE of the following is met: 1. Patient is 5 years or older AND has tried oxybutynin solution/syrup 2. Patient is < 5 years of age Note: If the patient has tried any oxybutynin-containing product (e.g., immediate-release or extended-release tablets), this would meet the requirement for a trial of an oxybutynin product.
Overactive Bladder Agents - Selective Beta-3 Adrenergic Receptor Agonists	Gemtesa® (vibegron)	Gemtesa is considered medically necessary 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
		Gemtesa is considered medically when the patient has tried and, according to the prescriber, has experienced inadequate efficacy OR significant intolerance with mirabegron 25 mg ER tablet (generic Myrbetriq)
	Myrbetriq® Granules (mirabegron 8 mg/mL granules for oral suspension)	Myrbetriq Granules is 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

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Product	Criteria
Creon® (pancrelipase delayed- release capsules)	Creon is considered medically necessary when the patient has tried BOTH of the following: 1. Pancreaze 2. Zenpep
Pertzye® (pancrelipase delayed- release capsules)	Pertzye is considered medically necessary when the patient has tried BOTH of the following: 1. Pancreaze 2. Zenpep
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
Carospir (spironolactone oral suspension)	Documented inability to swallow spironolactone tablets
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)
Ohtuvayre™ (ensifentrine inhalation suspension)	The state of the following is met: 1. Chronic obstructive pulmonary disease (COPD) in a patient ≥ 18 years of age AND the patient has tried, and according to the prescriber, experienced inadequate efficacy OR significant intolerance with BOTH of the following products used concurrently: a. a Long-Acting Muscarinic Antagonist (LAMA) product AND b. a Long-Acting Beta-Agonist (LABA) product. Note: Examples of LAMA/LABA Inhalers: Anoro Ellipta, Bevespi Aerosphere,
	Creon® (pancrelipase delayed- release capsules) Pertzye® (pancrelipase delayed- release capsules) Fosrenol® (lanthanum carbonate oral powder packet) Carospir (spironolactone oral suspension) Pokonza™ (potassium chloride powder for solution) Ohtuvayre™ (ensifentrine inhalation

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Therapeutic Category	Product	Criteria
Category		Note: Examples of LAMA Inhalers: Incruse Ellipta, tiotropium inhaler (Spiriva HandiHaler, generics), Spiriva Respimat, Tudorza Pressair. Note: Examples of LABA Inhalers/Nebulized: Serevent Diskus, Striverdi Respimat, formoterol fumarate inhalation solution (Perforomist, generics). Note: Examples of ICS/LABA Inhalers: fluticasone-salmeterol HFA (Advair HFA, authorized generic), fluticasone- salmeterol diskus, Wixela (Advair Diskus, generics), fluticasone-vilanterol (Breo Ellipta, authorized generic), Dulera, fluticasone-salmeterol respiclock (AirDuo RespiClick, authorized generic), AirDuo Digihaler, or budesonide- formoterol (Symbicort, generics).
Respiratory - Long-Acting Muscarinic Antagonist (LAMA) Inhalers	Tudorza® Pressair® (aclidinium bromide inhalation powder)	Tudorza Pressair is considered medically necessary when the patient has tried, and according to the prescriber, has experienced inadequate efficacy OR significant intolerance to BOTH of the following: 1. Incruse Ellipta 2. tiotropium [Spiriva Respimat, Spiriva Handihaler, generics]
Serotonin and Norepinephrine Reuptake Inhibitors (SNRIs)	desvenlafaxine ER	Desvenlafaxine ER is considered medically necessary when ONE of the following is met: 1. Patient has tried TWO of the following: a. desvenlafaxine succinate extended-release b. duloxetine capsules c. venlafaxine extended-release capsules or tablets 2. Patient is currently taking or has taken desvenlafaxine ER at any time in the past 3. Patient has suicidal ideation
	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)

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		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 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

