PREMERA HMO

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PHARMACY / MEDICAL UTILIZATION MANAGEMENT GUIDELINE – 5.01.605

Medical Necessity Criteria for Pharmacy Edits

Effective Date:	**May 6, 2025***
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Replaces:	N/A

*This policy has been revised. Click here to view the current policy.

RELATED GUIDELINES / POLICIES:

5.01.520	Antidepressants: Pharmacy Medical Necessity Criteria for Brands
5.01.521	Pharmacologic Treatment of Neuropathy, Fibromyalgia, and Seizure Disorders
5.01.529	Management of Opioid Therapy
5.01.541	Medical Necessity Exception Criteria for Closed Formulary Benefits and for Dispense as Written (DAW) Exception Reviews
5.01.547	Medical Necessity Criteria and Dispensing Quantity Limits for Exchange Formulary Benefits
5.01.552	Hetlioz (tasimelteon)
7.01.557	Gender Transition/Affirmation Surgery

Select a hyperlink below to be directed to that section.

COVERAGE GUIDELINE | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Pharmacy prior authorization helps members receive the most appropriate therapy. The program also helps reduce unnecessary prescription drug use, waste, and error. Before a medication can be covered, certain medical criteria need to be met. This helps ensure medications are safe and effective for a particular condition while offering the greatest value. This policy describes coverage criteria for drugs in the plan's pharmacy prior authorization program.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Index of Drugs, Drug Classes, and Disease States

The Pharmacy Benefit medications in the following hyperlink table are affected by the Company's Pharmacy Prior Authorization program:

Drug / Drug Class	Indications	Individual Agents
Acid Blockers	Acid reflux, Erosive esophagitis	Voquezna
Adapalene Products, Brand and Generic	Acne	Differin, Plixda, generic adapalene, (all prescription strengths and formulations)
ADHD Drugs, Brands	ADHD	Adderall, Adderall XR, Adhansia XR, Adzenys ER, Adzenys XR-ODT, Aptensio XR; Azstarys, Concerta, Cotempla XR-ODT; Daytrana, Desoxyn, Dexedrine, DyanavelXR, Evekeo, Evekeo ODT, Focalin, Focalin XR, Intuniv, Jornay PM, Kapvay, Methylin, Methylphenidate ER 72mg, Mydayis, Onyda XR, Qelbree, Quillichew ER, Quillivant XR; Relexxii, Ritalin, Ritalin LA 10mg, 60mg, Strattera, Vyvanse; Xelstrym, Zenzedi
Allergic Conjunctivitis	Allergies	Alocril, Alomide, Bepreve, Pazeo, Zerviate
Alpha Adrenergic Agonist	Acute agitation, Blepharoptosis, Opioid withdrawal	Igalmi, Lucemyra, Upneeq
Angiotensin-Converting Enzyme Inhibitors, Brands	Hypertension, Cardiovascular Disease	Accupril, Altace, Epaned, Lotensin, Qbrelis, Vasotec, and Zestril
Angiotensin-Converting Enzyme Inhibitor Combinations, Brands	Hypertension, Cardiovascular Disease	Accuretic, Lotrel, Vaseretic, Lotensin HCT, Zestoretic, and Prestalia
Angiotensin II Receptor Blockers, Brands	Hypertension, Cardiovascular Disease	Atacand, Avapro, Benicar, Cozaar, Diovan, Edarbi, Micardis, Tekturna, Valsartan solution
Angiotensin II Receptor Blocker Combinations, Brands	Hypertension, Cardiovascular Disease	Atacand HCT, Avalide, Benicar HCT, Diovan HCT, Edarbyclor, Hyzaar, Micardis HCT, Tekturna HCT, Teveten HCT
Antibiotics	Cystic fibrosis,	Arikayce, Cayston

Drug / Drug Class	Indications	Individual Agents
	MAC lung disease	
Anticonvulsants	Partial-onset seizure, Dravet Syndrome, Lennox-Gastaut Syndrome, Refractory complex partial seizures, Infantile Spasms	Aptiom, Banzel, Topiramate Extended-Release, Briviact, Diacomit, Epidiolex, Fintepla, Fycompa, Libervant, Motpoly XR, generic oxcarbazepine ER, Oxtellar XR, Peganone, Qudexy XR, Sabril, Spritam, Sympazan, Trokendi XR, vigabatrin, Vigadrone, Vigpoder, Vimpat, Xcopri, Zonisade, Zonisamide Suspension, Ztalmy
Antifungals	Aspergillosis, Blastomycosis, Enterobiasis, Histoplasmosis, Mucormycosis, Oropharyngeal Candidiasis, Vulvovaginal Candidiasis	Brexafemme, Cresemba, Emverm, Noxafil, Oravig, Tolsura, Vivjoa
Antifungals, Topical Brand	Infectious Disease	Ciclodan, Ecoza, Ertaczo, Exelderm, Extina, Loprox, luliconazole, Luzu, Mentax, miconazole-zinc oxide-petrolatum, Naftin, Oxistat, sulconazole nitrate, Vusion, Xolegel
Antihistamines, Oral	Allergic reactions	Karbinal ER, Ryclora, Ryvent
Antihypertensive/Diuretic	Edema, hypertension, severe heart failure	Carospir
Antiparasitic Agents	Tuberculosis	Daraprim, Humatin, Pyrimethamine
Antiprotozoal Agents	Diarrhea	Alinia
Antipsychotics (Second Generation, "Atypicals"), Brands	Psychoses, Bipolar Disorder, MDD, etc.	Abilify, Abilify MyCite, brand clozapine, brand clozapine ODT, brand quetiapine, Caplyta, Clozaril, Cobenfy, Fanapt, Geodon, Invega, Latuda, Lybalvi, Nuplazid, Opipza, Risperdal, Rexulti, Saphris, Secuado, Seroquel, Seroquel XR, Symbyax, Versacloz, Vraylar, Zyprexa, Zyprexa Zydis

Drug / Drug Class	Indications	Individual Agents
Antitubercular Agents	Tuberculosis	Sirturo
Brand Blepharitis Agents	Blepharitis	Xdemvy
Brand Oral Antibiotics and Their Generics	Acne; Rosacea; Infections	Acticlate, Adoxa, Avidoxy, generic bismuth subcitrate potassium-metronidazole-tetracycline, Doryx, Doryx MPC, Doxycycline IR-DR, Emrosi, Helidac, Lymepak, Minocin, Minocycline ER, Minolira, Minolira ER, Monodox, Morgidox, Omeclamox-Pak, Oracea, Orlynvah, Pivya, Pylera, Seysara, Solodyn, Solosec, Talicia, Targadox, Voquezna Dual Pak, Voquezna Triple Pak, Ximino
Brand Oral NSAIDs	Pain, Inflammation	Coxanto, brand Diclofenac, brand fenoprofen, Indocin, brand meloxicam, Nalfon, Naprelan, brand oxaprozin, Pennsaid, Relafen DS, Tivorbex, Tolectin 600, Vivlodex, Voltaren, Zipsor, Zorvolex
Brand Topical Acne or Rosacea Agents	Acne; Rosacea	Acanya, Aczone, Aklief, Aktipak, Altreno, Amzeeq, Arazlo, Atralin, Avage, Avar, Avar-E, Avar-E LS, Avar LS, Avita, Azelex, Benzamycin, Benzamycinpak, Cabtreo, Clenia Plus, Cleocin T, Clindagel, Clindamycin/Benzoyl Peroxide, Clindamycin Phosphate, Dapsone, Epiduo, Epiduo Forte, Evoclin, Fabior, Finacea, Neuac, Onexton, Plexion, Retin-A, Retin-A Micro, Retin-A Micro Pump, Rosanil, Rosula, Sodium sulfacetamide-sulfur, Sumadan, Sumaxin, and Sumaxin TS, Tazorac, Tretin-X, Twyneo, Vanoxide-HC, Veltin, Winlevi, Zilxi, Ziana
Brand Topical Rosacea Agent	Rosacea	Epsolay, Metrocream, Metrogel, Noritate, Soolantra
Calcimimetics	Hyper-parathyroidism; Parathyroid carcinoma	Generic cinacalcet, Sensipar
Calcium Channel Blockers	Angina, Hypertension, Cardiovascular Disease	Azor, brand levamlodipine, Caduet, Cardizem, Cardizem CD, Cardizem LA, Conjupri, Exforge, Exforge HCT, Katerzia, Lotrel, Norliqva, Norvasc, Procardia XL, Prestalia, Sular, Tarka, Tiazac, Tribenzor, Twynsta, Verelan PM
Cancer Related Antiemetics	Nausea and vomiting	Akynzeo, Emend, Sancuso, Varubi

Drug / Drug Class	Indications	Individual Agents
Chelating Agents	Cystinuria, Lead poisoning, Wilson's disease,	Chemet, Clovique, Cuprimine, Cuvrior, Depen, generic penicillamine, generic trientine, Syprine
Combination Medications (Misc.)	Various	Consensi
Constipation	IBS-C, CIC, OIC	Amitiza Linzess, Motegrity, Movantik, Pizensy, Trulance
Chronic Obstructive Pulmonary Disease (COPD) Medications	COPD	Ohtuvayre
Corticosteroids, Suppository Brand	Various	Anusol-HC, brand hydrocortisone-pramoxine, Proctocort, and Zypram
Corticosteroids, Topical Brand	Various	Ala-Scalp HP, Analpram-HC, Anti-Itch Lotion, Anti-Itch Spray, Anti-Itch Plus Cream, Aveeno, Bryhali, Capex Shampoo, Clobex, Clocortolone Pivalate, Cloderm, Cordran, Cortifoam, Cortizone, Dermasorb TA, Dexonto, Diprolene, Duobrii, First-Hydrocortisone, Halobetasol propionate, Halog, Hydrocortisone-pramoxine, Impoyz, Lexette, Locoid, Locoid Lipocream, Luxiq, Neo-Synalar, Noble Formula HC, Nucort, Olux, Olux-E, Pandel, Pediaderm HC, Pediaderm TA, Pramosone, Proctocort, Psorcon, Sernivo, Synalar, Temovate, Texacort, Topicort, Tridesilon, Ultravate, Vanos, Verdeso
Crohn's Disease Agents	Crohn's disease	Entocort EC, Ortikos
Chronic Kidney Disease Treatment	Kidney disease	Kerendia
Cystic Fibrosis	Cystic fibrosis	Bronchitol, Pulmozyme
Cystitis Agents	Cystitis	Elmiron
Cystine Binding Drugs	Cystine stone prevention	Thiola, Thiola EC, Tiopronin
Diabetic Test Strips	Diabetes	Non-One Touch (manufactured by LifeScan) and non-Contour (manufactured by Ascensia) branded test strips
Digestive Enzymes	Pancreatic insufficiency	Pancreaze, Pertzye
Dry Eye Treatment	Dry eyes	Cequa, Eysuvis, Miebo, Restasis, Tyrvaya, Vevye, Xiidra

Drug / Drug Class	Indications	Individual Agents
Eosinophilic Esophagitis Agents	Eosinophilic esophagitis	Eohilia
Gabapentin Products	Neuralgia, Sleep-related movement disorders	Gabapentin extended release, Gralise, Horizant
Gastrointestinal Stimulants	Gastroparesis	Gimoti
Heart Disease Prevention Agents	Heart Disease	Lodoco
Heart Failure Agents	Heart Failure, Obstructive HCM	Camzyos, Corlanor, Inpefa, generic ivabradine, Verquvo
Human Nerve Growth Factor	Neurotrophic keratitis	Oxervate
Hypertension Agents, Brands	Hypertension	Tryvio
Hypnotics, Non-Benzodiazepine, Brands	Insomnia	Ambien, Ambien CR, Belsomra, Dayvigo, brand quazepam, Doral, Edluar, Lunesta, Quviviq, Rozerem, Silenor, brand zolpidem tartrate, Zolpimist
Hypoxia-inducible factor prolyl hydroxylase (HIF PH)	Anemia due to chronic kidney disease	Jesduvroq (daprodustat), Vafseo (vadadustat)
Low Molecular Weight Heparins (LMWHs)	Thrombosis	Fragmin (dalteparin), Lovenox (enoxaparin)
Inhaled Corticosteroids	Asthma	Alvesco, Asmanex HFA, Asmanex Twisthaler, Pulmicort Flexhaler
Inherited Metabolic Disorders	Tyrosinemia	Generic nitisinone, Nityr, Orfadin
Intranasal Antihistamine Products, Brand	Allergic Rhinitis	Patanase
Intranasal Corticosteroid Products, Brands	Allergic Rhinitis Nasal Polyps	Omnaris, Qnasl, Ryaltris, Xhance, Zetonna
Iron Replacement Products	Iron Deficiency	Accrufer
Irritable Bowel Syndrome with Diarrhea (IBS-D) Agents	IBS-D	Viberzi
Miscellaneous Infectious Disease Agents	Cytomegalovirus	Lithostat
Molluscum Contagiosum Agents, Brands	Molluscum Contagiosum	Cantharidin, Ycanth, Zelsuvmi

Drug / Drug Class	Indications	Individual Agents
Muscle Relaxants	Spasticity	Baclofen oral solution (brand), Fleqsuvy, Lyvispah, Norgesic, Norgesic Forte, Ozobax, Baclofen oral suspension (brand)
Myasthenia Gravis Agents	Myasthenia gravis	Mestinon
NHE3 Inhibitors	IBS-C	Ibsrela (tenapanor)
Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and Combinations	Pain and Inflammation	Brand diclofenac potassium for oral solution, Cambia, Diclofenac epolamine, Duexis, Flector, Ibuprofen/famotidine, Ketorolac Nasal Spray, Licart, Naproxen/Esomeprazole, Sprix, Vimovo
Ophthalmic Beta Blockers, Brands	Glaucoma	Betoptic, Istalol, Timoptic
Ophthalmic Cholinergic Agonists	Presbyopia	Qlosi, Vuity
Ophthalmic Corticosteroids, Brands	Eye infections	TobraDex, TobraDex ST, Tobramycin-Dexamethasone
Ophthalmic Prostaglandin Analogs, Brands	Glaucoma	Durysta, iDose TR, Iyuzeh, Lumigan, Travatan Z, Vyzulta, Xalatan, Xelpros, Zioptan
Opvee (nalmefene)	Emergency treatment of known or suspected opioid overdose	Opvee (nalmefene)
Oral Corticosteroids, Brand	Inflammation	Alkindi Sprinkle, Cortef, Dxevo, Hemady, Medrol, Orapred ODT, Pediapred, Taperdex, Zcort
Overactive Bladder Agents	Overactive bladder	Brand oxybutynin, Gelnique, Gemtesa, generic mirabegron, Myrbetriq, Oxytrol, Toviaz
Parkinson's Disease Agents	Parkinson's disease	Generic apomorphine, Apokyn, Crexont, Dhivy, Duopa, Gocovri, Lodosyn, Inbrija, Kynmobi, Nourianz, Ongentys, Osmolex ER, Rytary, Sinemet, Stalevo, Xadago, Zelapar
Peanut Immunotherapy	Peanut Allergies	Palforzia
Potassium Binders	Hyperkalemia	Lokelma, Veltassa
Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)	Autosomal dominant polycystic kidney disease (ADPKD)	Jynarque
Proton Pump Inhibitors	Acid reflux, Ulcers	Aciphex, Aciphex Sprinkle, brand esomeprazole, generic dexlansoprazole, Dexilant, Nexium, generic omeprazole/sodium bicarbonate,

Drug / Drug Class	Indications	Individual Agents
		Konvomep, Prevacid, Prevacid Solutab, Prilosec, Protonix, brand rabeprazole, Zegerid
Pseudobulbar Affect	Pseudobulbar Affect	Nuedexta
Hyperhidrosis Agents	Hyperhidrosis	Qbrexza, Sofdra
Rho Kinase Inhibitor	Elevated intraocular pressure	Rhopressa, Rocklatan
Rifamycin Antibiotics	Traveler's Diarrhea, Hepatic Encephalopathy, IBS-D	Xifaxan, Aemcolo
Samsca (tolvaptan)	Hypervolemic or euvolemic hyponatremia	Generic tolvaptan, Samsca
Short-Acting Beta Agonists Step Therapy	Asthma	Airsupra, brand albuterol HFA, brand levalbuterol HFA, ProAir RespiClick, Ventolin HFA, Xopenex HFA
Tardive Dyskinesia & Huntington's Disease	Tardive Dyskinesia, Huntington's Disease	Ingrezza, Austedo, Austedo XR, Xenazine
Testosterone Replacement	Low Testosterone	Androderm, AndroGel, Fortesta, Jatenzo, Kyzatrex, Methitest, Natesto, Striant, Testim, Testosterone gel (brand), Tlando, Undecatrex, Vogelxo, Xyosted
Topical Antibiotic	Impetigo	Centany, Xepi
Transplant Agents	Transplant support	Envarsus XR, Myhibbin
Antivirals, Brand	Herpes Labialis, Genital Herpes	Denavir, Xerese, Valtrex, Zovirax
Topical Seborrheic Dermatitis Agents, Brand	Seborrheic Dermatitis	Klaron, Ovace Plus Cream, Ovace Plus Lotion, Ovace Plus Shampoo, Ovace Plus Wash, Ovace Plus Wash Cleansing Gel, Ovace Wash, Plexion NS, Selrx, Tersi, Zoryve
Topical Wart Agents, Brand	Genital Warts	Condylox, Veregen
Treatment of Nausea/Vomiting	Nausea/Vomiting	Bonjesta, Diclegis
Tryptophan Hydroxylase Inhibitor	Carcinoid Syndrome Diarrhea	Xermelo

Drug / Drug Class	Indications	Individual Agents
Ulcerative Colitis Agents	Ulcerative colitis	Apriso, Asacol HD, Colazal, Delzicol, Dipentum, Giazo, Lialda, Pentasa, Uceris
Wound Care	Wound debridement	Nexobrid
Vitamin Agents	Vitamin B12 deficiency, Hyper-parathyroidism	Nascobal, cyanocobalamin spray, Zemplar
Veozah (fezolinetant)	Vasomotor symptoms due to menopause	Veozah
Zylet (loteprednol etabonate and tobramycin ophthalmic suspension)	Steroid-responsive inflammatory ocular conditions	Zylet

The Pharmacy Benefit medications in the following hyperlink table are affected by the Company's quantity limits:

Drug / Drug Class	Indications	Individual Agents
Continuous Glucose Monitoring (CGM) Supplies	Diabetes management	Dexcom G6 Sensor, Dexcom G6 Transmitter, Dexcom G7 Sensor, Freestyle Libre Sensor, Freestyle Libre 2 Sensor, Freestyle Libre 3 Sensor
Contraceptives	Prevent pregnancy	Opill
Epinephrine Agents	Allergic reactions	Auvi-Q, Epinephrine auto-injector, EpiPen, EpiPen Jr, Neffy, Symjepi
Ivermectin, Stromectol (ivermectin)	Parasitic infections	Ivermectin, Stromectol
Ketorolac	Acute pain	Ketorolac 10 mg tablets
Santyl (collagenase)	Wound debridement	Santyl
SARS-CoV-2 Inhibitors	COVID-19 treatment	Lagevrio, Paxlovid
Short-Acting Beta Agonists Quantity Limit	Asthma	Airsupra, albuterol HFA inhaler, Levalbuterol HFA inhaler, ProAir Respiclick, Proventil HFA, Ventolin HFA, Xopenex HFA
Xofluza (baloxavir marboxil)	Influenza	Xofluza

The Pharmacy/Medical Benefit medications in the following hyperlink table are affected by the Company's Pharmacy Prior Authorization and Medical Prior Authorization program:

Drug / Drug Class	Indications	Individual Agents
Interferons	CGD, SMO	Actimmune

The Medical Benefit medications in the following hyperlink table are affected by the Company's Medical Prior Authorization program:

Drug / Drug Class	Indications	Individual Agents
Kappa Opioid Receptor (KOR) Agonist	CKD associated pruritus	Korsuva
Melanocortin 1 Receptor (MC1-R) Agonist	Erythropoietic Protoporphyria (PEP)	Scenesse
Testosterone Replacement Products	Low Testosterone	Aveed, Testopel

Coverage Guideline

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Acid Blockers	
Voquezna (vonoprazan)	**Voquezna (vonoprazan) may be considered medically necessary for the treatment of erosive esophagitis in adult individuals when all the following are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with erosive esophagitis **AND** • Has received 8 consecutive weeks or more of therapy with a proton pump inhibitor (e.g., esomeprazole, lansoprazole, omeprazole)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

	Voquezna (vonoprazan) may be considered medically necessary for the relief of heartburn associated with non-erosive gastroesophageal reflux disease when all the following are met:
	• The individual is aged 18 years or older
	AND
	• Has tried and failed or had intolerance to three of the following generic medications:
	  ○ Esomeprazole*
	  ○ Lansoprazole*
	  ○ Omeprazole*
	  ○ Pantoprazole
	  ○ Rabeprazole
	
	***Note**: Use of OTC esomeprazole, lansoprazole, and omeprazole qualifies when use is documented in chart notes.

Brand Drugs for ADHD and Stimulants for Other Psychiatric Conditions	
Brand stimulants	**Brand stimulants for ADHD and other psychiatric conditions may be considered medically necessary when:** • The individual has tried and failed a previous an adequate generic stimulant agent **OR** • A suitable generic alternative is not currently available **OR** • Has tried and failed a previous an adequate oral stimulant agent (brand or generic) and is or will be placed on a transdermal brand stimulant
Qelbree (viloxazine extended release)	**Qelbree (viloxazine extended release) may be considered medically necessary for the treatment of attention deficit hyperactivity disorder (ADHD) when the following criteria are met:** • The individual is aged 6 years or older **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has tried and failed one generic stimulant or has contraindications to use of stimulants **AND** • Has tried and failed generic atomoxetine or has contraindications to the use of atomoxetine **AND** • The dose prescribed is ≤ 600 mg per day
Vyvanse (lisdexamfetamine dimesylate)	**Vyvanse (lisdexamfetamine dimesylate) may be considered medically necessary for the treatment of ADHD when the individual has tried and failed or is intolerant to generic lisdexamfetamine dimesylate.** **Vyvanse (lisdexamfetamine dimesylate) may be considered medically necessary for the treatment of Binge Eating Disorder (BED) when medical records show that ALL of the DSM-5 criteria below for BED are met:** 1. Recurrent episodes of binge eating. An episode of binge eating is characterized by both of the following: o Eating, in a discrete period of time (for example, within any 2-hour period), an amount of food that is definitely larger than most people would eat in a similar period of time under similar circumstances o A sense of lack of control overeating during the episode (for example, a feeling that one cannot stop eating or control what or how much one is eating) 2. The binge-eating episodes are associated with three (or more) of the following: o Eating much more rapidly than normal o Eating until feeling uncomfortably full o Eating large amounts of food when not feeling physically hungry o Eating alone because of feeling embarrassed by how much one is eating o Feeling disgusted with oneself, depressed, or very guilty afterwards

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	3. Marked distress regarding binge eating is present 4. The binge eating occurs, on average, at least once a week for three months 5. The binge eating is not associated with the recurrent use of inappropriate compensatory behavior (for example, purging) and does not occur exclusively during the course of Anorexia Nervosa, Bulimia Nervosa, or Avoidant/Restrictive Food Intake Disorder **AND** • Has tried and failed or is intolerant to generic lisdexamfetamine dimesylate **AND** • The individual is aged 18 years or older
Allergic Conjunctivitis	
• **Alocril (nedocromil)** • **Alomide (lodoxamide)** • **Bepreve (bepotastine)** • **Pazeo (olopatadine)** • **Zerviate (cetirizine)**	**Alocril (nedocromil), Alomide (lodoxamide), Bepreve (bepotastine), Pazeo (olopatadine), and Zerviate (cetirizine) may be considered medically necessary for the treatment of allergic conjunctivitis when the individual has had an inadequate response or intolerance to two of the following generic drugs:** • Azelastine • Cromolyn • Epinastine • Olopatadine
Alpha Adrenergic Agonist	
Igalmi (dexmedetomidine sublingual film)	**Igalmi (dexmedetomidine sublingual film) may be considered medically necessary for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder when the following criteria are met:** • The individual is aged 18 years or older **AND** • Is experiencing agitation associated with schizophrenia or bipolar I or II disorder **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Igalmi is administered under the supervision of a healthcare provider **AND** • The quantity prescribed does not exceed 3 doses per agitation episode
Lucemyra (lofexidine)	**Lucemyra (lofexidine) may be considered medically necessary when medical records show lofexidine is used for adults currently experiencing or expecting acute opioid withdrawal symptoms who have tried and failed clonidine.** **Note:** Duration of approval is 14 days per episode of treatment.
Upneeq (oxymetazoline ophthalmic solution)	**Upneeq (oxymetazoline ophthalmic solution) may be considered medically necessary for the treatment of acquired blepharoptosis when the following criteria are met:** • The individual is aged 13 years or older **AND** • Documentation the blepharoptosis interferes with vision as confirmed by a visual field test **AND** • The dose is limited to one single use dropper per affected eye per day
Angiotensin-Converting Enzyme Inhibitors (ACEIs), Brand	
• **Accupril (quinapril)** • **Altace (ramipril)** • **Lotensin (benazepril)** • **Vasotec (enalapril)** • **Zestril (lisinopril)**	**Brand Angiotensin-converting enzyme inhibitors may be considered medically necessary when the individual has tried and failed two generic ACEIs due to an inadequate response or intolerance.**
• **Epaned (enalapril solution)** • **Qbrelis (lisinopril solution)**	**Epaned (enalapril solution) and Qbrelis (lisinopril solution) may be considered medically necessary when the following conditions are met:** • The individual has had an inadequate response or intolerance to two generic ACEIs **OR**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Documentation is provided that the product is medically necessary (e.g., individual body weight and no generic available than can provide the equivalent dose, unable to swallow)
Angiotensin-Converting Enzyme Inhibitor (ACEI) Combinations, Brand	
• **Accuretic (quinapril/HCTZ)** • **Lotensin HCT (benazepril/HTCZ)** • **Lotrel (amlodipine/benazepril)** • **Prestalia (amlodipine/perindopril)** • **Vaseretic (enalapril/HCTZ)** • **Zestoretic (lisinopril/HCTZ)**	**Brand Angiotensin-converting enzyme inhibitor combinations may be considered medically necessary when the following criteria are met:** • The individual has tried and failed two generic ACEI combinations due to an inadequate response or intolerance **OR** • Has tried a generic ACEI and generic hydrochlorothiazide, generic chlorthalidone, or generic amlodipine separately **AND** • There is a documented specific rationale for why the individual is not able to continue to use a generic ACEI and generic hydrochlorothiazide, generic chlorthalidone, or generic amlodipine separately
Angiotensin II Receptor Blockers (ARBs), Brand	
• **Atacand (candesartan)** • **Avapro (irbesartan)** • **Benicar (olmesartan)** • **Cozaar (losartan)** • **Diovan (valsartan)** • **Edarbi (azilsartan)** • **Micardis (telmisartan)** • **Tekturna (aliskiren)** • **Valsartan solution**	**Brand Angiotensin II receptor blockers may be considered medically necessary when the individual has tried and failed two generic ARBs due to an inadequate response or intolerance.** **Brand valsartan solution may be considered medically necessary when the following conditions are met:** • The individual is aged 6 years or older **AND** • Has had an inadequate response or intolerance to two generic ARBs **OR** • Documentation is provided that brand valsartan solution is medically necessary (e.g., individual body weight and no generic available than can provide the equivalent dose, unable to swallow)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Angiotensin II Receptor Blocker (ARB) Combinations, Brand	
• **Atacand HCT (candesartan/HCTZ)** • **Avalide (irbesartan/HCTZ)** • **Benicar HCT (olmesartan/HCTZ)** • **Diovan HCT (valsartan/HCTZ)** • **Edarbyclor (azilsartan/chlorthalidone)** • **Hyzaar (losartan/HCTZ)** • **Micardis HCT (telmisartan/HCTZ)** • **Tekturna HCT (aliskiren/HCTZ)** • **Teveten HCT (eprosartan/HCTZ)**	**Brand Angiotensin II receptor blocker combinations may be considered medically necessary when the following criteria are met:** • The individual has tried and failed two generic ARB combinations due to an inadequate response or intolerance **OR** • Has tried a generic ARB and generic hydrochlorothiazide, generic chlorthalidone, or generic amlodipine separately **AND** • There is a documented specific rationale for why the individual is not able to continue to use a generic ARB and generic hydrochlorothiazide, generic chlorthalidone, or generic amlodipine separately
Antipsychotics, Second Generation	
• **Abilify (aripiprazole)** • **Brand clozapine** • **Brand clozapine ODT** • **Brand quetiapine** • **Caplyta (lumateperone)** • **Clozaril (clozapine)** • **Fanapt (iloperidone)** • **Geodon (ziprasidone) oral** • **Invega (paliperidone)** • **Latuda (lurasidone)** • **Lybalvi (olanzapine and samidorphan)** • **Risperdal (risperidone)** • **Saphris (asenapine)** • **Secuado (asenapine transdermal)** • **Seroquel (quetiapine)** • **Seroquel XR (quetiapine extended release)** • **Symbyax (fluoxetine-olanzapine)** • **Versacloz (clozapine)**	**Brand second-generation antipsychotics (SGAs, formerly known as "atypicals") may be considered medically necessary when the individual has tried and failed one generic SGA.**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Vraylar (cariprazine)** • **Zyprexa (olanzapine)** • **Zyprexa Zydis (olanzapine)**	
Abilify MyCite (aripiprazole with sensor)	**Abilify MyCite (aripiprazole with sensor) may be considered medically necessary when the individual has met all of the following criteria:** • Documentation of low medication adherence (<80%) **AND** • Tried and failed an injectable depot antipsychotic (e.g., Risperdal Consta, Invega Sustenna and Invega Trinza, Abilify Maintena, etc.)
Cobenfy (xanomeline and trospium chloride)	**Cobenfy (xanomeline and trospium chloride) may be considered medically necessary for the treatment of schizophrenia when all the following are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with schizophrenia based on the most updated Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria **AND** • Has tried and failed three generic second-generation antipsychotics **AND** • Prescribed by or in consultation with a psychiatrist **AND** • The dose is ≤ 125 mg/30 mg capsule twice daily
Latuda (lurasidone HCL)	**Latuda (lurasidone HCL) may be considered medically necessary for the treatment of bipolar depression after generic lurasidone was tried and failed.**
Nuplazid (pimavanserin)	**Nuplazid (pimavanserin) may be considered medically necessary for the treatment of hallucinations and delusions associated with Parkinson's disease psychosis.** **Note:** Nuplazid is not subject to the criteria of other brand name second generation antipsychotics outlined above, and its use is restricted to individuals with Parkinson's disease psychosis only.

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Opipza (aripiprazole oral film)	**Opipza (aripiprazole oral film) may be considered medically necessary when all the following are met:** • The individual has tried and failed two generic second-generation antipsychotics **OR** • Documentation is provided that the oral film is clinically necessary (e.g., trouble swallowing, etc.) **AND** • The dose is ≤ 30 mg per day
Rexulti (brexpiprazole)	**Rexulti (brexpiprazole) may be considered medically necessary when the individual has tried and failed aripiprazole.** **Rexulti (brexpiprazole) may be considered medically necessary for the treatment of agitation associated with dementia due to Alzheimer's disease when the following criteria are met:** • The individual has agitation (e.g., pacing, gesturing, profanity, shouting, shoving, hitting) associated with dementia due to Alzheimer's disease (documentation required) **AND** • The maximum dose prescribed is 3 mg once daily **Note:** Rexulti is not approved for the treatment of individuals with dementia-related psychosis without agitation associated with dementia due to Alzheimer's disease (boxed warning).
Vraylar (cariprazine)	**Vraylar (cariprazine) may be considered medically necessary for the treatment of bipolar depression when all the following are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with bipolar depression **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has tried and failed a generic second-generation antipsychotic
Anticonvulsants	
Aptiom (eslicarbazepine)	**Aptiom (eslicarbazepine) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals aged 4 years and older **AND** • Has tried and failed two generic anti-seizure medications **AND** • The dose is ≤ 1,600 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Banzel (rufinamide), Rufinamide, generic	**Banzel (rufinamide) and generic rufinamide may be considered medically necessary for the following labeled indication:** • Treatment of seizures associated with Lennox-Gastaut syndrome in individuals 1 year of age and older **AND** • For Banzel (rufinamide) oral suspension the individual has tried generic rufinamide oral suspension and had an inadequate response or intolerance to generic rufinamide oral suspension **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Briviact (brivaracetam)	**Briviact (brivaracetam) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals 1 month of age and older **AND** • Has tried and failed two generic anti-seizure medications

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • The dose is ≤ 200 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Diacomit (stiripentol)	**Diacomit (stiripentol) may be considered medically necessary for the following labeled indication:** • Treatment of seizures associated with Dravet syndrome in individuals 6 months of age and older taking clobazam **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Epidiolex (cannabidiol)	**Epidiolex (cannabidiol) may be considered medically necessary for the following labeled indications:** • Treatment of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in individuals aged 1 year and older **AND** • Has tried and failed at least one generic anti-seizure medication **AND** • The dose is ≤ 20 mg/kg/day for seizures associated with Lennox-Gastaut syndrome or Dravet syndrome **OR** • The dose is ≤ 25 mg/kg/day for seizures associated with tuberous sclerosis complex **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Fintepla (fenfluramine)	**Fintepla (fenfluramine) may be considered medically necessary for the following labeled indication:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Treatment of seizures associated with Dravet syndrome and Lennox-Gastaut syndrome in individuals aged 2 years and older **AND** • Has tried four anti-seizure medications **AND** • The maximum total daily dose is ≤ 26 mg without concomitant Diacomit (stiripentol) **OR** • The maximum total daily dose is ≤ 17 mg with concomitant clobazam plus Diacomit (stiripentol) **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Fycompa (perampanel)	**Fycompa (perampanel) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals aged 4 years and older **OR** • Treatment of generalized tonic-clonic seizures in individuals aged 12 years or older **AND** • Has tried and failed two generic anti-seizure medications **AND** • The dose is ≤ 12 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Libervant (diazepam)	**Libervant (diazepam) may be considered medically necessary for the following:** • Acute treatment of intermittent episodes of frequent seizure activity **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is aged 2 to 5 years **AND** • The quantity is limited to 10 films per 30 days
Motpoly XR (lacosamide extended release)	**Motpoly XR (lacosamide extended release) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals weighing at least 50 kg **OR** • Treatment of primary generalized tonic-clonic seizures in individuals weighing at least 50 kg **AND** • Has tried generic lacosamide first and had an inadequate response or intolerance to generic lacosamide **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 400 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Generic oxcarbazepine extended release	**Generic oxcarbazepine extended release may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals aged 6 years or older **AND** • Has tried generic oxcarbazepine and had an inadequate response or intolerance to generic oxcarbazepine **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 2,400 mg per day

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.
Oxtellar XR (oxcarbazepine extended release)	**Oxtellar XR (oxcarbazepine extended release) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals aged 6 years or older **AND** • Has tried generic oxcarbazepine and had an inadequate response or intolerance to generic oxcarbazepine **AND** • Has tried generic oxcarbazepine extended release and had an inadequate response or intolerance to generic oxcarbazepine extended release **AND** • The dose is ≤ 2,400 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Peganone (ethotoin)	**Peganone (ethotoin) may be considered medically necessary for the following:** • Treatment of tonic-clonic and complex partial seizures **AND** • The individual has tried and failed two generic anti-seizure medications **AND** • The dose is ≤ 3,000 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
• **Qudexy XR (topiramate extended-release capsules)** • **Brand topiramate extended-release capsules**	**Qudexy XR (topiramate extended-release capsules) and brand topiramate extended-release capsules may be**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	considered medically necessary for the treatment of epilepsy when the following criteria are met: • The individual is aged 2 years or older **AND** • Medication is being used for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome **AND** • Has tried generic topiramate first and had an inadequate response or intolerance to generic topiramate **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 400 mg per day **Qudexy XR (topiramate extended-release capsules) and brand topiramate extended-release capsules may be considered medically necessary for the preventive treatment of migraines when the following criteria are met:** • The individual is aged 12 years or older **AND** • Has tried generic topiramate first and had an inadequate response or intolerance to generic topiramate **AND** • The dose is ≤ 100 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Sabril (vigabatrin)	**Sabril (vigabatrin) may be considered medically necessary for the following labeled indications:** • Refractory complex partial seizures as adjunctive therapy in individuals aged 2 years or older who have responded inadequately to ≥ 3 alternative treatments

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	OR • Monotherapy for pediatric individuals with infantile spasms 1 month to 2 years of age **AND** • Has tried generic vigabatrin, Vigpoder (vigabatrin), or Vigadrone (vigabatrin) first and had an inadequate response or intolerance to generic vigabatrin, Vigpoder, or Vigadrone (documentation required) **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Spritam (levetiracetam tablets for oral suspension)	**Spritam (levetiracetam tablets for oral suspension) may be considered medically necessary for the following:** • Partial onset seizures in individuals aged 4 years or older **OR** • Myoclonic seizures in individuals aged 12 years or older **OR** • Primary generalized tonic-clonic seizures in individuals aged 6 years or older **AND** • Has tried generic levetiracetam tablet or levetiracetam solution first and had an inadequate response or intolerance to generic levetiracetam tablet or levetiracetam solution **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 3,000 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Sympazan (clobazam oral film)	**Sympazan (clobazam oral film) may be considered medically necessary for the following:** • Treatment of seizures associated with Lennox-Gastaut syndrome in individuals aged 2 years or older **AND** • Has tried generic clobazam tablet or clobazam suspension first and had an inadequate response or intolerance to generic clobazam tablet or clobazam suspension **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 40 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Trokendi XR (topiramate extended-release capsules)	**Trokendi XR (topiramate extended-release capsules) may be considered medically necessary for the treatment of epilepsy when the following criteria are met:** • The individual is aged 6 years or older **AND** • Trokendi XR is being used for the treatment of partial-onset, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome **AND** • Has tried generic topiramate first and had an inadequate response or intolerance to generic topiramate **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 400 mg per day

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	Trokendi XR (topiramate extended-release capsules) may be considered medically necessary for the preventive treatment of migraines when the following criteria are met: • The individual is aged 12 years or older **AND** • Has tried generic topiramate first and had an inadequate response or intolerance to generic topiramate **AND** • The dose is ≤ 100 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
• **Vigabatrin, generic** • **Vigadrone (vigabatrin), generic** • **Vigpoder (vigabatrin), generic**	**Generic vigabatrin, Vigadrone (vigabatrin), and Vigpoder (vigabatrin) may be considered medically necessary for the following labeled indications:** • Refractory complex partial seizures as adjunctive therapy in individuals aged 2 years and older who have responded inadequately to ≥ 3 alternative treatments **OR** • Monotherapy for pediatric individuals with infantile spasms 1 month to 2 years of age **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Vigafyde (vigabatrin)	**Vigafyde (vigabatrin) may be considered medically necessary for the treatment of infantile spasms when all the following are met:** • The individual is aged 1 month to 2 years **AND** • Has been diagnosed with infantile spasms **AND** • Vigafyde (vigabatrin) will be used as monotherapy **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has tried and had generic vigabatrin, Vigpoder (vigabatrin), or Vigadrone (vigabatrin) first and had an inadequate response or intolerance to generic vigabatrin, Vigpoder, or Vigadrone (documentation required) **Initial authorization may be approved for up to 1 year. Re-authorization may be approved up to 1 year and requires documentation of continued clinical response.**
Vimpat (lacosamide)	**Vimpat (lacosamide) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals aged 4 years and older **AND** • Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures in individuals aged 4 years and older **AND** • Has tried generic lacosamide first and had an inadequate response or intolerance to generic lacosamide **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 400 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Xcopri (cenobamate)	**Xcopri (cenobamate) may be considered medically necessary for the treatment of partial-onset seizures in adult individuals when the individual has:** • The individual is aged 18 years or older **AND** • Has tried and failed two generic anticonvulsants

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.
• **Zonisade (zonisamide oral suspension)** • **Zonisamide (zonisamide oral suspension)**	**Zonisamide (zonisamide oral suspension) may be considered medically necessary for the following:** • Treatment of partial-onset seizures in individuals aged 16 years and older **AND** • Has tried generic zonisamide capsules first and had an inadequate response or intolerance to generic zonisamide capsules **OR** • Documentation is provided that oral suspension is clinically necessary (e.g., trouble swallowing, etc.) **AND** • Has tried and failed at least one additional generic anti-seizure medication **AND** • The dose is ≤ 600 mg per day **Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.**
Ztalmy (ganaxolone)	**Ztalmy (ganaxolone) may be considered medically necessary for the treatment of seizures associated with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder (CDD) when:** • The individual is aged 2 years or older **AND** • Has tried and failed two generic anticonvulsants **AND** • The dose is ≤ 1,800 mg per day (taken as 600 mg three times daily) **AND** • Prescribed by or in consultation with a neurologist

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	Initial authorization may be approved for up to 1 year. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.
Antibiotics	
Arikayce (amikacin liposome), inhalation suspension	**Arikayce (amikacin liposome) may be considered medically necessary for the treatment of *Mycobacterium avium* complex lung disease if all the following are met:** • The individual is aged 18 years or older **AND** • Has completed 6 consecutive months or more of a background multidrug regimen **AND** • Has a positive sputum culture for *Mycobacterium avium* complex collected within the past 3 months after the individual had completed their 6 consecutive months or more of a background multidrug regimen **AND** • *Mycobacterium avium* complex isolate is susceptible to amikacin **AND** • Arikayce (amikacin liposome) will be used in conjunction with a background multidrug regimen
Cayston (aztreonam), inhalation solution	**Cayston (aztreonam) may be considered medically necessary for the following:** • Individuals aged 7 years and older to improve respiratory symptoms in cystic fibrosis **AND** • Has a known *Pseudomonas aeruginosa* infection **AND** • The FEV_1 is between 25% to 75% predicted **AND** • The maximum quantity prescribed is 3 vials per day (one single-use 75 mg vial administered 3 times a day)
Antifungals	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Brexafemme (ibrexafungerp) tablets	**Brexafemme (ibrexafungerp) may be considered medically necessary for the treatment of vulvovaginal candidiasis (VVC) when all the following criteria are met:** • The individual is an adult or post-menarchal pediatric females with VVC **AND** • Has tried and failed fluconazole for VVC or has contraindications or documented resistance to fluconazole **AND** • Pregnancy status has been verified and the individual is not pregnant **AND** • The dose prescribed does not exceed 600 mg (four 150 mg tablets) per course **Brexafemme (ibrexafungerp) may be considered medically necessary for the reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) when all the following are met:** • The individual is an adult or post-menarchal pediatric female **AND** • Has tried and failed fluconazole for VVC or has contraindications or documented resistance to fluconazole **AND** • Pregnancy status has been verified and the individual is not pregnant **AND** • The dose prescribed does not exceed 600 mg (four 150 mg tablets) monthly for 6 months
Cresemba (isavuconazonium) oral	**Cresemba (isavuconazonium) oral may be considered medically necessary for the following:** • Individuals aged 6 years and older for the treatment of invasive aspergillosis **OR**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Individuals aged 6 years and older for the treatment of invasive mucormycosis **OR** • Individuals started on intravenous Cresemba and are being transitioned to oral Cresemba **Initial approval will be for 3 months.** **Reauthorization criteria:** • Continued therapy will be approved for 3 months as long as the medical necessity criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.

Emverm (mebendazole) oral	**Emverm (mebendazole) oral may be considered medically necessary when the following criteria are met:**
	• Used to treat enterobius vermicularis (pinworm)
	AND
	• Individual has a history of intolerance to over-the-counter pyrantel pamoate
	OR
	• Used to treat one of the following conditions:
	  ○ Ancylostoma/necatoriasis (hookworm)
	  ○ Ascariasis (roundworm)
	  ○ Baylisascaris
	  ○ Capillariasis
	  ○ Echinococcosis (tapeworm)
	  ○ Toxocariasis (roundworm)
	  ○ Trichinellosis
	  ○ Trichuriasis (whipworm)
	
	Initial approval will be for 3 months.
	
	Reauthorization criteria:
	• Continued therapy will be approved for 3 months as long as medical necessity criteria above are met, and chart notes

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	demonstrate that the individual continues to show a positive clinical response to therapy.
Noxafil (posaconazole) tablets	**Noxafil (posaconazole) tablets may be considered medically necessary for the treatment of fungal infections when the following criteria are met:** • The individual is aged 13 years or older **AND** • Has tried generic posaconazole tablets first and had an inadequate response or intolerance to generic posaconazole tablets (documentation required) **Initial approval will be for 3 months.** **Reauthorization criteria:** • Continued therapy will be approved for 6 months as long as the medical necessity criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy
Oravig (miconazole) tablets	**Oravig (miconazole) tablets may be considered medically necessary if the individual has had an inadequate response or intolerance to generic oral clotrimazole or generic oral nystatin**
Tolsura (itraconazole) capsules	**Tolsura (itraconazole) capsules may be considered medically necessary for the treatment of fungal infections when the following criteria are met:** • The individual is aged 18 years or older **AND** • Has tried generic itraconazole first and had an inadequate response or intolerance to generic itraconazole (documentation required) **Initial approval will be for 3 months.** **Reauthorization criteria:** • Continued therapy will be approved for 6 months as long as the medical necessity criteria are met, and chart notes

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	demonstrate that the individual continues to show a positive clinical response to therapy
Vfend (voriconazole) tablets and oral suspension	**Vfend (voriconazole) tablets and oral suspension may be considered medically necessary if the individual has had an inadequate response or intolerance to generic voriconazole tablets or generic voriconazole oral suspension**
Vivjoa (oteseconazole) capsules	**Vivjoa (oteseconazole) may be considered medically necessary for the treatment of vulvovaginal candidiasis (VVC) when all the following criteria are met:** • The individual is an adult or post-menarchal pediatric females with VVC **AND** • Has tried and failed fluconazole for VVC or has contraindications or documented resistance to fluconazole **AND** • Pregnancy status has been verified and the individual is not pregnant
Antifungals, Topical Brand	
• **Ciclodan (ciclopirox/urea)** • **Ecoza (econazole)** • **Ertaczo (sertaconazole)** • **Exelderm (sulconazole)** • **Extina (ketoconazole)** • **Loprox (ciclopirox)** • **Luliconazole** • **Luzu (luliconazole)** • **Mentax (butenafine)** • **Miconazole/Zinc Oxide/Petrolatum** • **Naftin (naftifine)** • **Oxistat (oxiconazole)** • **Sulconazole nitrate** • **Vusion (miconazole/zinc/petrolatum)** • **Xolegel (ketoconazole)**	**Brand topical antifungals may be considered medically necessary when the individual has tried and failed two generic topical antifungals such as clotrimazole, ketoconazole, or econazole due to an inadequate response or intolerance.**
Antihistamines, Oral	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Karbinal ER (carbinoxamine)** • **Ryclora (dexchlorpheniramine)** • **Ryvent (carbinoxamine)**	**Karbinal ER (carbinoxamine), Ryclora (dexchlorpheniramine), and Ryvent (carbinoxamine) may be considered medically necessary when the individual has tried and failed two generic oral antihistamines such as cetirizine, cyproheptadine, diphenhydramine, and levocetirizine due to an inadequate response or intolerance.**
Antiparasitic Agents	
Daraprim (pyrimethamine)	**Daraprim (pyrimethamine) may be considered medically necessary for the following:** • Treatment of toxoplasmosis **OR** • Prophylaxis of toxoplasmosis in individuals with HIV who have tried sulfamethoxazole/trimethoprim first and had an inadequate response or intolerance to sulfamethoxazole/trimethoprim unless there is a contraindication to use (documentation required) **AND** • The individual has tried generic pyrimethamine first and had an inadequate response or intolerance to generic pyrimethamine (documentation required) **AND** • The medication is prescribed by or in consultation with a physician who specializes in infectious disease or the treatment of HIV
Humatin (paromomycin)	**Humatin (paromomycin) may be considered medically necessary for the following:** • Treatment of intestinal amebiasis **OR** • Management of hepatic coma as adjunctive therapy
Generic pyrimethamine	**Generic pyrimethamine may be considered medically necessary for the following:** • Treatment of toxoplasmosis **OR**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Prophylaxis of toxoplasmosis in individuals with HIV who have tried sulfamethoxazole/trimethoprim first and had an inadequate response or intolerance to sulfamethoxazole/trimethoprim unless there is a contraindication to use (documentation required) **AND** • The medication is prescribed by or in consultation with a physician who specializes in infectious disease or the treatment of HIV
Antiprotozoal Agents	

Alinia (nitazoxanide)	**Alinia (nitazoxanide) may be considered medically necessary for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* when the following criteria are met:**
	• The individual is aged between 12 and 36 months of age
	OR
	• Is aged > 36 months and has tried and failed one of the following:
	  ○ Tinidazole
	  ○ Metronidazole
	
	Initial approval will be for 3 days.
	