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Therapeutic Category	Product	Criteria
Thyroid Supplements	Ermeza™ (levothyroxine sodium oral solution, 150mcg/5mL)	Ermeza is considered medically necessary when ONE of the following is met: 1. Patient has tried ALL of the following levothyroxine products: a. levothyroxine tablets (Synthroid generics) b. Levoxyl (generics) c. Euthyrox (generics) 2. Patient cannot swallow or has difficulty swallowing tablets or capsules
	levothyroxine capsules (Tirosint® generic)	Standard/Performance/Value/Advantage/ Total Savings Drug List Plans: Levothyroxine capsules is considered medically necessary when the patient has tried ALL of the following levothyroxine products: 1. levothyroxine tablets (Synthroid generics) 2. Levoxyl (generics) 3. Euthyrox (generics)
	Thyquidity™ (levothyroxine sodium oral solution, 100mcg/5mL)	Thyquidity is considered medically necessary when ONE of the following is met: 1. Patient has tried ALL of the following levothyroxine products: a. levothyroxine tablets (Synthroid generics) b. Levoxyl (generics) c. Euthyrox (generics) 2. Patient cannot swallow or has difficulty swallowing tablets or capsules
	Tirosint® (levothyroxine sodium capsules)	Standard/Performance/Value/Advantage/ Total Savings Drug List Plans: Tirosint is considered medically necessary when the patient has tried ALL of the following levothyroxine products: 1. levothyroxine tablets (Synthroid generics) 2. Levoxyl (generics) 3. Euthyrox (generics)
	Tirosint®-SOL (levothyroxine sodium oral solution)	Standard/Performance/Value/Advantage/ Total Savings Drug List Plans: Tirosint-SOL is considered medically necessary when ONE of the following is met: 1. Patient has tried ALL of the following levothyroxine products: a. levothyroxine tablets (Synthroid generics) b. Levoxyl (generics) c. Euthyrox (generics)

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Therapeutic Category	Product	Criteria
		Patient cannot swallow or has difficulty swallowing tablets or capsules
Thyroid Supplements - Desiccated Thyroid Supplements	Adthyza® (16.25mg, 32.5mg, 65mg, 97.5mg, and 130mg thyroid tablets, USP)	Adthyza is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE levothyroxine product (e.g., levothyroxine, Synthroid, Levoxyl) AND ONE other desiccated thyroid product (e.g., Armour Thyroid, NP Thyroid) 2. Patient is currently receiving Adthyza AND has tried ONE other desiccated thyroid product (e.g., Armour Thyroid, NP Thyroid) Note: Some desiccated thyroid products are currently not available, such as Nature thyroid, WP thyroid, Westhroid, and Thyroid tablet, but a previous trial of these would count as a trial of a desiccated thyroid product.
	Armour® Thyroid (thyroid tablets, USP)	Armour Thyroid is considered medically necessary when ONE of the following is met: 1. Patient has tried ONE levothyroxine product (e.g., levothyroxine, Synthroid, Levoxyl) AND ONE other desiccated thyroid product (e.g., Adthyza, NP Thyroid) 2. Patient is currently receiving Armour Thyroid AND has tried ONE other desiccated thyroid product (e.g., Adthyza, NP Thyroid) Note: Some desiccated thyroid products are currently not available, such as Nature thyroid, WP thyroid, Westhroid, and Thyroid tablet, but a previous trial of these would count as a trial of a desiccated thyroid product.
Topical Corticosteroid- containing Agents – Halobetasol Agents	Lexette® Foam (halobetasol propionate 0.05% topical foam)	Lexette is considered medically necessary when the patient has tried, and according to the prescriber has experienced inadequate efficacy OR significant intolerance with four generic prescription-strength topical corticosteroid products. Note: Examples of prescription-strength topical corticosteroids products include: halobetasol propionate, betamethasone dipropionate, clobetasol propionate, diflorasone diacetate. NOTE: The products must be chemically unique.
	Ultravate® (halobetasol propionate 0.05% lotion)	Ultravate is considered medically necessary when the patient has tried, and according to the prescriber has experienced inadequate efficacy OR significant intolerance with four generic

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Therapeutic Category	Product	Criteria
		prescription-strength topical corticosteroid products. Note: Examples of prescription-strength topical corticosteroids products include: halobetasol propionate, betamethasone dipropionate, clobetasol propionate, diflorasone diacetate. NOTE: The products must be chemically unique.
Topical Dermatological Drugs - Miscellaneous	Lidocaine 3% lotion	Lidocaine 3% lotion is considered medically necessary when the patient has tried BOTH of the following: 1. lidocaine 3% cream 2. lidocaine 5% ointment
	Lidocan™ II (lidocaine 5% patch)	Lidocan II is considered medically necessary when the patient has tried lidocaine 5% topical patch (generic for Lidoderm) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
	Lidocan™ IV (lidocaine 5% patch)	Lidocan IV is considered medically necessary when the patient has tried <u>lidocaine 5% topical patch</u> (generic for <u>Lidoderm</u>) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
	Lidocan™ V (lidocaine 5% patch)	Lidocan V is considered medically necessary when the patient has tried lidocaine 5% topical patch (generic for Lidoderm) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
	Lido-K (lidocaine 3% lotion)	Lido-K is considered medically necessary when the patient has tried BOTH of the following: 1. lidocaine 3% cream 2. lidocaine 5% ointment