	Re-authorization criteria:
	• A future episode for the treatment of diarrhea caused by *Giardia lamblia* or *Cryptosporidium parvum* will be reviewed as an initial request

Impavido (miltefosine)	**Impavido (miltefosine) may be considered medically necessary for the following:** • Individuals aged 12 years and older and weighing at least 30 kg (66 lbs) **AND** • Diagnosed with one of the following: ○ Visceral leishmaniasis due to *Leishmania donovani*

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	○ Cutaneous leishmaniasis due to Leishmania braziliensis, Leishmania guyanensis, and Leishmania panamensis ○ Mucosal leishmaniasis due to *Leishmania braziliensis* **AND** • The dose prescribed is limited to: ○ 30 kg to 44 kg: One 50 mg capsule twice daily ○ ≥ 45 kg: One 50 mg capsule three times daily **Initial approval will be for 28 days.** **Re-authorization criteria:** • Future re-authorization of continuous use of Impavido (miltefosine) beyond 28 days will be reviewed on a case-by-case basis for medically necessity.
Antitubercular Agents	
Sirturo (bedaquiline)	**Sirturo (bedaquiline) oral may be considered medically necessary for the following:** • Individuals aged 5 years and older and weighing at least 15 kg **AND** • Diagnosed with pulmonary tuberculosis due to *Mycobacterium tuberculosis* resistant to at least rifampin and isoniazid **AND** • Sirturo is used in combination with at least 3 other drugs that have been shown to be susceptible *in vitro* **OR** • Sirturo is used in combination with at least 4 other drugs to which the individual's infection isolate is likely to be susceptible **AND** • Total treatment duration is 24 weeks **Initial approval will be for 24 weeks.** **Reauthorization criteria:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Future re-authorization of continuous use of Sirturo (bedaquiline) beyond 24 weeks is considered not medically necessary
Calcimimetics	

Generic cinacalcet	**Generic cinacalcet may be considered medically necessary when all the following are met:**
	• The individual is aged 18 years or older
	AND
	• Meets one of the following:
	  ○ Has been diagnosed with secondary hyperparathyroidism (HPT) in individuals with chronic kidney disease on dialysis
	  ○ Has been diagnosed with hypercalcemia in individuals with parathyroid carcinoma
	  ○ Has been diagnosed with severe hypercalcemia in individuals with primary HPT who are unable to undergo parathyroidectomy

Sensipar (cinacalcet)	**Sensipar (cinacalcet) may be considered medically necessary when all the following are met:**
	• The individual is aged 18 years or older
	AND
	• Meets one of the following:
	  ○ Has been diagnosed with secondary hyperparathyroidism (HPT) in individuals with chronic kidney disease on dialysis
	  ○ Has been diagnosed with hypercalcemia in individuals with parathyroid carcinoma
	  ○ Has been diagnosed with severe hypercalcemia in individuals with primary HPT who are unable to undergo parathyroidectomy
	AND
	• Has tried generic cinacalcet first and had an inadequate response or intolerance to generic cinacalcet (documentation required)

Calcium Channel Blockers	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Brand Calcium Channel Blockers: • **Cardizem (diltiazem)** • **Cardizem CD (diltiazem extended-release)** • **Cardizem LA (diltiazem extended-release)** • **Norvasc (amlodipine)** • **Procardia XL (nifedipine extended-release)** • **Sular (nisoldipine extended-release)** • **Tiazac (diltiazem extended-release)** • **Verelan PM (verapamil extended-release)**	**Cardizem (diltiazem), Cardizem CD (diltiazem extended-release), Cardizem LA (diltiazem extended-release), Norvasc (amlodipine), Procardia XL (nifedipine extended-release), Sular (nisoldipine extended-release), Tiazac (diltiazem extended-release), and Verelan PM (verapamil extended-release) may be considered medically necessary when the individual has tried and failed two generic calcium channel blockers due to an inadequate response or intolerance.**
Brand Calcium Channel Blocker Combinations: • **Azor** • **Caduet** • **Exforge** • **Exforge HCT** • **Lotrel** • **Tarka** • **Tribenzor** • **Twynsta**	**Azor (amlodipine/olmesartan), Caduet (amlodipine/atorvastatin), Exforge (amlodipine/valsartan), Exforge HCT (amlodipine/valsartan/hydrochlorothiazide), Lotrel (amlodipine/benazepril), Tarka (verapamil/trandolapril), Tribenzor (amlodipine/olmesartan/hydrochlorothiazide), and Twynsta (amlodipine/telmisartan) may be considered medically necessary when the following criteria are met:** • The individual has tried the generic to the requested brand calcium channel blocker combination first and had an inadequate response or intolerance to the generic calcium channel blocker combination (documentation required)
• **Brand levamlodipine** • **Conjupri (levamlodipine)**	**Brand levamlodipine and Conjupri (levamlodipine) may be considered medically necessary when the following criteria are met:** • The individual is aged 6 years or older **AND** • Has tried generic amlodipine and had an inadequate response or intolerance to generic amlodipine (documentation required) **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has tried one additional generic calcium channel blocker (e.g., diltiazem, felodipine, nifedipine, verapamil) and had an inadequate response or intolerance to the generic calcium channel blocker (documentation required)
• **Katerzia (amlodipine suspension)** • **Norliqva (amlodipine solution)**	**Katerzia (amlodipine suspension) and Norliqva (amlodipine solution) may be considered medically necessary when the following conditions are met:** • The individual has tried and failed two generic calcium channel blockers due to an inadequate response or intolerance **OR** • Documentation is provided that the product is medically necessary (e.g., individual body weight and no generic is available than can provide the equivalent dose, unable to swallow)
Prestalia (amlodipine/perindopril)	**Prestalia (amlodipine/perindopril) may be considered medically necessary for the treatment of hypertension when the following criteria are met:** • The individual has tried generic amlodipine and generic perindopril separately **AND** • There is a documented specific rationale for why the individual is not able to continue to use generic amlodipine and generic perindopril separately
Cancer Related Antiemetics	
• **Akynzeo (netupitant and palonosetron) [oral use only],** • **Varubi (rolapitant)**	**Akynzeo (netupitant and palonosetron) and Varubi (rolapitant) may be considered medically necessary for the prevention of nausea and vomiting associated with oncologic treatment when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has moderate-to-high emetic risk **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Medication is being used in combination with dexamethasone and a serotonin receptor antagonist (e.g., ondansetron)
Emend (aprepitant) [oral use only]	**Emend (aprepitant) may be considered medically necessary for the prevention of nausea and vomiting associated with oncologic treatment when all the following criteria are met:** • The individual is aged 12 years or older **AND** • Has moderate-to-high emetic risk **AND** • Medication is being used in combination with dexamethasone and a serotonin receptor antagonist (e.g., ondansetron) **AND** • Has tried generic aprepitant and had an inadequate response or intolerance to generic aprepitant **Emend (aprepitant) may be considered medically necessary for the prevention of nausea and vomiting associated with oncologic treatment when all the following criteria are met:** • The individual is aged 11 years or younger **AND** • Has moderate-to-high emetic risk **AND** • Medication is being used in combination with a serotonin receptor antagonist (e.g., ondansetron) **Emend (aprepitant) may be considered medically necessary for the prevention of post-operative nausea and vomiting when all the following criteria are met:** • The individual is aged 18 years or older **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has tried generic aprepitant and had an inadequate response or intolerance to generic aprepitant
Sancuso (granisetron transdermal system)	**Sancuso (granisetron transdermal system) may be considered medically necessary for the prevention of nausea and vomiting associated with oncologic treatment when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has moderate-to-high emetic risk
Chelating Agents	
Chemet (succimer)	**Chemet (succimer) may be considered medically necessary to treat acute lead poisoning when all the following criteria are met:** • The individual is aged 12 months to 18 years **AND** • Prior to treatment the blood lead level was >45 mcg/dL **AND** • Use is not intended as a prophylaxis against lead poisoning in a lead-containing environment **AND** • Use is prescribed by or in consultation with a professional experienced in the use of chelation therapy (e.g., medical toxicologist or a poison control center specialist) **Chemet (succimer) may be considered medically necessary to treat acute intoxication or poisoning by arsenic or mercury when the following criteria are met:** • Use was recently initiated in the hospital and further treatment is needed to finish the course of therapy **AND** • Use is prescribed by or in consultation with a professional experienced in the use of chelation therapy (e.g., medical toxicologist or a poison control center specialist).
Generic penicillamine	**Generic penicillamine may be considered medically necessary for the treatment of Wilson's disease when:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• At the time of diagnosis, the 24-hour urinary copper excretion is > 100 micrograms (1.6 micromoles) **AND** • The individual has tried and failed zinc acetate (e.g., Galzin) or has contraindications to use of zinc acetate **AND** • The medication is prescribed by or in consultation with a gastroenterologist or hepatologist **Generic penicillamine may be considered medically necessary for the treatment of cystinuria when:** • The diagnosis of cystinuria is supported by one of the following: o Stone analysis showing cystine **OR** o Positive family history of cystinuria **OR** o Identification of pathognomonic hexagonal cystine crystals on urinalysis **AND** • The individual has tried and failed Thiola (tiopronin) or has contraindications to use of Thiola **Generic penicillamine may be considered medically necessary for the treatment of severe, active rheumatoid arthritis when:** • The individual has failed to adequately respond to five other medications FDA-approved for the treatment of rheumatoid arthritis
• **Cuprimine (penicillamine)** • **Depen (penicillamine)**	**Cuprimine (penicillamine) and Depen (penicillamine) may be considered medically necessary for the treatment of Wilson's disease when:** • At the time of diagnosis, the 24-hour urinary copper excretion is > 100 micrograms (1.6 micromoles) **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual has tried and failed zinc acetate (e.g., Galzin) or has contraindications to use of zinc acetate **AND** • The medication is prescribed by or in consultation with a gastroenterologist or hepatologist **AND** • The individual has tried generic penicillamine first and had an inadequate response or intolerance to generic penicillamine (documentation required) **Cuprimine (penicillamine) and Depen (penicillamine) may be considered medically necessary for the treatment of cystinuria when:** • The diagnosis of cystinuria is supported by one of the following: o Stone analysis showing cystine **OR** o Positive family history of cystinuria **OR** o Identification of pathognomonic hexagonal cystine crystals on urinalysis **AND** • The individual has tried and failed Thiola (tiopronin) or has contraindications to use of Thiola **AND** • The individual has tried generic penicillamine first and had an inadequate response or intolerance to generic penicillamine (documentation required) **Cuprimine (penicillamine) and Depen (penicillamine) may be considered medically necessary for the treatment of severe, active rheumatoid arthritis when:** • The individual has failed to adequately respond to five other medications FDA-approved for the treatment of rheumatoid arthritis **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual has tried generic penicillamine first and had an inadequate response or intolerance to generic penicillamine (documentation required) **Note:** The FDA is allowing import of D-Penamine (penicillamine) from Australia into the United States due to the current shortage of Depen (penicillamine). During this shortage a request for D-Penamine will be treated the same as a request for Depen.
Cuvrior (trientine tetrahydrochloride)	**Cuvrior (trientine tetrahydrochloride) may be considered medically necessary for the treatment of adult individuals with stable Wilson's disease when:** • The individual is aged 18 years or older **AND** • At the time of diagnosis, the 24-hour urinary copper excretion is > 100 micrograms (1.6 micromoles) **AND** • Has tried and failed zinc acetate (e.g., Galzin) or has contraindications to use of zinc acetate **AND** • Has tried generic trientine hydrochloride or Clovique (trientine hydrochloride) first and had an inadequate response or intolerance to generic trientine hydrochloride or Clovique (documentation required) **AND** • Has tried generic penicillamine first and is tolerant to penicillamine (documentation required) **AND** • The medication is prescribed by or in consultation with a gastroenterologist or hepatologist **AND** • The dose is ≤ 3000 mg/day
• **Generic trientine hydrochloride** • **Clovique (trientine hydrochloride)**	**Generic trientine hydrochloride or Clovique (trientine hydrochloride) may be considered medically necessary for the treatment of Wilson's disease when:** • At the time of diagnosis, the 24-hour urinary copper excretion is > 100 micrograms (1.6 micromoles)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • The individual has tried and failed zinc acetate (e.g., Galzin) or has contraindications to use of zinc acetate **AND** • The medication is prescribed by or in consultation with a gastroenterologist or hepatologist **AND** • The dose is ≤ 2000 mg/day for adults or ≤ 1500 mg/day for pediatric individuals aged 12 or under
• **Syprine (trientine hydrochloride)** • **Brand trientine hydrochloride**	**Syprine (trientine hydrochloride) and brand trientine hydrochloride may be considered medically necessary for the treatment of Wilson's disease when:** • At the time of diagnosis, the 24-hour urinary copper excretion is > 100 micrograms (1.6 micromoles) **AND** • The individual has tried and failed zinc acetate (e.g., Galzin) or has contraindications to use of zinc acetate **AND** • Has tried generic trientine hydrochloride or Clovique (trientine hydrochloride) first and had an inadequate response or intolerance to generic trientine hydrochloride or Clovique (documentation required) **AND** • The medication is prescribed by or in consultation with a gastroenterologist or hepatologist **AND** • The dose is ≤ 2000 mg/day for adults or ≤ 1500 mg/day for pediatric individuals aged 12 or under
Combination Medications (Misc.)	
Consensi (amlodipine and celecoxib)	**Consensi (amlodipine and celecoxib) may be considered medically necessary when the individual has tried and failed generic amlodipine in combination with generic celecoxib for at least 3 months and there is documented clinical rationale why the individual cannot continue with each of the generic ingredients separately.**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Constipation	
Amitiza (lubiprostone)	**Amitiza (lubiprostone) may be considered medically necessary for the treatment of irritable bowel syndrome with constipation (IBS-C) when the following criteria are met:** • The individual is aged 18 years or older **AND** • Is female **AND** • Has been diagnosed with IBS-C **AND** • Has tried and failed or is intolerant to generic lubiprostone **Amitiza (lubiprostone) may be considered medically necessary for the treatment of chronic idiopathic constipation (CIC) when the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with CIC **AND** • Has tried and failed or is intolerant to generic lubiprostone **Amitiza (lubiprostone) may be considered medically necessary for the treatment of opioid-induced constipation (OIC) with chronic, non-cancer pain when the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with OIC with chronic, non-cancer pain **AND** • Has tried and failed or is intolerant to generic lubiprostone
Linzess (linaclotide)	**Linzess (linaclotide) may be considered medically necessary for the treatment of irritable bowel syndrome with constipation (IBS-C) when all the following criteria are met:** • The individual is aged 18 years or older

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Has been diagnosed with IBS-C **AND** • Has had at least 3-months trial and treatment failure, or intolerance of at least 3 of the following drugs: bulk-forming laxatives (e.g., Metamucil or Citrucel), osmotic agents (e.g., lactulose, PEG, or magnesium citrate) **OR** • Has tried and failed or is intolerant to generic lubiprostone **Linzess (linaclotide) may be considered medically necessary for the treatment of chronic idiopathic constipation (CIC) when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with CIC **AND** • Has tried and failed or is intolerant to generic lubiprostone **Linzess (linaclotide) may be considered medically necessary for the treatment of functional constipation (FC) when all the following criteria are met:** • The individual is aged 6 to 17 years **AND** • Has been diagnosed with FC **AND** • Has had at least 3-months trial and treatment failure, or intolerance of at least 3 of the following drugs: bisacodyl, lactulose, polyethylene glycol, docusate sodium, senna-sennosides, or sodium phosphate enema **OR** • Has tried and failed or is intolerant to generic lubiprostone
Motegrity (prucalopride)	**Motegrity (prucalopride) may be considered medically necessary for the treatment of chronic idiopathic constipation (CIC) when all the following criteria are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is aged 18 years or older **AND** • Has been diagnosed with CIC **AND** • Has tried and failed or is intolerant to generic lubiprostone
Movantik (naloxegol)	**Movantik (naloxegol) may be considered medically necessary for the treatment of opioid-induced constipation (OIC) with chronic, non-cancer pain when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with OIC with chronic, non-cancer pain, including individuals with chronic pain related to prior cancer or its treatment who do not require frequent (e.g., weekly) opioid dosage escalation **AND** • Has tried and failed or is intolerant to generic lubiprostone
Pizensy (lactitol oral solution)	**Pizensy (lactitol oral solution) may be considered medically necessary for the treatment of chronic idiopathic constipation (CIC) when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with CIC **AND** • Has tried and failed or is intolerant to generic lubiprostone
Trulance (plecanatide)	**Trulance (plecanatide) may be considered medically necessary for the treatment of chronic idiopathic constipation (CIC) when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has been diagnosed with CIC **AND** • Has tried and failed or is intolerant to generic lubiprostone

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	Trulance (plecanatide) may be considered medically necessary for the treatment of irritable bowel syndrome with constipation (IBS-C) when all the following criteria are met: • The individual is aged 18 years or older **AND** • Has been diagnosed with IBS-C **AND** • Has had at least 3-months trial and treatment failure, or intolerance of at least 3 of the following drugs: bulk-forming laxatives (e.g., Metamucil or Citrucel), osmotic agents (e.g., lactulose, PEG, or magnesium citrate) **OR** • Has tried and failed or is intolerant to generic lubiprostone
Chronic Obstructive Pulmonary Disease (COPD) Medications	
Ohtuvayre (ensifentrine)	**Ohtuvayre (ensifentrine) may be considered medically necessary for the maintenance treatment of chronic obstructive pulmonary disease (COPD) when the following criteria are met:** • The individual is aged 18 years or older **AND** • Diagnosed with COPD confirmed by spirometry demonstrating an FEV_1/FVC ratio <0.7 **AND** • Has an FEV_1 ≥30% and ≤70% of predicted normal **AND** • Has tried a combination LAMA/LABA product for ≥ 90 days, unless the LAMA/LABA product is not tolerated, and continues to have documented symptom control issues **AND** • Ohtuvayre (ensifentrine) is used as add-on therapy to a combination LAMA/LABA product unless the LAMA/LABA product is not tolerated **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Ohtuvayre (ensifentrine) is not used in combination with the oral PDE4 inhibitor roflumilast **AND** • The dose prescribed is 3 mg (one ampule) twice daily **AND** • Prescribed by or in consultation with a pulmonologist
Corticosteroids, Suppository Brand	
• **Anusol-HC (hydrocortisone)** • **Brand hydrocortisone-pramoxine** • **Proctocort (hydrocortisone)** • **Zypram (hydrocortisone-pramoxine)**	**Anusol-HC (hydrocortisone), brand hydrocortisone-pramoxine, Proctocort (hydrocortisone), and Zypram (hydrocortisone-pramoxine) may be considered medically necessary when the following conditions are met:** • The individual must try and fail a generic steroid suppository prior to using a branded steroid suppository • A generic alternative does not qualify if it is not the exact same dosage form
Corticosteroids, Topical Brand	
• **Ala-Scalp HP** • **Analpram-HC** • **Anti-Itch Lotion** • **Anti-Itch Spray** • **Anti-Itch Plus Cream** • **Aveeno** • **Bryhali** • **Capex Shampoo** • **Clobex** • **Clocortolone Pivalate** • **Cloderm** • **Cordran** • **Cortifoam** • **Cortizone** • **Dermasorb TA** • **Dexonto** • **Diprolene** • **Duobrii** • **First-Hydrocortisone** • **Halobetasol proprionate** • **Halog**	**Topical brand corticosteroids may be considered medically necessary when the following conditions are met:** • The individual must try and fail two prescription generic topical steroids prior to using a branded topical steroid • A generic alternative does not qualify if it is not the exact same dosage form

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Hydrocortisone/pramoxine** • **Impoyz** • **Lexette** • **Locoid** • **Locoid Lipocream** • **Luxiq** • **Neo-Synalar** • **Noble Formula HC** • **Nucort** • **Olux** • **Olux-E** • **Pandel** • **Pediaderm HC** • **Pediaderm TA** • **Pramosone** • **Proctocort** • **Psorcon** • **Sernivo** • **Synalar** • **Temovate** • **Texacort** • **Topicort** • **Tridesilon** • **Ultravate** • **Vanos** • **Verdeso**	
Crohn's Disease Agents	
• **Entocort EC (budesonide delayed-release capsules)** • **Ortikos (budesonide extended-release capsules)**	**Entocort EC (budesonide delayed-release capsules) and Ortikos (budesonide extended-release capsules) may be considered medically necessary for the treatment of Crohn's disease in individuals 8 years and older when the individual has had an inadequate response or intolerance to generic budesonide delayed-release capsules.**
Chronic Kidney Disease Treatment	
Kerendia (finerenone)	**Kerendia (finerenone) may be considered medically necessary for the treatment of chronic kidney disease associated with type 2 diabetes when the following criteria are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is aged 18 years or older **AND** • Diagnosed with type 2 diabetes **AND** • Receiving concurrent therapy with an angiotensin-converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB), unless ACEi and ARBs are not tolerated **AND** • Serum potassium is ≤ 4.8 mEq/L at initiation **AND** • Tried and failed one sodium-glucose cotransporter 2 (SGLT2) inhibitor (e.g., Farxiga [dapagliflozin], Invokana [canagliflozin]), Jardiance [empagliflozin], Steglatro [ertugliflozin]) **AND** • Dose is ≤ 20 mg per day
Diabetic Test Strips	
Nonpreferred diabetic test strips (other than One Touch [manufactured by LifeScan] and Contour [manufactured by Ascensia])	**Nonpreferred diabetic test strips may be considered medically necessary when the individual:** • Has tried and failed One Touch (manufactured by LifeScan) or Contour (manufactured by Ascensia) branded test strips **OR** • Is stabilized on an insulin pump where it is medically necessary to use a nonpreferred diabetic test strip
Digestive Enzymes	
• **Pancreaze (pancrelipase)** • **Pertzye (pancrelipase)**	**Pancreaze (pancrelipase) and Pertzye (pancrelipase) may be considered medically necessary for the treatment of exocrine pancreatic insufficiency due to cystic fibrosis or other condition when the individual has had an inadequate response or intolerance to both of the following:** • Creon (pancrelipase) • Zenpep (pancrelipase)
Dry Eye Treatment	
Xiidra (lifitegrast ophthalmic solution)	**Xiidra (lifitegrast ophthalmic solution) may be considered medically necessary when the following criteria are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older **AND** • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic **AND** • Xiidra (lifitegrast ophthalmic solution) is not being used concurrently with an ophthalmic cyclosporine product (e.g., Cequa, Restasis, Vevye), Miebo (perfluorohexyloctane ophthalmic solution), or Tyrvaya (varenicline solution nasal spray)
Cequa (cyclosporine ophthalmic solution)	**Cequa (cyclosporine ophthalmic solution) may be considered medically necessary when the following criteria are met:** • The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older **AND** • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic **AND** • Cequa (cyclosporine ophthalmic solution) is not being used concurrently with another ophthalmic cyclosporine product (e.g., Restasis or Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution)
Miebo (perfluorohexyloctane ophthalmic solution)	**Miebo (perfluorohexyloctane ophthalmic solution) may be considered medically necessary when the following criteria are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older **AND** • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic **AND** • Miebo (perfluorohexyloctane ophthalmic solution) is not being used concurrently with an ophthalmic cyclosporine product (e.g., Cequa, Restasis, Vevye), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution)
Restasis (cyclosporine ophthalmic emulsion)	**Restasis (cyclosporine ophthalmic emulsion) may be considered medically necessary when the following criteria are met:** • The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older **AND** • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic **AND** • Restasis (cyclosporine ophthalmic emulsion) is not being used concurrently with another ophthalmic cyclosporine product (e.g., Cequa or Vevye), Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution)
Verkazia (cyclosporine ophthalmic emulsion)	**Verkazia (cyclosporine ophthalmic emulsion) may be considered medically necessary for the treatment of vernal keratoconjunctivitis when all the following are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is aged 4 years or older **AND** • Has moderate-to-severe vernal keratoconjunctivitis **AND** • Has tried two ophthalmic medications to treat this condition (e.g., cromolyn, Alomide, Zerviate, azelastine, bepotastine, epinastine, ketotifen, Lastacaft, and olopatadine) **AND** • Verkazia (cyclosporine ophthalmic emulsion) is prescribed by or in consultation with an optometrist or ophthalmologist
Vevye (cyclosporine ophthalmic solution)	**Vevye (cyclosporine ophthalmic solution) may be considered medically necessary when the following criteria are met:** • The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older **AND** • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% **AND** • Vevye (cyclosporine ophthalmic solution) is not being used concurrently with another ophthalmic cyclosporine product (e.g., Cequa or Restasis), Miebo (perfluorohexyloctane ophthalmic solution), Tyrvaya (varenicline solution nasal spray), or Xiidra (lifitegrast ophthalmic solution)
Eysuvis (loteprednol etabonate ophthalmic suspension)	**Eysuvis (loteprednol etabonate ophthalmic suspension) may be considered medically necessary when the following criteria are met:** • The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

	AND
	• Has tried and failed two of the following ophthalmic drugs for dry eye disease:
	  ○ Dexamethasone eye drops
	  ○ Loteprednol etabonate eye drops
	  ○ Fluorometholone eye drops
	  ○ Prednisolone eye drops

Tyrvaya (varenicline solution nasal spray)	**Tyrvaya (varenicline solution nasal spray) may be considered medically necessary when the following criteria are met:** • The individual is being treated for the signs and symptoms of dry eye disease **AND** • Is aged 18 years or older **AND** • Has tried and failed generic cyclosporine ophthalmic emulsion 0.05% unless there is a contraindication to use with cyclosporine ophthalmic **AND** • Tyrvaya (varenicline solution nasal spray) is not being used concurrently with an ophthalmic cyclosporine product (e.g., Cequa, Restasis, Vevye), Miebo (perfluorohexyloctane ophthalmic solution), or Xiidra (lifitegrast ophthalmic solution)
Eosinophilic Esophagitis Agents	
Eohilia (budesonide oral suspension)	**Eohilia (budesonide oral suspension) may be considered medically necessary for the treatment of eosinophilic esophagitis when the following criteria are met:** • The individual is aged 11 years or older **AND** • Is diagnosed with eosinophilic esophagitis as confirmed by an endoscopic biopsy demonstrating ≥ 15 intraepithelial eosinophils per high-power field (HPF) (or 60 eosinophils/mm^2) **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has received ≥ 8 weeks of therapy with a proton pump inhibitor (e.g., esomeprazole, lansoprazole, or omeprazole) **OR** • Has severe disease with esophageal stricture **AND** • Has tried dietary modification to treat their condition (e.g., elemental diet or an elimination diet) **OR** • Prescriber has determined that the individual is not an appropriate candidate for dietary modifications **AND** • Eohilia (budesonide oral suspension) is prescribed by or in consultation with an allergist/immunologist or gastroenterologist **AND** • Dose is limited to 2 mg twice daily **AND** • Treatment duration is limited to ≤ 12 weeks **Initial authorization may be approved for up to 12 weeks.** **Re-authorization may be approved for up to 12 weeks if the individual has not been treated with Eohilia (budesonide oral suspension) within the last 6 months OR the individual is experiencing recurrent worsening dysphagia after discontinuing Eohilia (budesonide oral suspension) therapy**
Gabapentin Products	
• **Gabapentin extended-release** • **Gralise (gabapentin extended release)** • **Horizant (gabapentin extended release)**	**Horizant (gabapentin extended release) may be considered medically necessary for restless leg syndrome when the following criteria are met:** • The individual has had at least 3-months trial and treatment failure, or intolerance with generic gabapentin or generic pregabalin **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

	• Has had at least 3-months trial and treatment failure, or intolerance with generic ropinirole or pramipexole
	
	Horizant (gabapentin extended release) may be considered medically necessary for neuropathic pain when the following criteria are met:
	• The individual has had at least 3-months trial and treatment failure, or intolerance with generic gabapentin or generic pregabalin
	AND
	• Has had at least 3-months trial and treatment failure, or intolerance with one of the following:
	  ○ Duloxetine, venlafaxine, nortriptyline, or amitriptyline
	
	Generic gabapentin extended release and Gralise (gabapentin extended release) may be considered medically necessary for neuropathic pain when the following criteria are met:
	• The individual has had at least 3-months trial and treatment failure, or intolerance with generic gabapentin or generic pregabalin
	AND
	• Has had at least 3-months trial and treatment failure, or intolerance with one of the following:
	  ○ Duloxetine, venlafaxine, nortriptyline, or amitriptyline
	
	Initial authorization may be approved for up to 3 years. Re-authorization may be approved up to 3 years and requires documentation of continued clinical response.

Gastrointestinal Stimulants	
Gimoti (metoclopramide nasal spray)	**Gimoti (metoclopramide nasal spray) may be considered medically necessary for the relief of symptoms from acute and recurrent diabetic gastroparesis when ALL of the following criteria are met:** • The individual is aged 18 years or older

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Tried and failed dietary modification **AND** • Has tried oral metoclopramide first and had an inadequate response or intolerance to oral metoclopramide
Heart Disease Prevention Agents	
Lodoco (colchicine)	**Lodoco (colchicine) may be considered medically necessary when ALL of the following criteria are met:** • The individual is aged 18 years or older • Diagnosed with a history of atherosclerotic cardiovascular disease (ASCVD) • Is on maximally tolerated statin therapy, unless contraindicated or not tolerated • Has tried generic oral colchicine first and had an inadequate response
Heart Failure Agents	
Camzyos (mavacamten)	**Camzyos (mavacamten) may be considered medically necessary when ALL of the following criteria are met:** • The individual is aged 18 years or older • Diagnosed with symptomatic New York Heart Association (NYHA) class II-III obstructive hypertrophic cardiomyopathy (HCM) • Receiving concurrent therapy with a beta-blocker (BB) or a calcium channel blocker (CCB), unless BB and CCB are not tolerated or there is a contraindication to use • Documented left ventricular ejection fraction (LVEF) ≥ 55% • Prescribed dose is ≤ 15 mg per day • Use is prescribed by or in consultation with a cardiologist or a cardiac care specialist
Corlanor (ivabradine)	**Corlanor (ivabradine) may be considered medically necessary for adults when ALL the following criteria are met:** • The individual is aged 18 years or older **AND** • Has a diagnosis of *stable, symptomatic heart failure

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Has normal sinus rhythm with a resting heart rate of ≥70 beats per minute **AND** • Has a left ventricular ejection fraction (LVEF) ≤ 35% **AND** • Previous therapy with the maximum tolerated dose of a beta blocker was ineffective, not tolerated, or contraindicated **AND** • Has tried and had an inadequate response to generic ivabradine **AND** • Use is prescribed by or in consultation with a cardiologist or cardiac care specialist **Corlanor (ivabradine) may be considered medically necessary for pediatric individuals when ALL of the following criteria are met:** • The individual has a diagnosis of *stable, symptomatic heart failure due to dilated cardiomyopathy (DCM) **AND** • Has normal sinus rhythm with an elevated heart rate **AND** • Is aged 6 months and older **AND** • Has tried and had an inadequate response to generic ivabradine **AND** • Use is prescribed by or in consultation with a cardiologist or cardiac care specialist ***Note:** Per the package insert, stable, symptomatic heart failure is defined as NYHA Class II to IV.

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Inpefa (sotagliflozin)	**Inpefa (sotagliflozin) may be considered medically necessary for adults with heart failure when ALL of the following criteria are met:** • The individual has a diagnosis of chronic heart failure (NYHA Class II to IV) • Inpefa (sotagliflozin) will be used in combination with a beta blocker unless contraindicated or not tolerated • Inpefa (sotagliflozin) will be used in combination with an angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB), or Entresto (sacubitril/valsartan) unless contraindicated or not tolerated • Is aged 18 years or older **Inpefa (sotagliflozin) may be considered medically necessary for adults with type 2 diabetes mellitus when ALL of the following criteria are met:** • The individual has a diagnosis of type 2 diabetes mellitus • Inpefa (sotagliflozin) will be used in combination with metformin unless contraindicated or not tolerated • Is aged 18 years or older **Inpefa (sotagliflozin) may be considered medically necessary for adults with chronic kidney disease when ALL of the following criteria are met:** • The individual has a diagnosis of chronic kidney disease • Inpefa (sotagliflozin) will be used in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated • Is aged 18 years or older **Inpefa (sotagliflozin) may be considered medically necessary for adults with other cardiovascular risk factors when ALL of the following criteria are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual has a diagnosis that is a cardiovascular risk factor* • Is aged 18 years or older *Note: There is specific criteria above for individuals with heart failure, type 2 diabetes mellitus, or chronic kidney disease
Generic ivabradine	**Generic ivabradine may be considered medically necessary for adults when ALL the following criteria are met:** • The individual is aged 18 years or older **AND** • Has a diagnosis of *stable, symptomatic heart failure **AND** • Has normal sinus rhythm with a resting heart rate of ≥70 beats per minute **AND** • Has a left ventricular ejection fraction (LVEF) ≤ 35% **AND** • Previous therapy with the maximum tolerated dose of a beta blocker was ineffective, not tolerated, or contraindicated **AND** • Use is prescribed by or in consultation with a cardiologist or cardiac care specialist **Generic ivabradine may be considered medically necessary for pediatric individuals when ALL of the following criteria are met:** • The individual has a diagnosis of *stable, symptomatic heart failure due to dilated cardiomyopathy (DCM) **AND** • Has normal sinus rhythm with an elevated heart rate **AND** • Is aged 6 months and older **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Use is prescribed by or in consultation with a cardiologist or cardiac care specialist ***Note:** Per the package insert, stable, symptomatic heart failure is defined as NYHA Class II to IV.
Verquvo (vericiguat)	**Verquvo (vericiguat) may be considered medically necessary when ALL of the following criteria are met:** • The individual is aged 18 years or older • Has a diagnosis of chronic heart failure (NYHA Class II to IV) with reduced ejection fraction of 45% or less • Was hospitalized for heart failure within the past 6 months or required outpatient IV diuretics for heart failure within the past 3 months • Use is prescribed by or in consultation with a cardiologist or a cardiac care specialist
Antihypertensive/Diuretic	

Carospir (spironolactone oral suspension)	**Carospir (spironolactone oral suspension) may be considered medically necessary when the following criteria are met:**
	• The individual has been diagnosed with ONE of the following:
	  ○ Severe heart failure defined as New York Heart Association (NYHA) class III-IV and a left ventricular ejection fraction (LVEF) ≤ 35 %
	  ○ Hypertension
	  ○ Edema
	AND
	• Documentation that an oral liquid is clinically necessary (e.g., trouble swallowing, etc.) and the individual cannot use spironolactone tablets
	AND
	• Has had an inadequate response or intolerance to generic spironolactone oral suspension

Hypertensive Agents, Brands	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

Tryvio (aprocitentan)	**Tryvio (aprocitentan) may be considered medically necessary for the treatment of hypertension when ALL the following are met:**
	• The individual has been diagnosed with hypertension
	• Has tried ALL the following in combination and had an inadequate response or intolerance:
	  ○ Calcium channel blocker (e.g., amlodipine)
	  ○ Angiotensin receptor blocker (e.g., losartan) OR angiotensin-converting enzyme inhibitor (e.g., lisinopril)
	  ○ Diuretic (e.g., hydrochlorothiazide)
	• Has tried and had an inadequate response or intolerance to a generic mineralocorticoid receptor antagonist (e.g., spironolactone or eplerenone)
	• Dose is limited to 12.5 mg once daily

Hypnotics	
• **Ambien (zolpidem)** • **Ambien CR (zolpidem)** • **Belsomra (suvorexant)** • **Dayvigo (lemborexant)** • **Brand quazepam** • **Doral (quazepam)** • **Edluar (zolpidem sublingual)** • **Lunesta (eszopiclone)** • **Quviviq (daridorexant)** • **Rozerem (ramelteon)** • **Silenor (doxepin)** • **Brand zolpidem tartrate** • **Zolpimist (zolpidem oral spray)**	**Ambien (zolpidem), Ambien CR (zolpidem), Belsomra (suvorexant), Dayvigo (lemborexant), brand quazepam, Doral (quazepam), Edluar (zolpidem sublingual), Lunesta (eszopiclone), Quviviq (daridorexant), Rozerem (ramelteon), Silenor (doxepin), brand zolpidem tartrate, and Zolpimist (zolpidem oral spray) may be considered medically necessary for treatment of insomnia when the individual has tried and failed two of the following generic drugs:** • Eszopiclone • Ramelteon • Zolpidem • Zaleplon (unless such therapy would be inappropriate)
Hypoxia-inducible factor prolyl hydroxylase (HIF PH)	
Jesduvroq (daprodustat)	**Jesduvroq (daprodustat) may be considered medically necessary for the treatment of anemia due to chronic kidney disease when:** • The individual is aged 18 years or older **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Is receiving dialysis for at least four months **AND** • Has had an inadequate response or intolerance to erythropoietin stimulating agents (e.g., epoetin alpha, darbepoetin)
Vafseo (vadadustat)	**Vafseo (vadadustat) may be considered medically necessary for the treatment of anemia due to chronic kidney disease when:** • The individual is aged 18 years or older **AND** • Is receiving dialysis for at least three months **AND** • Has had an inadequate response or intolerance to erythropoietin stimulating agents (e.g., epoetin alpha, darbepoetin)
Low Molecular Weight Heparins (LMWHs)	
• **Fragmin (dalteparin)** • **Lovenox (enoxaparin)** **Managed under pharmacy benefit only**	**Fragmin (dalteparin) and Lovenox (enoxaparin) may be considered medically necessary when the individual has tried and had an inadequate response or intolerance to generic enoxaparin or unfractionated heparin**
Human Nerve Growth Factors	

Oxervate (cenegermin-bkbj)	**Oxervate (cenegermin-bkbj) ophthalmic solution may be considered medically necessary for the treatment of neurotrophic keratitis when:**
	• The individual is aged 2 years or older
	AND
	• Diagnosis of stage 2 or 3 neurotrophic keratitis in one or both eyes, as shown by the presence of one of the following:
	  ○ Persistent epithelial defect(s)
	  ○ Corneal ulcer(s)
	AND
	• Evidence of decreased corneal sensitivity in at least one corneal quadrant

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Treatment failure with at least one preservative-free artificial tear, gel or ointment **AND** • Prescribed by or in consultation with an ophthalmologist **AND** • Dose does not exceed 1 vial per affected eye per day **Initial approval will be for 8 weeks.** **Re-authorization criteria:** • Future re-authorization of Oxervate (cenegermin-bkbj) beyond 8 weeks is considered investigational.
Parkinson's Disease Agents	
Generic apomorphine	**Generic apomorphine may be considered medically necessary for the intermittent treatment of OFF episodes in individuals with Parkinson's disease when:** • Treated with carbidopa/levodopa **AND** • Tried one of the following medications before generic apomorphine: ○ Dopamine agonist (e.g., pramipexole, ropinirole) **OR** ○ COMT (catechol-O-methyltransferase) inhibitor (e.g., entacapone) **OR** ○ Monoamine oxidase B inhibitor (e.g., rasagiline, selegiline)
Apokyn (apomorphine)	**Apokyn (apomorphine) may be considered medically necessary for the intermittent treatment of OFF episodes in individuals with Parkinson's disease when:** • Treated with carbidopa/levodopa **AND** • Tried and failed two generic medications from different drug classes among the following: ○ Dopamine agonist (e.g., pramipexole, ropinirole)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	○ COMT (catechol-O-methyltransferase) inhibitor (e.g., entacapone) ○ Monoamine oxidase B inhibitor (e.g., rasagiline, selegiline) **AND** • Has tried and had an inadequate response to generic apomorphine
• **Crexont (carbidopa-levodopa)** • **Dhivy (carbidopa-levodopa)** • **Duopa (carbidopa-levodopa)** • **Rytary (carbidopa-levodopa)** • **Sinemet (carbidopa-levodopa)**	**Crexont (carbidopa-levodopa), Dhivy (carbidopa-levodopa), Duopa (carbidopa-levodopa), Rytary (carbidopa-levodopa), and Sinemet (carbidopa-levodopa) may be considered medically necessary to treat Parkinson's disease when the individual has tried and failed or is intolerant to generic carbidopa and generic levodopa used in combination.**
Gocovri (amantadine)	**Gocovri (amantadine) may be considered medically necessary for the treatment of dyskinesia in patients with Parkinson's disease receiving levodopa-based therapy when the individual has:** • Tried and failed or is intolerant to generic amantadine **AND** • Dose is ≤ 274 mg per day (taken as two 137 mg capsules) **Gocovri (amantadine) may be considered medically necessary as adjunctive treatment to carbidopa/levodopa in individuals with Parkinson's disease experiencing OFF episodes when the individual has:** • Tried and failed two generic medications from different drug classes among the following: ○ Dopamine agonist (e.g., pramipexole, ropinirole) ○ COMT (catechol-O-methyltransferase) inhibitor (e.g., entacapone) ○ Monoamine oxidase B inhibitor (e.g., rasagiline, selegiline) **AND** • Dose is ≤ 274 mg per day (taken as two 137 mg capsules)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Inbrija (levodopa inhalation powder)	**Inbrija (levodopa inhalation powder) may be considered medically necessary for the intermittent treatment of OFF episodes in individuals with Parkinson's disease when:** • Treated with carbidopa/levodopa **AND** • Tried one of the following medications before Inbrija: ○ Dopamine agonist (e.g., pramipexole, ropinirole) **OR** ○ COMT (catechol-O-methyltransferase) inhibitor (e.g., entacapone) **OR** ○ Monoamine oxidase B inhibitor (e.g., rasagiline, selegiline)
Kynmobi (apomorphine sublingual film)	**Kynmobi (apomorphine sublingual film) may be considered medically necessary for the intermittent treatment of OFF episodes in individuals with Parkinson's disease when:** • Treated with carbidopa/levodopa **AND** • Tried and failed two generic medications from different drug classes among the following: ○ Dopamine agonist (e.g., pramipexole, ropinirole) ○ COMT (catechol-O-methyltransferase) inhibitor (e.g., entacapone) ○ Monoamine oxidase B inhibitor (e.g., rasagiline, selegiline) **AND** • Maximum quantity prescribed is 5 doses per day
Lodosyn (carbidopa)	**Lodosyn (carbidopa) may be considered medically necessary to treat Parkinson's disease when the individual has tried and failed or is intolerant to generic carbidopa.**
Nourianz (istradefylline)	**Nourianz (istradefylline) may be considered medically necessary as adjunctive treatment to carbidopa/levodopa in individuals with Parkinson's disease when the individual has:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

	• Tried and failed two generic medications from different drug classes among the following:
	  ○ Dopamine agonist (e.g., pramipexole, ropinirole)
	  ○ COMT (catechol-O-methyltransferase) inhibitor (e.g., entacapone)
	  ○ Monoamine oxidase B inhibitor (e.g., rasagiline, selegiline)

Ongentys (opicapone)	**Ongentys (opicapone) may be considered medically necessary as adjunctive treatment to carbidopa/levodopa in individuals with Parkinson's disease experiencing OFF episodes when the individual has:** • Tried and failed or had intolerance to entacapone or tolcapone
Osmolex ER (amantadine)	**Osmolex ER (amantadine) may be considered medically necessary to treat adult individuals with:** • Parkinson's disease **OR** • Drug-induced extrapyramidal reactions **AND** • Individual has tried and failed or is intolerant to generic amantadine **AND** • Dose is ≤ 322 mg per day (taken as 129 mg tablet and 193 mg tablet)
Stalevo (carbidopa-levodopa-entacapone)	**Stalevo (carbidopa-levodopa-entacapone) may be considered medically necessary to treat individuals with Parkinson's disease when the individual has tried and failed or is intolerant to generic carbidopa, generic levodopa, and generic entacapone used in combination**
Xadago (safinamide)	**Xadago (safinamide) may be considered medically necessary to treat Parkinson's disease when all the following criteria are met:** • The individual is aged 18 years or older **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

	• Is experiencing OFF episodes on carbidopa-levodopa therapy
	AND
	• Use is concomitant with carbidopa-levodopa
	AND
	• Has tried and failed or is intolerant to **TWO** of the following:
	  ○ Entacapone
	  ○ Pramipexole
	  ○ Pramipexole ER
	  ○ Rasagiline
	  ○ Selegiline
	  ○ Ropinirole
	  ○ Ropinirole ER
	  ○ Tolcapone

Zelapar (selegiline)	**Zelapar (selegiline) may be considered medically necessary to treat Parkinson's disease when all the following criteria are met:**
	• The individual is aged 18 years or older
	AND
	• Is experiencing OFF episodes on carbidopa-levodopa therapy
	AND
	• Use is concomitant with carbidopa-levodopa
	AND
	• Has tried and failed or is intolerant to **TWO** of the following:
	  ○ Entacapone
	  ○ Rasagiline
	  ○ Ropinirole
	  ○ Ropinirole ER
	  ○ Pramipexole
	  ○ Pramipexole ER
	  ○ Selegiline
	  ○ Tolcapone

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Ibsrela (tenapanor)	
Ibsrela (tenapanor)	**Ibsrela(tenapanor) may be considered medically necessary for the treatment of irritable bowel syndrome with constipation (IBS-C) when individual has had at least 3-months trial and treatment failure, or intolerance of at least 3 of the following drugs:** • Bulk-forming laxatives (e.g., Metamucil or Citrucel), osmotic agents (e.g., lactulose, PEG, or magnesium citrate)
Inhaled Corticosteroids	
• **Alvesco (ciclesonide)** • **Asmanex HFA (mometasone)** • **Asmanex Twisthaler (mometasone)** • **Pulmicort Flexhaler (budesonide)**	**Alvesco (ciclesonide), Asmanex HFA (mometasone), Asmanex Twisthaler (mometasone), and Pulmicort Flexhaler (budesonide) may be considered medically necessary for the treatment of asthma when the individual has had an inadequate response or intolerance to two of the following:** • Arnuity Ellipta (fluticasone furoate) • Fluticasone Propionate HFA/Fluticasone Propionate Diskus • QVAR Redihaler (beclomethasone)
Inherited Metabolic Disorders	
Generic nitisinone	**Generic nitisinone may be considered medically necessary when the following criteria are met:** • The individual is diagnosed with hereditary tyrosinemia type 1 **AND** • Diagnosis is confirmed by measurement of succinylacetone either in urine or in blood **AND** • Generic nitisinone is used in combination with dietary restriction of tyrosine and phenylalanine
Nityr (nitisinone)	**Nityr (nitisinone) may be considered medically necessary when the following criteria are met:** • The individual is diagnosed with hereditary tyrosinemia type 1 **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Diagnosis is confirmed by measurement of succinylacetone either in urine or in blood **AND** • Nityr (nitisinone) is used in combination with dietary restriction of tyrosine and phenylalanine **AND** • Has tried generic nitisinone first and had an inadequate response or intolerance to generic nitisinone (documentation required)
Orfadin (nitisinone)	**Orfadin (nitisinone) may be considered medically necessary when the following criteria are met:** • The individual is diagnosed with hereditary tyrosinemia type 1 **AND** • Diagnosis is confirmed by measurement of succinylacetone either in urine or in blood **AND** • Orfadin (nitisinone) is used in combination with dietary restriction of tyrosine and phenylalanine **AND** • Has tried generic nitisinone first and had an inadequate response or intolerance to generic nitisinone (documentation required)
Intranasal Brand Antihistamine Products	
Intranasal brand antihistamine products (e.g.): • **Patanase**	**Intranasal brand antihistamine products (e.g., Patanase) may be considered medically necessary for the treatment of allergic rhinitis when the individual has tried and failed at least two generic intranasal corticosteroids or antihistamine products (e.g., olopatadine).**
Intranasal Brand Corticosteroid Products	
Intranasal brand corticosteroid products (e.g.): • **Dymista** • **Omnaris** • **Qnasl** • **Ryaltris**	**Intranasal brand corticosteroid products (e.g., Dymista, Omnaris, Qnasl, Ryaltris, Xhance, Zetonna) may be considered medically necessary for the treatment of allergic rhinitis when the individual has tried and failed at least two generic intranasal corticosteroids.**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Xhance** • **Zetonna**	
Xhance (fluticasone propionate)	**Xhance (fluticasone propionate) may be considered medically necessary for the treatment of chronic rhinosinusitis without nasal polyps when the individual has tried and failed at least two generic intranasal corticosteroids.**
Iron Replacement Products	
Accrufer (ferric maltol)	**Accrufer (ferric maltol) may be considered medically necessary for the treatment of iron deficiency anemia in adults when the individual has:** • Inflammatory bowel disease **OR** • Non-dialysis dependent chronic kidney disease **AND** • Tried and failed or had intolerance to both oral iron and IV iron **AND** • Is aged 18 years or older **Note:** Examples of oral iron include ferrous fumarate, ferrous gluconate and ferrous sulfate. Examples of IV iron include ferric carboxymaltose (Injectafer), ferric pyrophosphate citrate (Triferic), ferumoxytol (Feraheme), iron dextran (INFeD), iron sucrose (Venofer), sodium ferric gluconate complex (Ferrlecit).
Irritable Bowel Syndrome with Diarrhea (IBS-D) Agents	
Viberzi (eluxadoline)	**Viberzi (eluxadoline) may be considered medically necessary for the treatment of irritable bowel syndrome with diarrhea (IBS-D) when the following criteria are met:** • The individual is aged 18 years or older **AND** • Has tried and failed two other anti-diarrheal agents (e.g., atropine/diphenoxylate, bismuth subsalicylate, dicyclomine, hyoscyamine, loperamide, tricyclic antidepressants) **AND** • Dose is ≤ 200 mg per day

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Miscellaneous Infectious Disease Agents	
Lithostat (acetohydroxamic acid)	**Lithostat (acetohydroxamic acid) may be considered medically necessary as adjunctive therapy for the treatment of chronic urea-splitting urinary infection when all the following criteria are met:** • The individual has been diagnosed with chronic urea-splitting urinary infection **AND** • Medication is being used in combination with antibiotics **AND** • Pregnancy status has been verified and the individual is not pregnant **AND** • The daily dose is ≤ 1.5 grams
Brand Molluscum Contagiosum Agents	
• **Brand cantharidin** • **Ycanth (cantharidin)**	**Brand cantharidin and Ycanth (cantharidin) may be considered medically necessary for the treatment of molluscum contagiosum when all the following criteria are met:** • The individual is aged 2 years or older **AND** • Has been diagnosed with molluscum contagiosum **AND** • Is not immunocompromised **AND** • All treated lesions are ≥ 10 cm from any mucosal surfaces **AND** • Has tried and had an inadequate response or intolerance to cryotherapy, generic topical podofilox, or Zelsuvmi (berdazimer) **AND** • Limited to two applicators per treatment
Zelsuvmi (berdazimer)	**Zelsuvmi (berdazimer) may be considered medically necessary for the treatment of molluscum contagiosum when all the following criteria are met:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual is aged 1 year and older **AND** • Has been diagnosed with molluscum contagiosum **AND** • Has tried and had an inadequate response or intolerance to cryotherapy**,** generic topical podofilox, brand cantharidin, or Ycanth (cantharidin) **AND** • Limited to topical application once daily for up to 12 weeks per treatment
Oral Corticosteroids, Brand	
• **Alkindi Sprinkle** • **Cortef** • **Dxevo** • **Hemady** • **Medrol** • **Orapred ODT** • **Pediapred** • **Taperdex** • **Zcort**	**Brand oral corticosteroids Alkindi Sprinkle (hydrocortisone), Cortef (hydrocortisone), Dxevo (dexamethasone), Hemady (dexamethasone), Medrol (methylprednisolone), Orapred ODT (prednisolone), Pediapred (prednisolone), Taperdex (dexamethasone), and Zcort (dexamethasone) may be considered medically necessary when the following conditions are met:** • The individual has had an inadequate response or intolerance to two generic oral corticosteroids (documentation required) **OR** • Documentation is provided that a brand oral corticosteroid is medically necessary (e.g., individual body weight, unable to swallow) and no generic oral corticosteroid is available that can provide the equivalent dose
Overactive Bladder Agents	
• **Brand oxybutynin** • **Gelnique (oxybutynin)** • **Gemtesa (vibegron)** • **Myrbetriq (mirabegron)** • **Oxytrol (oxybutynin)** • **Toviaz (fesoterodine)** • **Vesicare (solifenacin)** • **Vesicare LS (solifenacin)**	**Brand oxybutynin, Gelnique (oxybutynin), Gemtesa (vibegron), Myrbetriq (mirabegron), Oxytrol (oxybutynin), and Toviaz (fesoterodine), Vesicare (solifenacin), and Vesicare LS (solifenacin) may be considered medically necessary when the following conditions are met:** • The individual has had an inadequate response or intolerance to two of the following: generic oxybutynin

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	chloride, generic mirabegron, generic solifenacin, generic tolterodine, or generic trospium
Generic mirabegron	**Generic mirabegron may be considered medically necessary when the individual has had an inadequate response or intolerance to generic oxybutynin chloride, generic solifenacin, generic tolterodine, or generic trospium**
Peanut Immunotherapy	
Palforzia [peanut (*Arachis hypogaea*) allergen powder-dnfp]	**Palforzia [peanut (Arachis hypogaea) allergen powder-dnfp] may be considered medically necessary for the treatment of individuals with a confirmed diagnosis of peanut allergy when:** • The individual is aged 1 year and older **AND** • Prescribed concurrently with injectable epinephrine **AND** • Provider attestation to support necessity for oral immunotherapy **AND** • Used concurrently with attestation of peanut avoidance **AND** • Maximum dose is 300 mg daily **AND** • Palforzia is prescribed by or in consultation with an allergist/immunologist
Potassium Binders	
Lokelma (sodium zirconium cyclosilicate)	**Lokelma (sodium zirconium cyclosilicate) may be considered medically necessary for the treatment of hyperkalemia when:** • The individual has tried and failed or is intolerant to generic SPS (sodium polystyrene sulfonate) suspension **AND** • Maximum dose is 15 grams daily
Veltassa (patiromer)	**Veltassa (patiromer) may be considered medically necessary for the treatment of hyperkalemia when:**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• The individual has tried and failed or is intolerant to generic SPS (sodium polystyrene sulfonate) suspension **AND** • Maximum dose is 25.2 grams daily
Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)	

Jynarque (tolvaptan)	**Jynarque (tolvaptan) may be considered medically necessary for the treatment of progressing autosomal dominant polycystic kidney disease (ADPKD) when:**
	• The individual is aged 18 years or older
	AND
	• Is enrolled in the REMS program and all program requirements are being met:
	  ○ Has been counseled regarding risk of hepatotoxicity.
	  ○ ALT, AST and bilirubin are assessed prior to initiation of Jynarque, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter for the duration of therapy
	  ○ At the onset of signs or symptoms consistent with hepatic injury or if ALT, AST, or bilirubin increase to >2 times ULN, therapy must be immediately discontinued. If individual is stabilized, treatment may continue with increased monitoring frequency
	  ○ A maximum quantity limit of 120mg/day applies