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Therapeutic Category	Product	Criteria
	Synera (lidocaine and tetracaine patch)	Documented failure, contraindication, or intolerance to BOTH of the following: 1. lidocaine and prilocaine cream 2. lidocaine cream
	Tridacaine™ (lidocaine 5% patch)	Tridacaine is considered medically necessary when the patient has tried <u>lidocaine 5% topical</u> <u>patch</u> (generic for <u>Lidoderm</u>) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction.
Vertigo Agents	Meclizine 50 mg	Documented failure, contraindication or intolerance to meclizine 25 mg

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 trademark 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)

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- be identical in strength, dosage form, and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity, and quality
- be manufactured under the same strict standards of FDA's good manufacturing practice regulations required for innovator products

Off Label Uses

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

 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

- 1. Dellon ES, Gonsalves N, Hirano I, et al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE). Am J Gastroenterol 2013; 108.679-692?
- 2. McEvoy GK, ed. AHFS 2017 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2017.
- 3. Robbins MS, Starling AJ, Pringsheim TM, et al. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache 2016; 56:1093-1106.
- 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/a
 - pprovalapplications/abbreviatednewdrugapplicationandagenerics/ucm126389.htm
- 7. U.S Food and Drug Administration. Generic Drugs Questions and Answers: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	Added preferred product step requirement for	10/15/2024
	the following products:	
	Aplenzin, bupropion hydrochloride 450 mg	
	extended release tablets, Forfivo XL, Iopidine 1%,	
	baclofen 15 mg tablets, doxycycline monohydrate	
	IR 40 mg, ondansetron ODT, sitagliptin/metformin	
	tablets, Furoscix, Lidocan IV, Lidocan V, Tridacaine,	
	and Sovuna.	
	Updated preferred product step requirement	
	for the following products:	
	Cabtreo, Qbrelis, Firvang, Likmez, Solosec,	
	vancomycin 25 mg/mL oral solution, Primidone	

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	125mg tablets, Sitavig, Auvelity, Karbinal ER, Versacloz, Edecrin, ethacrynic acid, Tekturna HCT, Alkindi Sprinkle, dexamethasone 1.5 mg tablets dose pack, Dxevo 11-Day, TaperDex 6-Day, 7-Day, and 12-Day, Cortifoam, Halog Ointment, Halog Solution, , Kenalog Spray, Sernivo, triamcinolone acetonide 0.147 mg/gm topical aerosol, triamcinolone acetonide 0.05% ointment, Verdeso, Novolin 70/30, Novolin N, Novolin R, Novolog Mix 70/30, Rayos, Absorica LD, Kristalose, lactulose packets , Zyflo, Soaanz, GoNitro, Oxytrol, Vesicare LS, Gelnique 10% gel, Tudorza Pressair, desvenlafaxine ER, Lexette, and Ultravate. Removed the following medications: Accupril, Altace, Lotensin, Prinivil, Vasotec, Zestril, Lotrel, Tarka, EryPed 400, DDAVP, Elixophyllin, Dutoprol, Aldactazide 25mg/25mg, Aldactazide 50mg/50mg, Accuretic, Lotensin HCT, Vaseretic, Zestoretic, Cardizem CD, Clobex 0.05% Lotion, Clobex 0.05% Shampoo, Clobex 0.05% Spray, Cutivate, Halog 0.1% cream, hydrocortisone butyrate 0.1% cream, Trianex, Impeklo, Vanos, Iopidine 0.05%, Detrol, Detrol LA, Toviaz, Vesicare, Ativan, Parnate, Anafranil, Pamelor, Ditropan XL, Seebri Neohaler, Cymbalta, Lexapro, halobetasol 0.05% foam, and Pexeva.	
Selected Revision	Added preferred product step requirement for	11/01/2024
	the following products: Carac, Imiquimod 3.75% cream and cream pump,	
	Klisyri, Zyclara 2.5% cream pump, Zyclara 3.75%	
	cream and cream pump, valsartan oral solution, Edarbi, Edarbyclor, Posfrea, Focinvez,	
	carbinoxamine maleate ER suspension, Fanapt,	
	Innopran XL, Suflave, Clenpiq, Sutab, Katerzia,	
	Norliqva, Estratest F.S., Tradjenta, Jentadueto, Jentadueto XR, insulin glargine SoloStar U-300,	
	Myhibbin, dihydroergotamine mesylate nasal spray,	
	Migranal, Trudhesa, Creon, Pertzye, Ohtuvayre, Ermeza, levothyroxine capsules, Thyquidity,	
	Tirosint, Tirosint-SOL, Adthyza (16.25mg, 32.5mg,	
	65mg, 97.5mg, and 130mg) tablets, and Armour Thyroid	
	Updated preferred product step requirement	
	for the following products:	
	Hemangeol, Inderal XL, Kapspargo Sprinkle, Allopurinol 200 mg tablets , and Gemtesa	
	Anoparinoi 200 mg tablets, and demicesa	

The policy effective date is in force until updated or retired.

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