Proton Pump Inhibitors	
• **Aciphex (rabeprazole)** • **Aciphex Sprinkle (rabeprazole)** • **Generic dexlansoprazole** • **Dexilant (dexlansoprazole)** • **Brand esomeprazole** • **Generic omeprazole/sodium bicarbonate** • **Konvomep (omeprazole/sodium bicarbonate)** • **Nexium (esomeprazole)**	**Aciphex (rabeprazole), Aciphex Sprinkle (rabeprazole), generic dexlansoprazole, Dexilant (dexlansoprazole), brand esomeprazole, generic omeprazole/sodium bicarbonate, Konvomep (omeprazole/sodium bicarbonate), Nexium (esomeprazole), Prevacid (lansoprazole), Prevacid Solutab (lansoprazole), Prilosec (omeprazole), Protonix (pantoprazole), brand rabeprazole, and Zegerid (omeprazole/sodium bicarbonate) may be considered medically necessary when:** • The individual has tried and failed or had intolerance to three of the following generic medications:

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Prevacid (lansoprazole)** • **Prevacid Solutab (lansoprazole)** • **Prilosec (omeprazole)** • **Protonix (pantoprazole)** • **Brand rabeprazole** • **Zegerid (omeprazole/sodium bicarbonate)**	○ Esomeprazole* ○ Lansoprazole* ○ Omeprazole* ○ Pantoprazole ○ Rabeprazole **OR** • Documentation is provided that the individual is unable to swallow tablets or capsules and has tried and failed or had intolerance to one of the following generic medications: ○ Esomeprazole oral suspension ○ Lansoprazole orally disintegrating tablet ***Note**: Use of OTC esomeprazole, lansoprazole, and omeprazole qualifies when use is documented in chart notes.
Pseudobulbar Affect (PBA) Agents	
Nuedexta (dextromethorphan hydrobromide and quinidine sulfate)	**Nuedexta (dextromethorphan hydrobromide and quinidine sulfate) may be considered medically necessary for the treatment of Pseudobulbar Affect.** • Quantity may be approved up to 60 tablets per 30 days
Cystic Fibrosis	
Bronchitol (mannitol)	**Bronchitol (mannitol) may be considered medically necessary when the following criteria are met:** • The individual is diagnosed with cystic fibrosis **AND** • Is aged 18 years or older **AND** • Bronchitol Tolerance Test (BTT) has been administered to confirm the individual is appropriate for mannitol use **AND** • Use is as add-on maintenance therapy **AND** • Use is not concurrent with hypertonic saline **AND** • Dose prescribed is ≤ 800 mg per day (taken as 400 mg twice a day by oral inhalation)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Pulmozyme (dornase alfa)	**Pulmozyme (dornase alfa) may be considered medically necessary when the following criteria are met:** • The individual is diagnosed with cystic fibrosis **AND** • Forced expiratory volume in one second (FEV1) is below the normal range ○ **Exception**: For individuals less than 5 years of age there is no requirement to receive a documented FEV1 value **Note:** Pulmozyme is not FDA approved in children less than 5 years of age but has studies for children 3 months and older and an off-label indication for those less than 5 years of age. Adding an exception - spirometry testing would not be accurate.
Cystitis Agents	
Elmiron (pentosan polysulfate sodium)	**Elmiron (pentosan polysulfate sodium) may be considered medically necessary for the treatment of bladder pain or discomfort associated with interstitial cystitis when the individual has had an inadequate response or intolerance to amitriptyline**
Cystine Binding Drugs	
• **Thiola (tiopronin)** • **Thiola EC (tiopronin delayed-release)**	**Thiola (tiopronin) and Thiola EC (tiopronin delayed-release) may be considered medically necessary for the prevention of cystine stone formation in adult and pediatric patients when the following criteria are met:** • The individual weighs ≥ 20 kg (44 lbs.) **AND** • Medication is being used in combination with high fluid intake, alkali, and diet modification **AND** • Tried and failed or is intolerant to generic tiopronin
Generic tiopronin	**Generic tiopronin may be considered medically necessary for the prevention of cystine stone formation in adult and pediatric patients when the following criteria are met:** • The individual weighs ≥ 20 kg (44 lbs.)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Tiopronin is being used in combination with high fluid intake, alkali, and diet modification
Hyperhidrosis Agents	

Qbrexza (glycopyrronium cloth)	**Qbrexza (glycopurronium cloth) may be considered medically necessary for the treatment of primary axillary hyperhidrosis when all the following are met:**
	• The individual is aged 9 years or older
	AND
	• Has been diagnosed with primary axillary hyperhidrosis that meets all the following:
	  ○ Is significantly interfering with activities of daily living for at least 6 months
	  ○ Is not due to a secondary cause
	AND
	• Has tried and had an inadequate response to prescription antiperspirants
	AND
	• The prescribed dose is a single cloth of Qbrexza (glycopyrronium cloth) per underarm once a day

Sofdra (sofpironium)	**Sofdra (sofpironium) may be considered medically necessary for the treatment of primary axillary hyperhidrosis when all the following are met:**
	• The individual is aged 9 years or older
	AND
	• Has been diagnosed with primary axillary hyperhidrosis that meets all the following:
	  ○ Is significantly interfering with activities of daily living for at least 6 months
	  ○ Is not due to a secondary cause
	AND
	• Has tried and had an inadequate response to prescription antiperspirants
	AND

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Has tried and had an inadequate response to Qbrexza (glycopyrronium) or Botox (onabotulinumtoxinA) **AND** • The prescribed dose is 1 pump of Sofdra (sofpironium) per underarm once a day at bedtime
Tryptophan Hydroxylase Inhibitor	
Xermelo (telotristat ethyl)	**Xermelo (telotristat ethyl) may be considered medically necessary for use in adult individuals after failure of control of carcinoid-induced diarrhea following an adequate course (≥3 months) of dose escalation with octreotide-LAR to a maximum of 30 to 60mg/month.** • Must be used in combination with long-acting synthetic somatostatin analogue (SSA)
Muscle Relaxants	
• **Fleqsuvy (baclofen oral solution)** • **Lyvispah (baclofen oral granules)** • **Ozobax (baclofen oral solution)** • **Ozobax DS (baclofen oral solution)** • **Brand baclofen oral solution** • **Brand baclofen oral suspension**	**Fleqsuvy (baclofen oral solution), Lyvispah (baclofen oral granules), Ozobax (baclofen oral solution), brand baclofen oral solution and brand baclofen oral suspension may be considered medically necessary when individual has documentation in the form of medical records of the following:** • Documentation that the oral solution is clinically necessary (e.g., trouble swallowing, etc.) and the individual cannot use baclofen tablets **AND** • Has had an inadequate response or intolerance to generic baclofen oral solution
• **Norgesic (orphenadrine, aspirin, and caffeine)** • **Norgesic Forte (orphenadrine, aspirin, and caffeine)**	**Norgesic (orphenadrine, aspirin, and caffeine) and Norgesic Forte (orphenadrine, aspirin, and caffeine) may be considered medically necessary when:** • The individual has had an inadequate response or intolerance to generic cyclobenzaprine **AND** • Had had an inadequate response or intolerance to one of the following generic medications: ○ Baclofen

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	○ Carisoprodol ○ Chlorzoxazone ○ Methocarbamol ○ Orphenadrine ○ Tizanidine
Myasthenia Gravis Agents	
Mestinon (pyridostigmine)	**Mestinon (pyridostigmine) may be considered medically necessary for the treatment of myasthenia gravis when:** • The individual is aged 18 years or older **AND** • Has had an inadequate response or intolerance to generic pyridostigmine
Nexobrid	
Nexobrid (anacaulase-bcdb)	**Nexobrid (anacaulase-bcdb) may be considered medically necessary to treat deep partial thickness or full thickness thermal burns when documentation in the medical records supports the following:** • The individual is aged 18 years or older **AND** • Quantity does not exceed 110 grams per 30 days
Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and Combinations	
• **Brand diclofenac potassium for oral solution** • **Cambia (diclofenac potassium for oral solution)**	**Brand diclofenac potassium for oral solution and Cambia (diclofenac potassium for oral solution) may be considered medically necessary for:** • Acute treatment of migraine attacks in adults 18 years of age or older **AND** • Has tried and failed a generic diclofenac **AND** 2 other prescriptions only generic NSAIDs
• **Duexis (ibuprofen + famotidine)** • **Generic ibuprofen + famotidine (two-drug combination)**	**Duexis (ibuprofen + famotidine) and generic ibuprofen + famotidine (two-drug combination) may be considered medically necessary when:** • The individual has tried and failed use of generic ibuprofen **in combination** with generic famotidine **AND** 2 other

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	regimens **combining** a prescription only NSAID with either a PPI or an H2 Antagonist
• **Brand diclofenac epolamine** • **Flector (diclofenac epolamine)** • **Licart (diclofenac epolamine)**	**Brand diclofenac epolamine, Flector (diclofenac epolamine), and Licart (diclofenac epolamine) may be considered medically necessary when the individual has had an inadequate response or intolerance to all the following:** • Two oral generic NSAIDs (e.g., diclofenac, etodolac, ibuprofen, indomethacin, ketorolac, meloxicam, nabumetone, or naproxen) **AND** • Generic diclofenac 1% gel
• **Generic naproxen/ esomeprazole** • **Vimovo (naproxen/ esomeprazole)**	**Generic naproxen/esomeprazole and Vimovo (naproxen/ esomeprazole) may be considered medically necessary when:** • The individual has tried and failed use of generic naproxen **in combination** with esomeprazole (taken separately) **AND** • 2 other regimens **combining** a prescription only NSAID with a PPI
• **Brand ketorolac tromethamine nasal spray** • **Sprix (ketorolac tromethamine) nasal spray**	**Brand ketorolac tromethamine nasal spray and Sprix (ketorolac tromethamine) nasal spray may be considered medically necessary for the treatment of moderate to moderately severe pain when:** • The individual is aged 18 years or older **AND** • Has had an inadequate response or intolerance to two oral generic NSAIDs (e.g., diclofenac, etodolac, ibuprofen, indomethacin, ketorolac, meloxicam, nabumetone, naproxen) **OR** • Documentation is provided that the individual is unable to take oral medications (e.g., dysphagia, esophagitis, uncontrollable nausea/vomiting) **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• For individuals aged less than 65 years, the daily dose is ≤ 126 mg **OR** • For individuals aged 65 years and older, renally impaired individuals and individuals less than 50 kg (110 lbs.) the daily dose is ≤ 63 mg
Brand Ophthalmic Beta Blockers	
• **Betoptic S (betaxolol)** • **Istalol (timolol)** • **Timoptic (timolol)** • **Timoptic-XE (timolol)**	**Betoptic S (betaxolol), Istalol (timolol), Timoptic (timolol), and Timoptic-XE (timolol) may be considered medically necessary to reduce intraocular pressure in individuals with glaucoma when the individual has tried and failed TWO generic ophthalmic beta blockers.**
Ophthalmic Cholinergic Agonists	
• **Qlosi (pilocarpine)** • **Vuity (pilocarpine)**	**Qlosi (pilocarpine) and Vuity (pilocarpine) may be considered medically necessary for the treatment of presbyopia in adults when all the following criteria are met:** • The individual is aged 18 years or older **AND** • Has a diagnosis of presbyopia **AND** • Has had an inadequate response or intolerance to corrective eyeglasses or contact lenses **AND** • Has had an inadequate response or intolerance to generic pilocarpine ophthalmic solution **AND** • Medication is prescribed by or in consultation with an ophthalmologist or optometrist
Brand Ophthalmic Corticosteroids	
Brand Ophthalmic Corticosteroids (e.g.): • **TobraDex** • **TobraDex ST** • **Tobramycin-vancomycin**	**Brand ophthalmic corticosteroids (e.g., TobraDex, TobraDex ST, tobramycin-vancomycin) may be considered medically necessary when the individual has tried and failed use of generic ophthalmic tobramycin and generic ophthalmic dexamethasone.**
Brand Ophthalmic Prostaglandin Analogs	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Durysta (bimatoprost)	**Durysta (bimatoprost) may be considered medically necessary to reduce intraocular pressure when all the following are met:** • The individual has been diagnosed with open-angle glaucoma or ocular hypertension **AND** • Has tried and had an inadequate response or intolerance to two generic ophthalmic prostaglandin analogs (e.g., bimatoprost or latanoprost)
• **Iyuzeh (latanoprost)** • **Lumigan (bimatoprost)** • **Travatan Z (travoprost)** • **Vyzulta (latanoprostene bunod)** • **Xalatan (latanoprost)** • **Xelpros (latanoprost)** • **Zioptan (tafluprost)**	**Iyuzeh (latanoprost), Lumigan (bimatoprost), Travatan Z (travoprost), Vyzulta (latanoprostene bunod), Xalatan (latanoprost), Xelpros (latanoprost), and Zioptan (tafluprost) may be considered medically necessary to reduce intraocular pressure in individuals with glaucoma when the individual has tried and failed use of generic bimatoprost, latanoprost, or travoprost.**
iDose TR (travoprost intracameral implant)	**iDose TR (travoprost intracameral implant) may be considered medically necessary to reduce intraocular pressure in individuals with open-angle glaucoma or ocular hypertension when the individual has tried and failed TWO generic ophthalmic prostaglandin analogs.**
Brand Blepharitis Agents	

Xdemvy (lotilaner)	**Xdemvy (lotilaner) may be considered medically necessary for the treatment of *Demodex* blepharitis when the following criteria are met:**
	• The individual is aged 18 years or older
	AND
	• Has been diagnosed with *Demodex* blepharitis confirmed by ALL of the following:
	  ○ Presence of mild erythema of the upper eyelid margin in the eye requiring treatment
	  ○ Presence of mites upon examination of eyelashes by light microscopy OR presence of collarettes on 10 or more lashes on the upper lid upon slit lamp examination in the eye requiring treatment

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Dose is limited to one drop in each eye twice daily **AND** • Quantity is limited to one bottle per 6-week treatment course **AND** • Xdemvy (lotilaner) is prescribed by or in consultation with an optometrist or ophthalmologist **Initial approval will be for 6 weeks.** **Re-authorization criteria:** • Future re-authorization of Xdemvy (lotilaner) beyond 6 weeks is considered investigational. • Requests for Xdemvy (lotilaner) for the treatment of *Demodex* blepharitis after ≥ 1-year since completing a prior treatment course will be reviewed as a new request.
Brand Oral Antibiotics and Their Generics	
• **Acticlate (doxycycline)** • **Adoxa (doxycycline)** • **Avidoxy (doxycycline)** • **Doryx (doxycycline)** • **Doryx MPC (doxycycline)** • **Doxycycline IR-DR** • **Emrosi (minocycline)** • **Lymepak (doxycycline)** • **Minocin (minocycline)** • **Minocycline ER** • **Minolira** • **Minolira ER (minocycline hydrochloride extended release)** • **Monodox (doxycycline)** • **Morgidox (doxycycline)** • **Oracea (doxycycline)** • **Seysara (sarecycline)** • **Solodyn (extended-release minocycline)**	**Acticlate, Adoxa, Avidoxy, Doryx, Doryx MPC, Doxycycline IR-DR, Emrosi, Lymepak, Minocin, Minocycline ER, Minolira, Minolira ER, Monodox, Morgidox, Oracea, Seysara, Solodyn, Targadox, and Ximino may be considered medically necessary in individuals who have had at least a 3-months trial and treatment failure of the following drugs (documentation required in the form of medical records):** • Generic doxycycline **AND** • Generic minocycline

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Targadox (doxycycline)** • **Ximino (extended-release minocycline)**	

• **Generic bismuth subcitrate potassium-metronidazole-tetracycline**
• **Helidac (bismuth subsalicylate-metronidazole-tetracycline)**
• **Omeclamox-Pak (omeprazole-clarithromycin-amoxicillin)**
• **Pylera (bismuth subcitrate potassium-metronidazole-tetracycline)**
• **Talicia (omeprazole-amoxicillin-rifabutin)**
• **Voquezna Dual Pak (amoxicillin-vonoprazan)**
• **Voquezna Triple Pak (amoxicillin-clarithromycin-vonoprazan)**
	Generic bismuth subcitrate potassium-metronidazole-tetracycline, Helidac (bismuth subsalicylate, metronidazole, tetracycline), Omeclamox-Pak (omeprazole, clarithromycin, amoxicillin), Pylera (bismuth subcitrate potassium, metronidazole, tetracycline), Talicia (omeprazole, amoxicillin, rifabutin), Voquezna Dual Pak (amoxicillin, vonoprazan), and Voquezna Triple Pak (amoxicillin, clarithromycin, vonoprazan) may be considered medically necessary for the treatment of *Helicobacter pylori (H. pylori)* infection when all of the following criteria are met:
	• The individual has been diagnosed with *H. pylori* infection
	• Is aged 18 years or older
	• Has tried and had an inadequate response or intolerance to TWO of the following generic medication regimens used in combination:
	  ○ Proton pump inhibitor (PPI) such as lansoprazole or omeprazole, amoxicillin, and clarithromycin
	  ○ PPI, bismuth-containing product, tetracycline, and metronidazole
	  ○ PPI, amoxicillin, and rifabutin
	  ○ PPI and amoxicillin
	  ○ PPI, levofloxacin, and amoxicillin

Orlynvah (sulopenem etzadroxil and probenecid)	**Orlynvah (sulopenem etzadroxil and probenecid) may be considered medically necessary for treatment of uncomplicated urinary tract infections caused by susceptible isolates of *Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis* in adults when all the following are met:** • The individual is aged 18 years or older **AND** • Assigned female at birth **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**

	• Has tried and had an inadequate response or intolerance with three of the following:
	  ○ Ciprofloxacin
	  ○ Fosfomycin
	  ○ Levofloxacin
	  ○ Nitrofurantoin
	  ○ Sulfamethoxazole-trimethoprim
	AND
	• The dose is limited to 2 tablets daily for 5 days

Pivya (pivmecillinam)	**Pivya (pivmecillinam) may be considered medically necessary for treatment of uncomplicated urinary tract infections caused by susceptible isolates of *Escherichia coli*, *Proteus mirabilis*, and *Staphylococcus saprophyticus* in adults when all the following are met:**
	• The individual is aged 18 years or older
	AND
	• Assigned female at birth
	AND
	• Has tried and had an inadequate response or intolerance with three of the following:
	  ○ Ciprofloxacin
	  ○ Fosfomycin
	  ○ Levofloxacin
	  ○ Nitrofurantoin
	  ○ Sulfamethoxazole-trimethoprim
	AND
	• The dose is limited to 3 tablets daily for 7 days

Solosec (secnidazole)	**Solosec (secnidazole) may be considered medically necessary for treatment of bacterial vaginosis when:**
	• The individual is aged 12 years or older
	AND
	• Has had an inadequate response or intolerance to two of the following in the past 12 months:
	  ○ Clindamycin
	  ○ Metronidazole

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	○ Tinidazole **Solosec (secnidazole) may be considered medically necessary for treatment of trichomoniasis when:** • The individual is aged 12 years or older **AND** • Has had an inadequate response or intolerance to metronidazole
Brand Oral NSAIDs	
• **Anaprox (naproxen)** • **Arthrotec (diclofenac-misoprostol)** • **Celebrex (celecoxib)** • **Coxanto (oxaprozin)** • **Daypro (oxaprozin)** • **Diclofenac (diclofenac submicronized)** • **Brand fenoprofen** • **Feldene (piroxicam)** • **Indocin (indomethacin)** • **Lodine (etodolac)** • **Brand meloxicam** • **Mobic (meloxicam)** • **Nalfon (fenoprofen)** • **Naprelan (naproxen)** • **Naprosyn (naproxen)** • **Brand oxaprozin** • **Pennsaid (diclofenac)** • **Relafen DS (nabumetone)** • **Tivorbex (indomethacin submicronized)** • **Tolectin 600 (tolmetin)** • **Vivlodex (meloxicam)** • **Voltaren (diclofenac)** • **Zipsor (diclofenac)** • **Zorvolex (diclofenac submicronized)**	**Anaprox (naproxen), Arthrotec (diclofenac-misoprostol), Celebrex (celecoxib), Coxanto (oxaprozin), Daypro (oxaprozin), Diclofenac (diclofenac submicronized), brand fenoprofen, Feldene (piroxicam), Indocin (indomethacin), Lodine (etodolac), brand meloxicam, Mobic (meloxicam), Nalfon (fenoprofen), Naprelan (naproxen), Naprosyn (naproxen), brand oxaprozin, Pennsaid (diclofenac), Relafen DS (nabumetone), Tivorbex (indomethacin submicronized), Tolectin 600 (tolmetin), Vivlodex (meloxicam), Voltaren (diclofenac), Zipsor (diclofenac), and Zorvolex (diclofenac submicronized) may be considered medically necessary when:** • The individual received at least 3 months of treatment with at least 2 generic prescription NSAIDs. **Note**: Chart notes showing trial and failure, or intolerance are required.
Brand Topical Acne or Rosacea Products	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Acanya** • **Aczone** • **Aklief** • **Aktipak** • **Altreno** • **Amzeeq** • **Arazlo** • **Atralin** • **Avage** • **Avar** • **Avar LS** • **Avar-E** • **Avar-E LS** • **Avita** • **Azelex** • **Benzamycin** • **Benzamycinpak** • **Cabtreo** • **Clenia Plus** • **Cleocin T** • **Clindagel** • **Clindamycin/Benzoyl Peroxide** • **Clindamycin Phosphate** • **Dapsone** • **Epiduo** • **Epiduo Forte** • **Evoclin** • **Fabior** • **Finacea** • **Onexton** • **Neuac** • **Plexion** • **Retin-A** • **Retin-A Micro** • **Retin-A Micro Pump** • **Rosanil** • **Rosula** • **Sodium sulfacetamide-sulfur**	**Brand topical acne or rosacea products may be considered medically necessary for the treatment of acne or rosacea when individual has tried and failed (confirmed by medical records) ALL of the following alternatives within the last 2 years:** • Topical generic tretinoin gel or cream (any strength) **AND** • Generic oral tetracycline (minocycline or doxycycline) **AND** • Clindamycin/benzoyl peroxide gel (any strength).

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
• **Sumadan** • **Sumaxin** • **Sumaxin TS** • **Tazorac** • **Tretin-X** • **Twyneo** • **Vanoxide-HC** • **Veltin** • **Winlevi** • **Ziana** • **Zilxi**	
Differin brand and generic adapalene (all prescription strengths and formulations)	**Differin brand, Plixda and generic adapalene can be considered medically necessary for the treatment of acne if individual tried and failed (confirmed by the medical records) ALL of the following alternatives within the last 2 years:** • Topical generic tretinoin cream or gel (any strength) **AND** • Generic oral tetracycline (minocycline or doxycycline) **AND** • Clindamycin/benzoyl peroxide gel (any strength) **AND** • When a documented reason as to why OTC Differin (or its OTC generic equivalent) is not appropriate for the individual is provided
• **Epsolay (benzoyl peroxide cream),** • **Metrocream (metronidazole cream),** • **Metrogel (metronidazole gel),** • **Noritate (metronidazole cream),** • **Soolantra (ivermectin cream)**	**Epsolay (benzoyl peroxide cream), Metrocream (metronidazole cream), Metrogel (metronidazole gel), Noritate (metronidazole cream), and Soolantra (ivermectin cream) may be considered medically necessary for the treatment of inflammatory lesions of rosacea when individual has tried and failed (confirmed by medical records) ALL of the following alternatives within the last 2 years:** • Topical generic azelaic acid **AND** • Topical generic metronidazole

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Tardive Dyskinesia & Huntington's Disease Medications	
Ingrezza (valbenazine)	**Ingrezza may be considered medically necessary when individual has one of the following diagnosis (initial authorization of 3 months):** • DRBA (dopamine receptor blocking agents)-induced tardive dyskinesia **OR** • Chorea associated with Huntington's disease **Reauthorization criteria:** • Improvement as measured by a decrease in AIMS (abnormal involuntary movement scale) score or documentation in the form of medical records of improvement in involuntary movements
• **Austedo (deutetrabenazine)** • **Austedo XR (deutetrabenazine extended release)**	**Austedo (deutetrabenazine) and Austedo XR (deutetrabenazine extended release) may be considered medically necessary when individual has one of the following diagnoses (initial authorization of 3 months):** • DRBA (dopamine receptor blocking agents)-induced tardive dyskinesia **OR** • Chorea associated with Huntington's disease **Reauthorization criteria:** • Improvement as measured by a decrease in AIMS (abnormal involuntary movement scale) score or documentation in the form of medical records of improvement in involuntary movements
Xenazine (tetrabenazine)	**Xenazine (tetrabenazine) may be considered medically necessary for the treatment of chorea associated with Huntington's disease when:** • Individual has tried generic tetrabenazine first and had an inadequate response or intolerance to generic tetrabenazine
Testosterone Replacement Products	

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Nonpreferred Testosterone Replacement agents	**Nonpreferred Testosterone Replacement agents may be considered medically necessary for individuals assigned male at birth OR individuals assigned female at birth for the treatment of gender dysphoria when the individual has tried and failed use of testosterone gel 1%, testosterone gel 1.62% (e.g., Androgel), OR testosterone gel 2% (e.g., Fortesta)** **Nonpreferred Testosterone Replacement agents include:** • Androderm (testosterone transdermal system) • AndroGel (testosterone gel) • Fortesta (testosterone gel) • Jatenzo (testosterone capsules) • Kyzatrex (testosterone capsules) • Methitest (methyltestosterone tablets) • Striant (testosterone buccal system) • Testim (testosterone gel) • Testosterone gel (brand) • Tlando (testosterone capsules) • Undecatrex (testosterone capsules) • Vogelxo (testosterone gel)
Xyosted (testosterone enanthate injection)	**Xyosted (testosterone enanthate injection) may be considered medically necessary for individuals assigned male at birth OR individuals assigned female at birth for the treatment of gender dysphoria when the individual has tried and failed use of generic testosterone cypionate injection**
Rho Kinase Inhibitor	
• **Rhopressa (netarsudil)** • **Rocklatan (netarsudil and latanoprost)**	**Rhopressa (netarsudil) and Rocklatan (netarsudil and latanoprost) may be considered medically necessary to reduce intraocular pressure in individuals with open-angle glaucoma or ocular hypertension when:** • The individual has tried and failed two ophthalmic beta-blockers (e.g., timolol, betaxolol) **AND** two ophthalmic prostaglandins (e.g., latanoprost, bimatoprost)

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Rifamycin Antibiotics	

Xifaxan (rifaximin)	**Xifaxan (rifaximin) may be considered medically necessary when medical records show rifaximin will be used for the following indications:**
	• Adult individuals with Hepatic Encephalopathy
	  ○ Is aged 18 years or older
	  ○ Quantity may be approved up to 60 tablets per 30 days
	• Treatment of Traveler's Diarrhea (TD) when the individual has tried and failed azithromycin and a fluoroquinolone antibiotic (e.g., ciprofloxacin, levofloxacin) for TD or documentation is provided why azithromycin and a fluoroquinolone antibiotic are not clinically appropriate
	  ○ Is 12 years of age or older
	  ○ Quantity may be approved up to a three-day supply
	• Adult individuals with irritable bowel syndrome with diarrhea (IBS-D) when the individual has tried and failed two other anti-diarrheal agents (e.g., atropine/diphenoxylate, bismuth subsalicylate, dicyclomine, hyoscyamine, loperamide, tricyclic antidepressants)
	  ○ Is aged 18 years or older
	  ○ Quantity may be approved up to a 14-day supply with two refills
	• Adult individuals with Small Intestinal Bacterial Overgrowth (SIBO) when **ALL** of the following conditions are met:
	  ○ Is aged 18 years or older
	AND
	  ○ Confirmatory diagnosis of SIBO has been documented by positive breath test and clinical presentations (e.g., bloating, diarrhea, flatulence, abdominal discomfort)
	AND
	  ○ Prior therapy with two other antibiotic agents (e.g., amoxicillin-clavulanate, ciprofloxacin, doxycycline, metronidazole, tetracycline, trimethoprim-sulfamethoxazole) were ineffective unless individual

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	has documented allergies or contraindications to using two other antibiotics **AND** ○ Quantity may be approved up to a 14-day supply with one refill per year
Aemcolo (rifamycin)	**Aemcolo (rifamycin) may be considered medically necessary when medical records show Aemcolo will be used for the following indication:** • Treatment of Traveler's Diarrhea (TD) in individuals aged 18 years and older when the individual has tried and failed azithromycin and a fluoroquinolone antibiotic (e.g., ciprofloxacin, levofloxacin) for TD or documentation is provided why azithromycin and a fluoroquinolone antibiotic are not clinically appropriate **AND** • Quantity prescribed for TD is a one-time fill of Aemcolo 388 mg (two 194 mg tablets) taken twice daily for three days (12 tablets total).
Samsca (tolvaptan)	
• **Generic tolvaptan** • **Samsca (tolvaptan)**	**Generic tolvaptan and Samsca (tolvaptan) may be considered medically necessary for the following labeled indications:** • The individual has hypervolemic or euvolemic hyponatremia [serum sodium <125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction] which includes individuals with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH) **AND** • Is aged 18 years or older **AND** • Maximum daily dose is 60 mg once daily **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Total duration of treatment with generic tolvaptan and Samsca (tolvaptan) is 30 days or less per episode (to avoid liver injury) **Initial approval will be for 30 days.** **Re-authorization criteria:** • Future re-authorization of continuous use of generic tolvaptan or Samsca (tolvaptan) beyond 30-days is considered not medically necessary. A future episode of hypervolemic or euvolemic hyponatremia will be reviewed as an initial request.
Topical Antibiotic	
• **Centany (mupirocin)** • **Xepi (ozenoxacin)**	**Centany (mupirocin) and Xepi (ozenoxacin) may be considered medically necessary to treat impetigo when the individual has tried and use of generic topical mupirocin.**
Transplant Agents	
Envarsus XR (tacrolimus extended-release)	**Envarsus XR (tacrolimus extended-release) may be considered medically necessary if all the following are met:** • The individual has received a kidney transplant **AND** • Has tried generic immediate-release tacrolimus **AND** • Envarsus XR (tacrolimus extended-release) is prescribed by or in consultation with a nephrologist or transplant specialist
Myhibbin (mycophenolate mofetil oral suspension)	**Myhibbin (mycophenolate mofetil oral suspension) may be considered medically necessary if all the following are met:** • The individual has received a kidney, heart, or liver transplant **AND** • Has tried generic mycophenolate mofetil oral suspension **AND**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	• Myhibbin (mycophenolate mofetil oral suspension) is prescribed by or in consultation with a nephrologist, cardiologist, hepatologist, or transplant specialist
Antivirals, Brand	
• **Denavir (penciclovir)** • **Xerese (acyclovir/hydrocortisone)** • **Zovirax (acyclovir cream)**	**Denavir (penciclovir), Xerese (acyclovir and hydrocortisone), and Zovirax (acyclovir cream) may be considered medically necessary to treat herpes labialis (cold sores) if the individual is immunocompetent and has tried and failed or had intolerance with generic topical docosanol and generic penciclovir.**
Generic penciclovir	**Generic penciclovir may be considered medically necessary to treat herpes labialis (cold sores) if the individual is immunocompetent and has tried and failed or had intolerance with generic topical docosanol.**
• **Valtrex (valacyclovir)** • **Zovirax (acyclovir ointment)**	**Valtrex (valacyclovir) and Zovirax (acyclovir ointment) may be considered medically necessary to treat genital herpes or non-life-threatening mucocutaneous herpes simplex virus infections in immunocompromised individuals if the patient has tried and failed or had intolerance with two generic oral antiviral treatments such as acyclovir, famciclovir, or valacyclovir unless contraindicated.**
Topical Seborrheic Dermatitis Agents, Brand	
• **Klaron (sulfacetamide)** • **Ovace Plus Cream (sulfacetamide)** • **Ovace Plus Lotion (sulfacetamide)** • **Ovace Plus Shampoo (sulfacetamide)** • **Ovace Plus Wash (sulfacetamide)** • **Ovace Plus Wash Cleansing Gel (sulfacetamide)** • **Ovace Wash (sulfacetamide)** • **Plexion NS (sulfacetamide)** • **Selrx (selenium sulfide)** • **Tersi (selenium sulfide)**	**Brand topical seborrheic dermatitis agents may be considered medically necessary when the individual has tried and failed or had intolerance to generic topical selenium sulfide within the last 2 years.**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
Zoryve (roflumilast) foam	**Zoryve (roflumilast) foam may be considered medically necessary for the treatment of seborrheic dermatitis when all the following are met:** • The individual is aged 9 years or older **AND** • Has a diagnosis of seborrheic dermatitis involving ≤ 20% of his or her body surface area (BSA) **AND** • Has tried and had an inadequate response or intolerance to ONE topical antifungal agent (e.g., ketoconazole, ciclopirox, or clotrimazole) **AND** • Zoryve (roflumilast) foam is being prescribed by or in consultation with a dermatologist **AND** • Dose is limited to topical application once daily to affected areas
Topical Wart Agents, Brand	
Condylox (podofilox)	**Condylox (podofilox) may be considered medically necessary for the treatment of external genital warts when the individual has tried and failed or had intolerance to generic topical podofilox solution within the last 2 years OR for the treatment of perianal warts.**
Veregen (sinecatechins)	**Veregen (sinecatechins) may be considered medically necessary for the treatment of genital or perianal warts when the individual is 18 years or older and has tried and failed or had intolerance to all of the following within the last 2 years:** • Generic topical podofilox • Generic topical imiquimod
Treatment of Nausea/Vomiting	
• **Bonjesta (doxylamine and pyridoxine extended release)** • **Diclegis (doxylamine and pyridoxine delayed release)**	**Bonjesta (doxylamine and pyridoxine extended-release) and Diclegis (doxylamine and pyridoxine delayed-release) may be considered medically necessary for the treatment of nausea and vomiting of pregnancy when the individual**

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	has tried and failed or had intolerance to generic doxylamine/pyridoxine delayed-release.
Ulcerative Colitis Agents	
• **Apriso (mesalamine)** • **Asacol HD (mesalamine)** • **Colazal (balsalazide)** • **Delzicol (mesalamine)** • **Dipentum (olsalazine)** • **Giazo (balsalazide)** • **Lialda (mesalamine)** • **Pentasa (mesalamine)**	**Apriso (mesalamine), Asacol HD (mesalamine), Colazal (balsalazide), Delzicol (mesalamine), Dipentum (olsalazine), Giazo (balsalazide), Lialda (mesalamine), and Pentasa (mesalamine) may be considered medically necessary for the treatment of ulcerative colitis when the individual has had an inadequate response or intolerance to two of the following oral generic drugs:** • Balsalazide • Mesalamine • Sulfasalazine **Note**: Pentasa when used for Crohn's disease that affects the small intestine is exempt from requirement to use two generic drugs first.
Uceris (budesonide extended-release tablets)	**Uceris (budesonide extended-release tablets) may be considered medically necessary for the treatment of ulcerative colitis when the individual has had an inadequate response or intolerance to generic budesonide extended-release tablets.**
Vitamin Agents	
Nascobal (cyanocobalamin nasal spray)	**Nascobal (cyanocobalamin nasal spray) may be considered medically necessary when the individual has tried and had an inadequate response or intolerance to generic cyanocobalamin injection AND generic cyanocobalamin nasal spray**
Generic cyanocobalamin nasal spray	**Generic cyanocobalamin nasal spray may be considered medically necessary when the individual has tried and had an inadequate response or intolerance to generic cyanocobalamin injection**
Zemplar (paricalcitol)	**Zemplar (paricalcitol) may be considered medically necessary for the prevention and treatment of secondary hyperparathyroidism when the following criteria are met:** • The individual is aged 10 years or older

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Has chronic kidney disease (CKD) Stages 3 or 4 **OR** • Has CKD Stage 5 and is on hemodialysis or peritoneal dialysis **AND** • Has tried and had an inadequate response to generic paricalcitol
Veozah (fezolinetant)	
Veozah (fezolinetant)	**Veozah (fezolinetant) may be considered medically necessary for the treatment of moderate to severe vasomotor symptoms due to menopause when following criteria are met:** • The individual is aged 18 years or older **AND** • Maximum daily dose is 45 mg once daily **Initial approval will be for 3 years.** **Re-authorization criteria:** • Future re-authorization of the drugs listed may be approved up to 3 years as long as the medical necessity criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.
Zylet (loteprednol etabonate and tobramycin ophthalmic suspension)	
Zylet (loteprednol etabonate and tobramycin ophthalmic suspension)	**Zylet (loteprednol etabonate and tobramycin ophthalmic suspension) may be considered medically necessary when the individual has had an inadequate response or intolerance to generic ophthalmic tobramycin and generic ophthalmic loteprednol.**
Opvee (nalmefene)	
Opvee (nalmefene)	**Opvee (nalmefene) may be considered medically necessary when the following criteria are met:** • The individual is aged 12 years or older

Pharmacy Benefit Drugs	
Drug	**Medical Necessity**
	AND • Opvee is being used for the emergency treatment of known or suspected overdose induced by natural or synthetic opioid, as manifested by respiratory and/or central nervous system depression
Short-Acting Beta Agonists Step Therapy	
• **Airsupra (albuterol sulfate-budesonide)** • **Brand albuterol sulfate HFA** • **Brand levalbuterol tartrate HFA** • **ProAir RespiClick (albuterol sulfate)** • **Ventolin HFA (albuterol sulfate)** • **Xopenex HFA (levalbuterol tartrate)**	**Airsupra (albuterol sulfate-budesonide), brand albuterol sulfate HFA, brand levalbuterol tartrate HFA, ProAir RespiClick (albuterol sulfate), Ventolin HFA (albuterol sulfate), and Xopenex HFA (levalbuterol tartrate) may be considered medically necessary when the individual has tried and had an inadequate response or intolerance to generic albuterol sulfate HFA**

Quantity Limits	
Continuous Glucose Monitoring (CGM) Supplies	

• **Dexcom G6 Sensor**
• **Dexcom G6 Transmitter**
• **Dexcom G7 Sensor**
• **Freestyle Libre Sensor**
• **Freestyle Libre 2 Sensor**
• **Freestyle Libre 3 Sensor**
	Quantity:
	• Dexcom G6 Sensor
	  ○ 3 sensors per 30 days (10-day sensor)
	• Dexcom G6 Transmitter
	  ○ 1 transmitter per 90 days
	• Dexcom G7 Sensor
	  ○ 3 sensors per 30 days (10-day sensor)
	• Freestyle Libre Sensor
	  ○ 2 sensors per 28 days (14-day sensor)
	• Freestyle Libre 2 Sensor
	  ○ 2 sensors per 28 days (14-day sensor)
	• Freestyle Libre 3 Sensor
	  ○ 2 sensors per 28 days (14-day sensor)

Contraceptives	
Opill (norgestrel)	**Quantity:**

Quantity Limits	
	• 30 tablets per 30 days
Epinephrine Agents	
• **Auvi-Q auto-injector** • **Epinephrine auto-injector** • **EpiPen auto-injector** • **EpiPen Jr auto-injector** • **Neffy nasal spray** • **Symjepi syringe**	**Quantity:** • 4 auto-injectors/syringes/nasal spray devices per 30 days
Ketorolac	
Ketorolac 10 mg tablet	**Quantity:** • 20 tablets per 5 days. **Note:** Ketorolac tablets, a nonsteroidal anti-inflammatory drug (NSAID), are indicated for the short-term (up to 5 days in adults), management of moderately severe acute pain that requires analgesia at the opioid level and only as continuation treatment following IV or IM dosing of ketorolac, if necessary. The total combined duration of use of ketorolac should not exceed 5 days. **Quantities greater than 20 tablets per 5 days (40 mg per day) are considered not medically necessary.**
Santyl	
Santyl (collagenase)	**Quantity:** • 180 grams per 30 days. **Note:** 180 grams covers approximately one 3 x 3 inch (8 x 8 cm) wound when applying once daily for 30 days. **Quantities greater than 180 grams per 30 days will be covered at an additional 90 grams per 30 days for each additional 1.5 x 1.5 inch (4 x 4 cm) wound area being treated when applying once daily.** **For individuals being treated with twice daily administration of Santyl(collagenase) the covered quantity approved for wound area treated will be double the quantity listed above.**

Quantity Limits	
SARS-CoV-2 Inhibitors	
• **Lagevrio (molnupiravir capsules)** • **Paxlovid (nirmatrelvir tablets; ritonavir tablets)**	**Quantity:** • 1 treatment course every 90 days
Short-Acting Beta Agonists	
• **Airsupra (albuterol sulfate-budesonide)** • **Brand albuterol sulfate HFA** • **Generic albuterol sulfate HFA** • **Brand levalbuterol tartrate HFA** • **ProAir RespiClick (albuterol sulfate)** • **Ventolin HFA (albuterol sulfate)** • **Xopenex HFA (levalbuterol tartrate)**	**Quantity:** • 2 inhalers per 30 days
Ivermectin and Stromectol (ivermectin)	
• **Generic ivermectin** • **Stromectol (ivermectin)**	**Quantity:** • 20 tablets per 30 days
Xofluza	
Xofluza (baloxavir marboxil)	**Dosage:** • Single dose 2 mg/kg for individual body weight < 20 kg • Single dose of 40 mg (one 40 mg tablet or one bottle 40 mg/20 mL oral suspension) for individual body weight 20 kg to < 80 kg • Single dose of 80 mg (one 80 mg tablet or two bottles 40 mg/20 mL oral suspension) for individual body weight ≥ 80 kg **Doses greater than one 40 mg tablet per 30 days, one 80 mg tablet per 30 days, or two bottles 40 mg/20 mL oral suspension per 30 days are not supported by clinical evidence and therefore are considered not medically necessary.**

Pharmacy/Medical Benefit Drugs	
Drug	**Medical Necessity**
Interferons	
Actimmune (interferon gamma-1b) SC	**Actimmune (interferon gamma-1b) may be considered medically necessary for the following labeled indications:** • Reducing the frequency and severity of serious infections associated with Chronic Granulomatous Disease (CGD) **OR** • Delaying time to disease progression in individuals with severe, malignant osteopetrosis (SMO)

Medical Benefit Drugs	
Drug	**Medical Necessity**
Kappa Opioid Receptor (KOR) Agonist	

Korsuva (difelikefalin) IV	**Korsuva (difelikefalin) may be considered medically necessary for the treatment of pruritus associated with chronic kidney disease (CKD) when the following criteria are met:**
	• The individual is aged 18 years or older
	AND
	• Receiving hemodialysis
	AND
	• Has tried for at least 4 weeks and failed two of the following for the treatment of pruritus associated with CKD:
	  ○ Gabapentin
	  ○ Montelukast
	  ○ Oral Antihistamines (e.g., diphenhydramine, hydroxyzine)
	  ○ Phototherapy (UVA or UVB)
	  ○ Topical analgesics (e.g., capsaicin, pramoxine)
	
	Initial approval will be for 6 months.
	
	Reauthorization criteria:

Medical Benefit Drugs	
	• Continued therapy will be approved for 12 months as long as the medical necessity criteria are met, and chart notes document an improvement from baseline in pruritus.
Melanocortin 1 Receptor (MC1-R) Agonist	
Scenesse (afamelanotide) SC implant	**Scenesse(afamelanotide) may be considered medically necessary when the following criteria are met:** • The individual is aged 18 years or older and is diagnosed with erythropoietic protoporphyria (EPP) confirmed by elevated total erythrocyte protoporphyrin **AND** • Laboratory findings document measured metal-free protoporphyrin is 85% or greater of total erythrocyte protoporphyrin **AND** • Individual has documented symptoms of erythropoietic protoporphyria phototoxicity **Reauthorization criteria:** • Continued therapy will be approved for 12 months as long as the medical necessity criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy and has a full body skin exam every 6 months while on therapy. **Note**: Laboratory that is used for testing must measure total erythrocyte protoporphyrin and fractionate metal-free and zinc protoporphyrin
Testosterone Replacement Products	
Aveed (testosterone undecanoate) IM	**Aveed (testosterone undecanoate) may be considered medically necessary for individuals assigned male at birth OR individuals assigned female at birth for the treatment of gender dysphoria when the individual has tried and failed testosterone gel 1%, testosterone gel 1.62% (e.g., Androgel), OR testosterone gel 2% (e.g., Fortesta)**
Testopel (testosterone pellets) SC implant	**Testopel (testosterone pellets) may be considered medically necessary for individuals assigned male at birth OR individuals assigned female at birth for the treatment**

Medical Benefit Drugs	
	of gender dysphoria when the individual has tried and failed testosterone gel 1%, testosterone gel 1.62% (e.g., Androgel), OR testosterone gel 2% (e.g., Fortesta)

Drug	Investigational
As listed	Use of the drugs for conditions not listed in this policy are considered investigational. The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.

Drug	Not Medically Necessary
As listed	All other uses of the drugs for approved conditions listed in this policy are considered not medically necessary.

Length of Approval	
Approval	**Criteria**
Initial authorization	Non-formulary exception reviews for all drugs listed in the policy may be approved up to 12 months. All other reviews for all drugs listed in policy, unless noted otherwise for specific drugs under the medical necessity criteria, may be approved up to 12 months.
Re-authorization criteria	Non-formulary exception reviews for all drugs listed in the policy may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy. All other reviews for re-authorization of all drugs listed in policy, unless noted otherwise for specific drugs under the medical necessity criteria, may be approved up to 12 months as long as the drug-specific coverage criteria are met and chart

Length of Approval	
Approval	**Criteria**
	notes demonstrate that the individual continues to show a positive clinical response to therapy.

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

Code	Description
HCPCS	
C9164	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg) (code termed 03/18/2024)
C9399	Unclassified drugs or biologicals (Use to report Vafseo)
J0879	Injection, difelikefalin, (Korsuva) 0.1 microgram, (for ESRD on dialysis)
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)
J0901	Vadadustat, oral, 1 mg (for esrd on dialysis) (new code effective 01/01/2025)
J3145	Injection, testosterone undecanoate, (Aveed)1 mg
J3490	Unclassified drugs (used to report Ycanth)
J7352	Afamelanotide implant, 1 mg
J7353	Anacaulase-bcdb, 8.8% gel, 1 gram
J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (Ycanth) (3.2 mg) (new code effective 04/01/2024)
J7355	Injection, travoprost, intracameral implant, (iDose TR) 1 microgram (new code effective 07/01/2024)
J9216	Injection, interferon, gamma 1-b, 3 million units

Code	Description
S0189	Testosterone pellet, 75 mg

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

This policy applies to all pharmacy benefit contracts that include Pharmacy Prior Authorization Edits.

The Company's Pharmacy Prior Authorization program is a set of electronic "smart edits" designed to improve the quality of pharmacy care for our members and promote appropriate and cost-effective drug therapies.

The goals of this program are:

- To improve the quality of pharmacotherapy and its outcomes.
- To promote the appropriate and cost-effective use of medications.
- To ensure the appropriate length of drug therapy for each individual.

This policy briefly describes each edit and sets forth the clinical criteria upon which the computerized edit logic is based. The medications included in the Pharmacy Prior Authorization are listed within the **Index of Drugs** table at the beginning of the policy. Additional Prior Authorization drugs are contained in other medical policies (see **Related Guidelines/Policies**).

Benefit Application

This policy is managed through the pharmacy and medical benefit.

Evidence Review

Brand ADHD Agents

Stimulant drugs for ADHD fall into two categories: methylphenidate-based products and amphetamines. Within each category, pharmacokinetic profile is the primary differentiating characteristic. A wide variety of generic medications are currently available to meet the needs of most individuals.

Angiotensin II Receptor Blockers

All Angiotensin II Receptor Blockers (ARBs) are indicated for treatment of hypertension (HTN) as monotherapy or in combination with other anti-HTN agents. These agents have demonstrated efficacy comparable to angiotensin-converting enzyme inhibitors (ACEIs) in lowering diastolic (DBP) and systolic blood pressure (SBP) in randomized clinical trials. Studies comparing various ARBs to beta-blockers, diuretics and calcium channel blockers (CCBs) demonstrated comparable efficacy in lowering SBP and DBP. ARBs have favorable drug interaction and adverse reaction profiles compared to ACEIs. In general, there is no a priori reason to prefer one ARB over another.

Second Generation Antipsychotics (SGA)

Bipolar Depression

The other established medications for the treatment of bipolar depression are more problematic for the following reasons:

- Symbyax: The fixed dose combination makes dose adjustments difficult, and olanzapine metabolic side-effects are considerably more problematic than Latuda or Seroquel XR.
- Lithium: Multiple daily dosing needed, plus small window between therapeutic and toxic serum levels, plus more problematic side-effects, plus augmentation with an SGA antipsychotic is not infrequently needed.
- Lamotrigine: Multiple daily dosing needed, plus risk of SJ syndrome (and have to d/c with any rash, even if eventually not SJ syndrome), plus sub-optimal efficacy for acute depressive symptoms.
- Immediate-release quetiapine: Multiple daily dosing needed, plus more sedating than Latuda, plus XR formulation has a “smoother” clinical effect.

Parkinson’s Disease Psychosis

Psychotic symptoms in Parkinson's disease (PD) are relatively common and, in addition to creating a disturbance in individuals' daily lives, have consistently been shown to be associated with poor outcome. Our understanding of the pathophysiology of psychosis in PD has expanded dramatically over the past 15 years, from an initial interpretation of symptoms as dopaminergic drug adverse effects to the current view of a complex interplay of extrinsic and disease-related factors. PD psychosis has unique clinical features, namely that it arises within a context of a clear sensorium and retained insight, there is relative prominence of visual hallucinations and progression occurs over time. PD psychosis tends to emerge later in the disease course, and disease duration represents one risk factor for its development. The use of anti-PD medications (particularly dopamine receptor agonists) has been the most widely identified risk factor for PD psychosis. Other risk factors discussed in the literature include older age, disease severity, sleep disturbance, cognitive impairment, dementia and/or depression.

Traditionally, treatment begins with a search for correctable infectious, toxic, and metabolic etiologies. If symptoms persist, anti-Parkinson's disease medications are slowly reduced. However, withdrawal of these drugs usually worsens parkinsonism and is often not tolerated. Certain atypical antipsychotics can be used to treat psychosis without compromising motor function. The choice of atypical antipsychotic is largely based on ease of use and adverse effect profile as most have comparable efficacy in improving psychosis.

At the time of this update, Nuplazid is the first FDA-approved treatment for hallucinations and delusions associated with Parkinson’s disease psychosis.

Constipation

Linzess (linaclotide)

The efficacy and safety of Linzess (linaclotide) in irritable bowel syndrome with constipation (IBS-C) was established in one Phase IIb and two Phase III clinical trials. One additional Phase IIb and two Phase III trials evaluated linaclotide in chronic idiopathic constipation (CIC). In the Phase III clinical trials for IBS-C, for the first of four co-primary endpoints, a greater proportion of individuals treated with linaclotide 290mcg once daily compared to placebo achieved the US Food and Drug Administration (FDA)-recommended definition of response (33.6% and 33.7% for linaclotide vs. 21.0% and 13.9% for placebo, $p<0.0001$ for both). Linaclotide was also statistically

significantly superior to placebo for all three of the additional co-primary endpoints in both trials, as well as all pre-specified secondary endpoints in both trials. In the phase III clinical trials in CIC individuals, a greater proportion of individuals in the linaclotide 145mcg group vs. placebo achieved the primary endpoint of an increase of ≥ 1 complete spontaneous bowel movement (CSBM) from baseline and ≥ 3 CSBMs in ≥9/12 weeks in both trials (16.0% vs. 6.0%, p<0.01 for trial 01 and 21.2% vs. 3.3%, p<0.001 for trial 303). Linaclotide was statistically significantly superior to placebo for all pre-specified secondary endpoints in both trials.

The efficacy and safety of Linzess(linaclotide) was evaluated in 12-week, double-blind, randomized, placebo-controlled, multicenter trial were 328 pediatric individuals (6 to 17 years old) with functional constipation (FC) were randomized to receive treatment with Linzess72 mcg once daily or placebo once daily. The inclusion criteria required individuals to have modified Rome III criteria for child/adolescent FC criteria where individuals need to have less than 3 Spontaneous Bowel Movements (SBMs) per week. SBM is defined as a BM that occurs without any laxative, enema, or suppository usage on the calendar day of or before the BM. The primary efficacy of the Linzess treatment was the 12-week mean change from baseline in SBM frequency rate. At the end of week-12, the least squares 12-week mean change from baseline in SBM frequency rate in the treatment group was 2.6 compared to 1.3 in the placebo group, with treatment difference of 1.3[0.7,1.8].

Amitiza (lubiprostone)

The efficacy and safety of Amitiza (lubiprostone) was established in 2 double-blinded, placebo-controlled trials in individuals with chronic idiopathic constipation (CIC), comparing lubiprostone 24 mcg twice daily with placebo for 4 weeks. The primary endpoint was spontaneous bowel movement (SBM) frequency. Individuals treated with Amitiza had a higher frequency of SBMs during each week of therapy. Lubiprostone demonstrated increases in the % of individuals with SBMs in the first 24 hours (56.7% vs. 36.9% in Study 1 and 62.9% vs. 31.9% in Study 2). Time to first SBM was shorter with lubiprostone than placebo. Signs and symptoms related to constipation were also improved with lubiprostone versus placebo. The results were consistent in subpopulation analyses for gender, race, and elderly individuals (≥ 65 years of age). During a 7-week randomized withdrawal study, individuals who received lubiprostone during the treatment period were randomized to receive either placebo or to continue treatment with lubiprostone. In lubiprostone individuals randomized to placebo, SBM frequency rates returned toward baseline within 1 week and did not result in worsening compared to baseline. Individuals continued on lubiprostone maintained response to therapy over the additional 3 weeks of treatment.

The efficacy of lubiprostone in the treatment of opioid-induced constipation was assessed in three randomized, double-blinded, placebo-controlled studies. Individuals had been receiving stable opioid therapy for at least 30 days prior and continued during the 12-week treatment period. Baseline mean oral morphine equivalent daily doses (MEDDs) were 99 mg and 130 mg for placebo-treated and lubiprostone-treated individuals in Study 1, 237 mg and 265 mg in Study 2 and 330 mg and 373 mg in Study 3. The Brief Pain Inventory-Short Form (BPI-SF) was administered at baseline and monthly. In Study 1 "overall responders" were 27.1% in the lubiprostone group vs 18.9% with placebo (treatment difference = 8.2%; p-value = 0.03). Examination of gender and race subgroups did not identify differences in response to lubiprostone among these subgroups. In Study 2, overall response rates were 24.3% in the lubiprostone group and 15.4% with placebo. In Study 3, "overall responders" were 15.3% in the lubiprostone group vs 13.0% with placebo. Two double-blinded, placebo-controlled studies demonstrated similar results in women with IBS-C. Insufficient men were enrolled in this study.

Motegrity (prucalopride)

Motegrity (prucalopride) is a serotonin 5-HT_4 receptor agonist that leads to noncholinergic neurotransmission by enteric neurons leading to stimulation of the peristaltic reflex, intestinal secretions and gastrointestinal motility. The efficacy of prucalopride was established in six double-blind, placebo-controlled trials in 2484 adult individuals. For the primary efficacy endpoint, a responder was defined as an individual with an average of 3 or more complete, spontaneous bowel movements (CSBM). Across all six studies, the median time to first CSBM after dosing on day 1 ranged from 1.4 to 4.7 days compared with 9.1 to 20.6 days in the placebo group.

Trulance (plecanatide)

Trulance (plecanatide) is a peptide analog of uroguanylin, the endogenous agonist that binds and activates guanylate cyclase-C receptors expressed in the epithelial lining of the GI mucosa. It is indicated for the treatment of chronic idiopathic constipation. It is the first drug to successfully meet new, more stringent FDA criteria defining primary efficacy endpoints. The new criteria evaluate the durability of the response, requiring individuals to be complete spontaneous bowel movement responders in 3 of the last 4 treatment weeks in addition to 9 of the 12 weeks. The phase III trials showed that treatment groups were superior to placebo groups in both primary and secondary endpoints. There are no serious safety concerns with plecanatide, with the most common side effect being diarrhea. Due to the risk of dehydration, it is not recommended for

children less than 18 years old. There has been no comparative analysis or cost-effectiveness analysis done yet. Given the limited therapies specifically labeled for CIC, plecanatide provides another option for individuals with CIC.

Non-benzodiazepine Hypnotics Agents (Branded Single Source)

There are clear pharmacokinetic differences between zaleplon, zolpidem, eszopiclone, and benzodiazepines for the treatment of insomnia. Among the non-benzodiazepine agents, zolpidem seems to have optimal pharmacokinetics, and is, therefore, recommended as a preferred agent. Current evidence does not clearly demonstrate any advantage among zaleplon, eszopiclone, and zolpidem in efficacy.

Solodyn (minocycline HCl, USP)

Extended-release Solodyn tablets are available in eight strengths (45 mg, 55 mg, 65 mg, 80 mg, 90 mg, 105 mg, 115 mg, and 135 mg) for more precise weight-based dosing of Solodyn that narrows the actual dose ranges toward the target of 1 mg/kg/day for individuals with non-nodular, moderate to severe inflammatory acne 12 years and older weighing 99-300 lbs. In clinical trials of the 45 mg, 90 mg, and 135 mg strengths with 1,038 individuals, Solodyn demonstrated efficacy in a low dose (1 mg/kg/day). There was no evidence of improved efficacy with 2 mg/kg/day and 3 mg/kg/day.[5] Higher doses of Solodyn have not been shown to be of additional benefit in the treatment of inflammatory lesions of acne and may be associated with more acute vestibular adverse events. Clinical studies also showed that Solodyn tablets were well-tolerated, with an adverse event profile similar to placebo.

In a Phase II dose-response study of 233 subjects with the 45 mg, 90 mg, and 135 mg strengths, 1 mg/kg/day extended-release Solodyn tablets provided statistically significant inflammatory lesion reduction vs. placebo (n=114, 56.8% vs. 39.4%, p=0.015). In two Phase III clinical studies with the 45 mg, 90 mg, and 135 mg strengths, the mean percent improvement in inflammatory lesions was greater in individuals treated with Solodyn tablets than with placebo (Study 1, n=451, 43.1% vs. 31.7%, p=0.001; Study 2, n=473, 45.8% vs. 30.8%, p<0.001, respectively). There was no evidence of improved efficacy with 2 mg/kg/day and 3 mg/kg/day. No head-to-head data is reported. The manufacturers' trials are all unpublished and placebo-controlled, making it impossible to assess comparative effectiveness.

Adverse reactions reported in the clinical trials of Solodyn were not statistically different from placebo.[1] No comparative data versus other forms of minocycline or doxycycline were found. A

recent review article recommends doxycycline as a first-choice oral tetracycline for acne patients, due to the overall lower side effect profile.

Corlanor (ivabradine)

Corlanor (ivabradine) is the first in a new class of medications which block hyperpolarization-activated cyclic nucleotide-gated (HCN) channels. Selectively inhibiting if current in the sinoatrial node reduces the spontaneous pacemaker activity of the sinus node which results in heart rate reduction without affecting ventricular repolarization or contractility. It has been approved in Europe since 2005 to reduce heart failure hospitalizations in individuals with NYHA class II-IV heart failure who have an LVEF 35%, resting heart rate 70 bpm, and either have a contraindication to beta blockers or are on maximal tolerated therapy. The FDA approved it based on results from a randomized, double-blind, international trial. 6,558 individuals were randomized to receive ivabradine (n=3241) or placebo (n=3260). Over a median follow-up of 23 months, ivabradine resulted in a significant reduction in a composite of time for first HF hospitalization or CV death (24.5%) compared to placebo (28.7%), p<0.001). Ivabradine was associated with an improved HRQOL.

Xermelo (telotristat ethyl)

Xermelo (telotristat ethyl) is a novel, oral, tryptophan hydroxylase (TPH) inhibitor currently indicated for the symptomatic treatment of inadequately controlled carcinoid-induced diarrhea in combination with long-acting SSA therapy in adult individuals.[4] Unlike SSAs, which may slow tumor progression and provide relief of carcinoid-induced diarrhea and flushing,[5,6] evidence for the efficacy of telotristat ethyl is limited to the symptomatic relief of carcinoid-induced diarrhea and has not been studied in the context of disease progression.[1-3] In the pivotal phase III study,[1] treatment with telotristat ethyl 250 mg PO TID was associated with a small reduction in mean daily BMs compared to placebo (NS). Moreover, this finding is confounded by a lack of comparable key baseline characteristics (lower daily BM frequency for placebo than the telotristat ethyl 250 mg arm [p <0.05]) and unclear method of statistical analyses, which limits the interpretation of results. Results differed between the preplanned intention-to-treat (ITT) analysis (-1.43 BMs/day) and the post-hoc per-protocol analysis (-1.7 BMs/day); the latter was used to demonstrate the treatment benefit associated with telotristat ethyl 250 mg PO TID. In relation to safety, GI disorders were the most commonly reported AEs.[1-3] Currently, there is no real-world evidence for the comparative effectiveness of telotristat ethyl in individuals with inadequately treated carcinoid-induced diarrhea. As of March 2017, the National Comprehensive

Cancer Network (NCCN) guidelines for neuroendocrine tumors (NETs) recommend octreotide 150-250 µg SC TID or octreotide long-acting repeatable (LAR) 20-30 mg IM Q4W for symptom control of carcinoid-induced diarrhea, with an increase in dose and/or frequency as needed.[5]

Ingrezza (valbenazine) and Austedo (deutetrabenazine)

Ingrezza (valbenazine) is an FDA-approved VMAT2 inhibitor indicated for tardive dyskinesia (TD). The treatment landscape consists of strategies with either limited evidence to support or refute their efficacy, or with the magnitude of the risk outweighing the benefit.[1]

In one phase II (KINECT II) and one phase III (KINECT III) clinical trial, valbenazine (VBZ) demonstrated a reduction in the severity of tardive dyskinesia as shown by Abnormal Involuntary Movement Scale (AIMS) score.[2,3] These trials consistently demonstrated positive results, but it remains unclear what constitutes as a clinically significant change in the AIMS score.

In addition, although no conclusions on long-term efficacy can be drawn from the small, 6-week duration trials, a durable improvement in AIMS score was observed in a 48-week extension study. Furthermore, after VBZ was discontinued, the TD worsened. Both findings suggest long-term maintenance improvement in TD with VBZ.

KINECT II and KINECT III had similar safety profiles for VBZ, and the drug appears to be well-tolerated.[2,3] However, a movement disorder like TD is chronic and requires long-term management. Therefore, it is important to have a sufficient amount and duration of safety data. Until that data is available, VBZ should be utilized with caution.

The safety and efficacy of Ingrezza was evaluated in a randomized, double-blind, placebo-controlled trial where 128 individuals with chorea associated with Huntington's disease received either Ingrezza or placebo. The treatment duration was 12 weeks followed by a 2-week period off drug. Ingrezza achieved primary efficacy endpoint of improvement in total Maximal Chorea scores by 4.6 units compared to 1.4 units in the placebo group from baseline to the end of the treatment period. In a clinician-rated global impression of change (CGI-C), clinicals rated 43% of the patients treated with Ingrezza experienced "Much Improved" or "Very Much Improved" compared to 13% of patients treated with placebo. Similarly in a patient-rated global impression of change (PGI-C), 53% patients treated with Ingrezza experienced "Much Improved" or "Very Much Improved" compared to 26% of the patients treated with placebo.

Austedo (deutetrabenazine) is an FDA-approved VMAT2 inhibitor indicated for tardive dyskinesia and chorea associated with Huntington's disease. The efficacy of Austedo in the

treatment of chorea associated with Huntington's disease was established primarily in study 1, a randomized, double-blind, placebo-controlled, trial in 90 individuals with Huntington's disease. The primary efficacy endpoint was the Total Maximal Chorea score. Total Maximal Chorea scores for individuals receiving Austedo improved approximately 4.4 units from baseline, compared to 1.9 units in the placebo group. The efficacy of Austedo in the treatment of tardive dyskinesia was established in two, 12-week, randomized, double-blind, placebo-controlled trials in 335 individuals with tardive dyskinesia caused by dopamine receptor antagonists. The Abnormal Involuntary Movement Scale (AIMS) was the primary efficacy measure. AIMS score showed statistically significant improvement of 3.2-3.3 units compared to 1.4 units in placebo.

Korsuva (difelikefalin)

Korsuva (difelikefalin) is the first and only FDA-approved treatment for moderate to severe pruritus associated with chronic kidney disease in adults undergoing hemodialysis. It is the first-in-class kappa opioid receptor agonist that targets the body's peripheral nervous system. There were 2 phase III trials. Both phase III studies used the same primary endpoint (percent of individuals who demonstrated at least 3 points deductions from baseline on Worst Itch Numeric Rating Scale (WI-NRS) score) to access itch in moderate-to-severe pruritis individuals who undergo hemodialysis. At week 12, 21.2% more of individuals who received difelikefalin treatment showed ≥3 points decrease from baseline on the WI-NRS compared to the placebo group, which indicates moderate improvement in the pruritus intensity. Difelikefalin has improved pruritus associated quality of life, measured by 5D itch scale (5.0 points deduction from baseline) and Skindex-10 scores (17.2 points deduction from baseline after treatment). The most common adverse events include diarrhea, dizziness, nausea, gait disturbances (falls), hyperkalemia, headache, somnolence, and mental status changes.

Veozah (fezolinetant)

Veozah (Fezolinetant) is a neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. The safety and efficacy of Veozah for the treatment of moderate to severe vasomotor symptoms due to menopause was evaluated in the first 12-week portion of two phase 3, randomized, placebo-controlled, double-blind clinical trials. Subsequently, woman who were initially on the placebo were re-randomized to receive Veozah for 40-week extension study.

A total of 1022 women (522 in Trial 1 and 500 in Trial 2) with a minimum average of 7 moderate to severe vasomotor symptoms per day were randomized to receive either one of two doses of Fezolinetant or placebo. The primary efficacy endpoint was the mean change in the frequency and severity of the moderate to severe vasomotor symptoms at week 4 and 12, compared to baseline.

Results showed a statistically significant reduction in the frequency and severity of moderate to severe vasomotor symptoms from baseline at both week 4 and 12. At week 4 and week 12, the moderate to severe vasomotor symptoms reduced statically significant (P-value < 0.001) from baseline. Similarly at week 4 and week 12, the severity of the moderate to severe vasomotor symptoms reduced statistically significantly (P-value = 0.002 for week 4 and P-value = 0.007 for week 12). The most common adverse reactions during the Veozah trials included abdominal pain, diarrhea, insomnia, back pain, hot flush, and hepatic transaminase elevation.

Zylet (loteprednol etabonate and tobramycin ophthalmic suspension)

Zylet is a combination of a corticosteroid (loteprednol etabonate) and an aminoglycoside antibacterial (tobramycin). It is indicated for steroid -responsive inflammatory ocular conditions where the corticosteroid is indicated, and superficial bacterial ocular infection or a risk of bacterial ocular infection exists. The recommended dose of Zylet is one to two drops into the conjunctival sac of the affected eye every four to six hours.

The most common adverse effects were injection and superficial punctate keratitis, increased intraocular pressure, burning and stinging.

Opvee (nalmefene)

Opvee is an opioid antagonist which is indicated for the emergency treatment of known or suspected natural or synthetic opioid overdose in adults and pediatric individuals 12 years and older, as manifested by respiratory and/or central nervous system depression.

Jesduvroq (daprodustat)

Jesduvroq is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor which is indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. Jesduvroq is not indicated for patients who are not on dialysis,

and Jesduvroq is not a substitute for red blood cell transfusion when patients need immediate correction of anemia. Jesduvroq has not shown to improve quality of life, fatigue, or patient well-being. Prior to starting daprodustat, it is necessary to exclude other causes of anemia, including but not limited to vitamin deficiency, metabolic or chronic inflammatory conditions. Individuals also need to be tested for serum alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase, and total bilirubin prior to starting the treatment. The treatment with Jesduvroq should be started at the lowest dose possible to reduce the need for red blood cell transfusions. Jesduvroq is contraindicated in patients receiving strong CYP2C8 inhibitors, such as gemfibrozil or in patients with uncontrolled hypertension.

Daprodustat works by reversible inhibition of HIF-PH1, PH2, and PH3, which results in stabilization and nuclear accumulation of HIF- 1 alpha and HIF- 2 alpha transcription factors. This leads to increased levels of HIF-responsive genes (e.g., erythropoietin) transcription.

The efficacy and safety of Jesduvroq was evaluated in a randomized, active-controlled, multicenter, sponsor-blind trial where 2,964 adults with anemia due to CKD on dialysis were stratified by the dialysis type. Individuals on hemodialysis (HD) were randomized 1:1 to receive either oral Jesduvroq (n = 1316) or IV epoetin alfa (n = 1308), while individuals on peritoneal dialysis (PD) were randomized 1:1 to receive oral Jesduvroq (n = 171) or SQ darbepoetin alfa (n = 169). The primary efficacy endpoint was the mean change in hemoglobin from baseline to weeks 28 to 52 (evaluation period) and time to first adjudicated MACE comparing to rhEPO (epoetin alfa and darbepoetin alfa).

At the end of the evaluation period, the treatment with Jesduvroq demonstrated non-inferiority of Jesduvroq to rhEPO for the mean change in hemoglobin between baseline and over the evaluation period, and on MACE criteria.

The most common adverse events are hypertension, thrombotic vascular events (including major adverse cardiovascular events), and abdominal pain.

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36. Xelstrym (dextroamphetamine) [Package Insert]. Miami, FL; Noven Pharmaceuticals, Inc. Revised October 2023.
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38. Opvee (nalmefene) [Package Insert]. North Chesterfield, VA; Indivior Inc. Revised June 2023.
39. Jesduvroq (daprodustat) [Package Insert]. Durham, NC; GlaxoSmithKline. Revised August 2023.
40. Motpoly XR (lacosamide) [Package Insert]. Piscataway, NJ; Aucta Pharmaceuticals, Inc. Revised June 2024.
41. Fragmin (dalteparin) [Package Insert]. New York, NY; Pfizer, Inc. Revised October 2024.
42. Lovenox (enoxaparin) [Package Insert]. Bridgewater, NJ; Sanofi-Aventis. Revised December 2021.
43. Xdemvy (lotilaner) [Package Insert]. Irvine, CA; Tarsus Pharmaceuticals. Revised July 2023.
44. Vafseo (vadadustat) [Package Insert]. Cambridge, MA; Akebia Therapeutics, Inc. Revised March 2024.
45. Libervant (diazepam) [Package Insert]. Warren, NJ; Aquestive Therapeutics, Inc. Revised April 2024.
46. Restasis (cyclosporine) [Package Insert]. Irvine, CA. Allergan. Revised September 2024.

History

Date	Comments
12/13/05	Add to Prescription Drug Section - New Policy—effective January 1, 2006.
08/08/06	Replace Policy - Policy reviewed with literature search by Pharmacy and Therapeutic Committee on July 25, 2006. Policy statement updated with exenatide and thiazolindinediones added as medically necessary; Policy Guidelines and Rationale sections updated; references added.
05/08/07	Replace Policy - Policy statement for exenatide updated with additional criteria; Policy Guidelines updated to reflect addition to policy statement. Reviewed by P&T on March 27, 2007.
06/12/07	Replace Policy - Policy statement on coverage criteria for exenatide (Byetta), sitagliptin and esomeprazole (Nexium) expanded; medically necessary indications for 5HTR3R

Date	Comments
	antagonists, Actiq and Fentora added to policy statement. Policy Guidelines updated and Rationale updated; references added
12/11/07	Replace Policy - Policy reviewed with literature search by Pharmacy and Therapeutic Committee on May 15, 2007.Policy statement updated to include Pregabalin as either medically necessary or investigational under the criteria. Acyclovir, famciclovir and valacyclovir as medically necessary under criteria. References added.
04/08/08	Replace Policy - Policy updated with literature search by Pharmacy. The policy statement was updated to include fibromyalgia as a medically necessary indication under Pregabalin. References added.
12/16/08	Replace Policy - Policy updated with literature search by Pharmacy. Policy statement updated to include the use of leukotrience modifiers for the treatment of allergic rhinitis refractory to nasal corticosteroids under the medically necessary indication.
02/10/09	Replace Policy - Policy updated with literature search by Pharmacy. Policy statement updated to delete medically necessary and investigational statements relating to Pregabalin. Pregabalin statements moved to PR.5.01.521
07/14/09	Replace Policy - Policy updated with literature search by Pharmacy. Policy statement updated with addition of Nuvigil. Reference added
02/09/10	Replace Policy - Policy updated with literature search by Pharmacy. No change to the policy statement. Policy guidelines section updated.
03/09/10	Replace Policy - Policy updated with literature search. Policy statement updated with medically necessary indications for provigil and nuvigil when all criteria are met. New diabetes drugs also added to medically necessary statement. References added.
04/13/10	Replace Policy - Policy updated with literature search. Policy statement updated with medically necessary indication added for Leukotriene modifiers. References added.
06/08/10	Replace Policy - Policy updated with literature search. Pantoprazole added to policy guidelines. Reference added.
08/10/10	Replace Policy - Policy updated with the addition of 300mcg strength to Fentora Buccals (new strength available) in policy guideline; bolding of the beginning of paragraph in policy guidelines for antivirals; and the addition of HAS in sentence for leukotriences in policy guidelines, and a paragraph formatting in rationale/source.
02/08/11	Replace Policy - Reference to COX II inhibitors and transmucosal fentanyl citrate removed from the Policy statements and entirety of the policy and are now discussed in 5.01.529. References removed.
06/13/11	Replace Policy - Policy updated based on review by P&T May 2011. List of point-of-sale program drugs updated; antiemetics removed from the list and the medically necessary policy statement has been removed from the Policy section. The medically necessary policy statement on non-benzodiazepine hypnotic drugs has been updated to include zaleplon as one of the agents required for failed trial; Rationale updated. Phased-in additional changes are: August - Solodyn (extended-release minocycline)

Date	Comments
	considered medically necessary for the treatment of inflammatory lesions of acne following a failed trial of any generic tetracycline product, e.g., doxycycline or minocycline; September - Nonpreferred atypical antipsychotics considered medically necessary for labeled indications following failed trial of a preferred atypical antipsychotic agent AND orally-administered brand Bisphosphonate products considered medically necessary for treatment of osteoporosis following a failed a trial of generic alendronate; October - Nonpreferred ARBs considered medically necessary for the treatment of cardiovascular disease and diabetes following failed trial of a preferred ARB. Policy Guidelines updated for the October phase indicating preferred ARB allowable for patients unable to tolerate nonpreferred ARBs.
08/01/11	Replace Policy - Preapproved edits for August implementation added to policy; policy published.
09/10/11	Replace Policy – Preapproved edits for September implementation added to policy: September - Nonpreferred atypical antipsychotics considered medically necessary for labeled indications following failed trial of a preferred atypical antipsychotic agent AND orally-administered brand Bisphosphonate products considered medically necessary for treatment of osteoporosis following a failed a trial of generic alendronate.
09/07/11	Replace Policy – Policy updated and published with final changes, originally scheduled for October. The changes are as follows and carry the effective date of 9/7/11: Nonpreferred ARBs considered medically necessary for the treatment of cardiovascular disease and diabetes following failed trial of a preferred ARB; Policy Guidelines updated for the October phase indicating preferred ARB allowable for patients unable to tolerate nonpreferred ARBs. Description section updated: Atelvia (risendronate sodium delayed release) added to the list of biophosphates included in the Pharmacy Point-of-Sale program.
02/27/12	Replace policy. Policy updated with an additional policy statement indicating brand ophthalmic prostaglandin analogs as medically necessary to reduce intraocular pressure in patients with glaucoma when the patient has failed trial of generic latanoprost. Sitagliptin and simvastatin (Juvisync) added to the approved medically necessary medications to treat type 2 diabetes within the category of incretin mimetics or DPP4 inhibitors. Edarbi added to the list of ARBs approved for medically necessary treatment of CV and diabetes. Reviewed by P&T on January 24, 2012.
03/30/12	Minor update, Valtuma (aliskiren/valsartan) no longer covered by this policy; it was removed.
04/10/12	Replace policy. Policy updated with a new medically necessary policy statement for Intranasal brand corticosteroid products (e.g., Beconase AQ, Nasonex, Rhinocort Aqua, Omnaris, Veramyst) for allergic rhinitis when the patient has failed a trial of at least one generic intranasal corticosteroid. Newly approved brand and POS drugs added to policy.

Date	Comments
05/08/12	Qnasl was added to the list of intranasal steroids within the Policy section. Statins were removed from the policy.
05/30/12	Minor update: irbesartan and irbesartan/HCT added to the list of nonpreferred angiotensin II receptor blockers approved as medically necessary when a preferred medication has failed; and lansoprazole added to the list of proton pump inhibits approved as medically necessary for treatment of acid peptic diseases.
07/31/12	Minor update. Two updates were made to the Policy Guidelines: 1. an additional bullet point under the limitations of coverage for modafinil (Provigil) or armodafinil (Nuvigil) was added, indicating ttherapy with Nuvigil will be approved ONLY when the prescriber has documented an adverse reaction or intolerance to generic modafinil or Provigil; 2. clarification was added to the paragraph on non-benzodiazepines hypnotic agents (branded single source), pointing out zolpidem or zaleplon as examples of generic agents requiring a trial failure for approval. These edits are effective as of 8/1/12 for prior authorization and were approved by P&T May 2012.
10/09/12	Replace Policy – Policy section revised, Abilify has been added with 2 medically necessary statements; There is now a double-step edit requiring the use of metformin unless contraindicated; the use of any two generics or a generic and an insulin must be tried.
11/26/12	Update Related Policies. Add 5.01.529.
03/11/13	Replace policy. Policy updated with the following: 1) Brand non-insulin agents for the treatment of type 2 diabetes and TZD's combined – remove THIAZOLIDINEDIONES (TZD) language, and slight change in the Brand non-insulin products language. (There will be one Diabetic Agent Policy); Second generation antipsychotics (SGA) - Paragraph added to further clarify the SGA prior authorization criteria; Bisphosphonates - Addition of new medication, BINOSTO and remove BONIVA; Angiotensin receptor blockers - move DIOVAN HCT from preferred to non-preferred list and addition of 2 new generics to preferred list; Proton Pump Inhibitors – increase the number of failed trials to at least two of the listed medications before this class of drug would be approved for medical necessity in treating GERD, esophagitis or ulcer. 2) Policy updated with medically necessary indications for Abilify, with or without the failure of a generic SGA, removing criteria of the need for a legitimate medical reason to avoid the potential weight gain or metabolic effects of other SGAs and for concern about potential QT prolongation with ziprasidone: psychotic disorder or psychotic symptoms, Schizoaffective Disorder, Bipolar Disorders, disorders with subtle psychotic thinking (eating disorders, Post Traumatic Stress Disorder, personality disorders), severe agitation or Autism or Autism Spectrum Disorders, augmentation of antidepressant medication for depressive disorders when at least two antidepressants medications have failed, for the augmentation of an anxiolytic for Generalized Anxiety Disorder when at least two anxiolytic medications have failed and at least one of which is or was an SSRI, and for the augmentation of medication for Obsessive Compulsive Disorder when there have been at least two failed trials of medications for OCD.

Date	Comments
03/15/13	Replace policy. Added ibrandronate to the Bisphosphonates within the Policy section; removed text in Brand Non-Insulin Agents within the Description.
04/11/13	Minor update. Clarification made in Description section; brand SGAs bullet now preceded by "including but not limited to..."
05/13/13	Replace policy. Policy updated with two new policy statements: 1) Non-Preferred Combination Beta-2 Agonist / Corticosteroid Inhalers; Advair Diskus (fluticasone propionate / salmeterol) and Advair HFA (fluticasone propionate / salmeterol) may be considered medically necessary after the trial and failure of at least one Preferred Combination Beta-2 Agonist/Corticosteroid Inhalers (these have been defined); 2) Nonpreferred Testosterone Replacement agents (examples provided) may be considered medically necessary when the patient has failed a trial of the preferred agent, Androgel (testosterone gel). Policy Guidelines section updated with coverage criteria of newly added agents, which have also been listed in the Description section.
06/14/13	Update Related Policies. Add 11.01.504.
07/08/13	Replace policy. Policy section updated with Breo Ellipta (fluticasone furoate/ vilanterol) as an added product to the list of non-preferred combination beta-2 agonist/corticosteroid inhalers approved following trial and failure of at least on preferred product. Clarification was added to the policy that it is managed through the member's pharmacy benefit; this is now listed in the header and within the coding section.
08/12/13	Replace policy. Policy updated with the addition of Crofelemer as medically necessary for symptomatic relief of non-infectious diarrhea in adult patients with HIV/AIDS. The leukotriene modifier edit has been removed from the Policy section, as Singular went generic. The policy statement for brand ADHD drugs has been updated to indicate all brand ADHD drugs are subject to review and may be approved when a generic has failed, is not available, or is inappropriate as outlined. Travoprost is now added to the list of generics which must be tried and failed for a patient to qualify for coverage for brand ophthalmic prostaglandin analogs. Policy section reorganized for clarification with a table added to outline specifically those medications addressed in this policy which are subject to the Company's Pharmacy Prior Authorization program.
09/09/13	Replace policy. Xyrem added to Policy section with a medically necessary indication for treating narcolepsy when diagnosed through a sleep study. Rational section updated in support of this addition.
10/14/13	Replace policy. Policy section updated with addition of Homozygous Familial Hypercholesterolemia Agents Mipomersen (Kynamro) and lomitapide (Juxtapid), considered medically necessary as adjunctive therapy to lower low-density cholesterol (LDL), apolipoprotein B, total cholesterol and non-HDL cholesterol. The Policy Guidelines section has also been updated. Change title to policy 2.01.503.
12/04/13	Replace policy. Policy updated with medical necessity criteria for brand stimulant and brand non-stimulant ADHD drugs; Seroquel XR (quetiapine fumarate) added as medically necessary in the treatment of depressive disorders when criteria are met; and

Date	Comments
	Latuda (lurasidone HCL) and Seroquel XR (quetiapine fumarate) added as medically necessary to treat bi-polar disorder. Rationale section updated.
03/10/14	Annual review. Policy section updated to reflect expansion of brand stimulants and non-stimulants, previously only addressing ADHD, to now include other psychiatric conditions.
04/14/14	Interim review. Policy updated with the addition of Abilify (aripiprazole) as medically necessary for the augmentation of medication for OCD (without trial and failure of at least one generic SGA) when criteria are met; Versacloz (clozapine) Oral solution as medically necessary for Schizoaffective Disorder and bipolar disorder when trial and failure criteria are met; and Versacloz (clozapine) Oral solution as medically necessary for patients who require a liquid formulation instead of a pill.
05/12/14	Interim review. Policy updated with the addition of a new drug, Hetlioz, now included in the hypnotics category; Lunesta was removed from this same category, as it is now available generically. Eszopiclone has been added as a qualifier for coverage of a brand name hypnotic drug.
06/19/14	Update Related Policies. Add 5.01.552.
08/11/14	Interim review. Testosterone gel, Vogelxo added to the list of medically necessary agents for testosterone replacement therapy; Amitiza Linzess added to treat constipation; treatment of Cushing's removed (addressed in another policy). References 50 – 56 added.
09/08/14	Interim review. Jardiance added to the list of approved drugs within the category of non-insulin antidiabetic agents, brands as listed on the drug class table. A policy statement was added to indicate that the use of two or more branded non-stimulant medications for ADHD or other psychiatric conditions is considered to be not medically necessary. Another policy statement was added to clarify that the simultaneous use of two or more stimulant medications for ADHD or other psychiatric conditions is considered to be not medically necessary except when a short-acting stimulant is used to provide coverage for an additional few hours after a long-acting stimulant wears off.
10/13/14	Interim update. Removed all multisource brand medications as this policy will now only target SSB medications. Also cleaned up the formatting for superscript so that all were the same.
11/10/14	Interim update. Policy section updated with the addition of a medically necessary statement for nitrogen scavenging agents
12/08/14	Interim update. Additional drugs added to the Non-Insulin Antidiabetic Agents, brands section of the Policy section.
12/22/14	Interim update. Belsomra added to the list of non-benzodiazepine hypnotic brand drugs. Approved by P&T November 2014. Related Policy 11.01.504 updated; it is renumbered to 6.01.522.

Date	Comments
01/28/15	Annual review. Policy updated with the addition of 2 proton pump medications to support recent edits: Aciphex and Zegerid.
02/10/15	Minor update. Policy converted to UM Guideline. Modafinil: criterion removed requiring trial of two or more standard antidepressant medications that need to be stopped due to triggering or worsening hypomania or mania as related to fatigue and/or sleepiness.
03/10/15	Annual review. Updated criteria for ARB and PPI and added some additional language to the ADHD guidelines. Drugs that will no longer require a PA review removed from the policy.
04/14/15	Interim update. Natesto added to the list of Testosterone therapy agents. A not medically necessary policy statement for branded non-stimulants for psychiatric conditions for which there is no credible published scientific evidence of efficacy or effectiveness.
05/27/15	Interim Update. Added verbiage about additional formulary alternative needing to be tried for MSB medications and removed requirement for MedWatch form for both MSB and DAW reviews. Dosage information on Xyrem added.
06/09/15	Interim update. Policy updated with a new ADHD drug, Aptension XR; criteria added for Vyvanse regarding drug abuse or dependence. Removed Intuniv and criteria for Fulyzaq since the PA is being removed.
07/14/15	Interim update. Glyxambi added to miscellaneous brand anti-diabetics; Fulyzaq removed to align with PA edit removal; Xalatan removed and bimtoprost added to the qualifier list for ophthalmic prostaglandin analogs.
09/14/15	Interim update. Added new strength of Ritalin LA (60 mg); added Rexulti (new drug). Removed the following, edit retired: Advair/Breo Ellipta, Abilify and PPI's.
10/13/15	Interim Update. Update step table: Removed - line in table for diabetic medication combination products that include metformin; Provigil and modafinil from drug target table, criteria information for modafinil and Provigil as they are no longer requiring prior authorization; Updated – criteria section for Nuvigil to add indication for Shift Work Sleep Disorder as being covered with prior trial of modafinil or Provigil, indications for sleep apnea, narcolepsy and idiopathic hypersomnia to require prior trial of modafinil or Provigil; depression criteria to include requirement of trial of modafinil or Provigil; Added – Sentence to indicate all other used of Nuvigil other than those called out in the policy will be considered investigational.
11/10/15	Interim Update. Removed indication of Type 2 diabetes from the Non-Insulin Antidiabetic Agents criteria.
02/18/16	Annual Review. Policy updated with edits effective March 1, 2016 – ADHD: Strattera removed, Vyvanse added coverage for Binge Eating Disorder; Brand SGA: removed diagnosis requirement, added requirement of generic apiprzaole for Rexulti only; Constipation: removed OTC trial from Linzess, added OIC diagnosis for Amitizia and criteria for Movantik; Heart Failure: added criteria for Corlanor and Entresto; Non-

Date	Comments
	Insulin Antidiabetic, removed diagnosis requirement of DSM Type 2; NSAIDs and Combinations: added Criteria for Cambia, Duexis and Vimovo.
04/01/16	Minor update, approved March 8, 2016. DyanavelXR added to the list of ADHD brand drugs.
05/01/16	Minor update to policy, approved April 12, 2016. The following medications have been added: Adzenys XR-ODT, Quillichew ER, Ticanase, Aloglipton-Pioglitazone, generic testosterone to preferred agents for Testosterone Replacement Products. The following drugs were removed: Invega, Intermezzo, and Nasonex.
06/01/16	Minor update, approved May 10, 2016. Clarification on the criteria for Entresto.
07/01/16	Interim Update, approved June 14, 2016. Addition of a new agent, Nuplazid and its criteria to the policy (PA to label). Description section was also updated to include a summary of Parkinson's Disease Psychosis. Removal of Nuvigil from the policy due to a generic release.
09/01/16	Interim Update, approved August 9, 2016. Ticaspray added to the list of brand nasal corticosteroids.
10/01/16	Interim Update, approved September 13, 2016. Removal of the diabetes criteria (please see "Pharmacotherapy of Type I and Type II Diabetes Mellitus" policy for a set of new criteria).
11/01/16	Interim review, approved October 11, 2016. Insulin criteria put back in the policy due to staggered Prior-Authorization (PA) roll out. Will be in place until 1/1/17 when all Lines of Business are switched over to the same PA edit, then please refer to policy #5.01.569. Language change for hypnotic agents.
12/01/16	Interim review, approved November 8, 2016. Due to Benicar and Benicar/HCT going generic, removed drug names from the brand ARB criteria.
01/01/17	Interim review, approved December 13, 2016. Due to Seroquel XR going generic, removed drug name from the brand second generation anti-psychotic criteria.
03/01/17	Annual review, approved February 14, 2017. Removed travoprost from alternatives for brand-name ophthalmic drops due to drug no longer being available on the market.
03/15/17	Interim review, approved February 15, 2017. Added a new agent to the policy – Emflaza (deflazacort) – considered medically necessary to treat Duchenne Muscular Dystrophy (DMD) in patients 5 years of age and older, per labeled indication. Policy effective date will be March 15, 2017.
04/01/17	Interim review, approved March 14, 2017. Removed Focalin XR from the list of drugs requiring a prior authorization; added chart notes requirement for Vimovo, Duexis, and Cambia; updated criteria for deflazacort.
06/01/17	Interim Review, approved May 16, 2017. Policy moved into a new format. Updated coverage criteria for Entresto.

Date	Comments
07/01/17	Interim Review, approved June 22, 2017. Removed criteria for non-insulin diabetic drugs. Added criteria for: Xyrosa, Minolira, Livalo, Trulance, and Xermelo. Added summary statements for Livalo, Trulance, and Xermelo.
08/01/17	Interim Review, approved July 25, 2017. Update ADHD drugs (add Mydayis); update reauthorization criteria for Xyrem.
09/01/17	Interim Review, approved August 22, 2017. Added the drug Zypitamag and Updated ADHD drugs (add Cotempla XR-ODT).
09/15/17	Interim Review, approved September 12, 2017, effective September 15, 2017. Added Flolipid and Nikita, added brand oral acne products, updated Solodyn, Xyrosa, & Minolara criteria, added Ingrezza & Austedo, added Carospir.
11/01/17	Interim Review, approved October 3, 2017. Updated oral acne antibiotics criteria and updated brand testosterone products criteria.
12/01/17	Interim Update, approved November 9, 2017. Added criteria for Ximino.
01/01/18	Interim Update, approved December 6, 2017. Added statement that Entresto is considered investigational in pediatric patients (under age 18). Added Abilify MyCite and Vyzulta. Removed 2.01.503 from Related Policies as it was archived
03/01/18	Interim Review, approved February 27, 2018. Added Adzenys ER under the Individual Agent column for the drug class of ADHD Drugs, brands. Criteria for Xyrem was updated. Criteria for Trulance and Movantik were updated due to FDA label expansions.
05/01/18	Annual Review, approved April 17, 2018. Added criteria for Rhopressa and Xepi. Added note that this policy has been updated and included link to policy that becomes effective August 3, 2018.
07/01/18	Interim Review, approved June 22, 2018. Added criteria for nonpreferred diabetic test strips. Revised reauthorization criteria for Emflaza for clarity. Step therapies for Amitiza, Linzess, Movantik, and Trulance were added for various indications. Number of step agents for hypnotics and intranasal corticosteroids were changed.
08/01/18	Interim Review, approved July 13, 2018. Added criteria for Lucemyra and Xifaxan. Minor change was made to include the generics of branded oral antibiotics. References added.
08/03/18	Criteria for Testopel becomes effective, added HCPCS S0189.
09/01/18	Interim Review, approved August 23, 2018. Added criteria for brand topical corticosteroids, brand topical acne products, brand gabapentin products, additional brands of ADHD drugs and Nuedexta for pseudobulbar affect.
09/12/18	Interim Review, approved September 11, 2018. Added specific criteria for Differin/adapalene, Added brand acne products: Finacea, Clindamycin-Benzoyl Peroxide, Clindamycin Phosphate, Tazorac, and Avage. Added brand topical corticosteroid: Pediaderm HC.

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11/01/18	Interim Review, approved October 9, 2018. Added Brand Single-Source Oral NSAIDs, Epidiolex (cannabidiol), Jynarque (tolvaptan), Orilissa (elagolix), Minolira ER, and Qbrexza (glycopyrronium cloth). Added statin intolerance criteria. Clarified Cambia, Vimovo, and Duexis criteria. Added Plixda to adapalene products. Added step therapy criteria for Xifaxan in SIBO.
12/01/18	Interim Review, approved November 21, 2018. Updated criteria for Horizant, and Orilissa. Added pediatric indication for Xyrem (age 7 & older). Added Xyosted to testosterone brands list and removed branded generic testosterone gels.
02/01/19	Interim Review, approved January 8, 2019. Added criteria for Diacomit (stiripentol) and quantity limit for Xofluza (baloxavir marboxil). Updated criteria for Xifaxan, brand topical acne and rosacea products and adapalene products. Added Jornay PM to ADHD drugs, Seysara to brand oral antibiotics, Bryhali and Lexette to brand topical corticosteroids and Xelpros to ophthalmic prostaglandin analogues.
03/01/19	Interim Review, approved February 25, 2019. Updated criteria for Livalo, Nikita and Zypitamag. Updated criteria for nonpreferred testosterone replacement agents and Testopel.
04/01/19	Annual Review, approved March 12, 2019. Under constipation added Motegrity (prucalopride) and under rifamycin antibiotics added Aemcolo (rifamycin). Added references 40 and 41.
06/01/19	Interim Review, approved May 23, 2019. Added criteria for Rocklatan (netarsudil and latanoprost). Moved Xyrem (sodium oxybate) to policy 5.01.599 Pharmacologic Treatment of Sleep Disorders.
07/01/19	Interim Review, approved June 11, 2019. Added criteria for Inbrija (levodopa inhalation powder) and criteria for Xenazine (tetrabenazine). Added Duobrii (halobetasol propionate and tazarotene) to Corticosteroids, Topical Brand.
08/01/19	Interim Review, approved July 9, 2019. Added criteria for Vraylar (cariprazine). Updated criteria for Emflaza (deflazacort). Updated criteria for nonpreferred diabetic test strips. Removed Neuraptin (gabapentin) since not an FDA approved drug.
09/01/19	Interim Review, approved August 22, 2019. Added criteria for Ezallor Sprinkle (rosuvastatin) and Altreno (tretinoin).
10/01/19	Interim Review, approved September 10, 2019. Added generic ramelteon as qualifier to non-benzodiazepine hypnotic agents (branded single source). Added Zelnorm (tegaserod) to Constipation drugs. Added Banzel (rufinamide) to Anticonvulsant drugs. Added generic cinacalcet and Sensipar (cinacalcet) to Calcimimetics. Added Cresemba (isavuconazonium) to Antifungals. Added Nityr (nitisinone) and Orfadin (nitisinone) to Inherited Metabolic Disorders. Added generic penicillamine, Cuprimine (penicillamine) and Depen (penicillamine) to Chelating Agents. Added criteria for Pulmozyme (dornase alfa) to policy. Added criteria for Samsca (tolvaptan) to policy. Added Sirturo (bedaquiline) to Antitubercular Agents. Added Xiidra (lifitegrast ophthalmic solution)

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	to Dry Eye Treatment. Moved Ravicti (glycerol phenylbutyrate) to policy 5.01.611 Pharmacologic Treatment of Urea Cycle Disorders.
12/01/19	Interim Review, approved November 12, 2019. Added Cequa (cyclosporine ophthalmic solution) to Dry Eye Treatment. Added Nourianz (istradefylline) to Parkinson's Disease Agents. Added Accrufer (ferric maltol) to Iron Replacement Products. Under Inherited Metabolic Disorders added generic nitisinone and updated criteria for Nityr (nitisinone) and Orfadin (nitisinone). Added Adhansia XR to ADHD drugs.
02/01/20	Interim Review, approved January 14, 2020. Added Aklief (trifarotene) to brand topical acne/rosacea agents, Dayvigo (lemborexant) to hypnotics and travoprost as step therapy option for brand prostaglandin analogs. Added criteria for Scenesse (afemelanotide) for erythropoietic protoporphyria (EPP), Ibsrela (tenapanor) for IBS-C, Xcopri (cenobamate) for partial-onset seizures. Updated Pulmozyme criteria.
03/01/20	Interim Review, approved February 11, 2020. Added Palforzia [peanut (*Arachis hypogaea*) allergen powder-dnfp] to Peanut Immunotherapy. Added Consensi (amlodipine and celecoxib) to Combination Medications (Misc.). Added Jatenzo (testosterone capsules) and Striant (testosterone buccal system) to Testosterone Replacement Products. Added Secuado (asenapine transdermal) to brand second generation antipsychotics. Added Tovet (clobetasol propionate) to Corticosteroids, Topical Brand. Added Amzeeq (minocycline foam) to Brand Topical Acne or Rosacea Products.
04/01/20	Interim Review, approved March 10, 2020. Moved Emflaza to policy 5.01.570 Pharmacologic Treatment of Duchenne Muscular Dystrophy. Moved Ezallor Sprinkle (rosuvastatin), Flolipid (simvastatin liquid), Livalo (pitavastatin), Nikita (pitavastatin), and Zypitamag (pitavastatin) to policy 5.01.558 Pharmacologic Treatment of High Cholesterol. Added Conjupri (levamlodipine) to Calcium Channel Blockers. Added Sabril (vigabatrin) and generic vigabatrin to Anticonvulsants. Added Oxervate (cenegermin-bkbj) ophthalmic solution to Human Nerve Growth Factors. Added Adapalene/Benzoyl Peroxide/ Clindamycin and Adapalene/Benzoyl Peroxide/Niacinamide to Brand Topical Acne or Rosacea Products.
04/15/20	Interim Review, approved April 7, 2020, effective April 15, 2020. Added quantity limits to help control stockpiling of medications used for treatment of COVID-19 to the following: chloroquine, hydroxychloroquine, Plaquenil (hydroxychloroquine), lopinavir/ritonavir, Kaletra (lopinavir/ritonavir), azithromycin, Zithromax (azithromycin), albuterol HFA inhaler, levalbuterol HFA inhaler, ProAir Digihaler (albuterol), ProAir HFA (albuterol), ProAir Respiclick (albuterol), Proventil HFA (albuterol), Ventolin HFA (albuterol), Xopenex HFA (levalbuterol).
05/01/20	Interim Review, approved April 14, 2020. Removed Kynamro (mipomersen) and moved Juxtapid (lomitapide) to policy 5.01.558 Pharmacologic Treatment of High Cholesterol. Removed bullet on not targeting kits from Corticosteroids, Topical Brand. Added Syprine (trientine) and generic trientine to Chelating Agents. Added Benzoyl Peroxide/Clindamycin/Niacinamide, Benzoyl Peroxide/Clindamycin/Tretinoin, Clindamycin/Niacinamide, Clindamycin/Niacinamide/Spironolactone/Tretinoin,

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	Dapsone, Dapsone/Niacinamide, Dapsone/Niacinamide/ Spironolactone, Niacinamide/ Spironolactone/Tretinoin to Brand Topical Acne or Rosacea Products. Added generic naproxen/esomeprazole to NSAIDs and Combinations. Added Ozobax (baclofen oral solution) to Muscle Relaxants. Added Valtoco (diazepam nasal spray) to Anticonvulsants. Added Pizensy (lactitol oral solution) to Constipation. Updated criteria for all Constipation medications to include coverage when on existing therapy. Updated criteria for Epidiolex to require use of one anti-seizure medication first.
06/01/20	Interim Review, approved May 21, 2020. Added Androderm (testosterone transdermal system), AndroGel (testosterone gel), and Testosterone gel (brand) to Nonpreferred Testosterone Replacement agents. Added Olux and Olux-E to Corticosteroids, Topical Brand.
07/01/20	Interim Review, approved June 9, 2020. Updated criteria for Palforzia [peanut (Arachis hypogaea). Added Caplyta (lumateperone) to Antipsychotics, Second Generation. Updated criteria for Sirturo (bedaquiline) to include patients 5 years of age or older. Added Ongentys (opicapone) to Parkinson's Disease Agents.
08/01/20	Interim Review, approved July 14, 2020. Added Farxiga (dapagliflozin) to Heart Failure Agents. Added indication for treatment of pediatric heart failure to Entresto (sacubitril/valsartan). Updated antibiotic examples listed under Xifaxan (rifaximin) for the treatment of SIBO. Added Alvesco (ciclesonide), Asmanex HFA (mometasone), Asmanex Twisthaler (mometasone) and Pulmicort Flexhaler (budesonide) to Inhaled Corticosteroids. Added Fintepla (fenfluramine) and Vigadrone (vigabatrin) to Anticonvulsants. Added Clovique (trientine) to Chelating Agents. Added Bonjesta (doxylamine and pyridoxine extended-release) and Diclegis (doxylamine and pyridoxine delayed-release) to Treatment of Nausea/Vomiting. Removed Axiron (testosterone) from Testosterone Replacement Products as product is no longer available. Added a maximum daily dose to Epidiolex (cannabidiol). Added Zilxi (minocycline topical foam) to Brand Topical Acne or Rosacea Products. Updated criteria to include testosterone 2% gel as qualifier for the Testosterone Replacement Products. Added Alocril (nedocromil), Alomide (lodoxamide), Bepreve (bepotastine), Lastacaft (alcaftadine), Pataday (olopatadine), Pazeo (olopatadine), and Zerviate (cetirizine) to Allergic Conjuctivitis. Added Eucrisa (crisaborole) to Atopic Dermatitis. Added Sprix (ketorolac tromethamine) nasal spray to NSAIDs and Combinations. Added Solosec (secnidazole) to Brand Oral Antibiotics and their generics. Removed quantity limits from chloroquine, hydroxychloroquine, Plaquenil (hydroxychloroquine), lopinavir/ritonavir, Kaletra (lopinavir/ritonavir), azithromycin, and Zithromax (azithromycin).
09/01/20	Annual Review, approved August 20, 2020. Reviewed prescribing information for all drugs with drug specific coverage criteria. Added to Epidiolex (cannabidiol) a new indication for seizures associated with tuberous sclerosis complex and updated the coverage criteria from two to one year of age and older for seizures associated with Lennox-Gastaut syndrome and Dravet syndrome. Added generic tolvaptan (generic of Samsca) to policy with identical coverage criteria as Samsca (tolvaptan). Removed

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	Desonate from the Corticosteroids, Topical Brand. Added a quantity limit to Santyl (collagenase).
11/01/20	Interim Review, approved October 13, 2020. Added brand ketorolac tromethamine nasal spray to NSAIDs and Combinations. Added Aciphex (rabeprazole), Aciphex Sprinkle (rabeprazole), Dexilant (dexlansoprazole), generic omeprazole/sodium bicarbonate, Nexium (esomeprazole), Prevacid (lansoprazole), Prevacid Solutab (lansoprazole), Prilosec (omeprazole), Protonix (pantoprazole), and Zegerid (omeprazole/sodium bicarbonate) to Proton Pump Inhibitors. Added Daraprim (pyrimethamine) and generic pyrimethamine to Antiparasitic Agents. Added Apokyn (apomorphine) and Kynmobi (apomorphine sublingual film) to Parkinson's Disease Agents. Added Winlevi (clascoterone) to Brand Topical Acne or Rosacea Products. Added Pylera (bismuth subcitrate potassium, metronidazole, tetracycline) to Brand Oral Antibiotics and their generics. Added Gimoti (metoclopramide nasal spray) to Gastrointestinal Stimulants. Added Upneeq (oxymetazoline ophthalmic solution) to Alpha Adrenergic Agonist. Added Aptiom (eslicarbazepine), Briviact (brivaracetam), Fycompa (perampanel), Nayzilam (midazolam nasal spray), Oxtellar XR (oxcarbazepine extended-release), Peganone (ethotoin), Qudexy XR (topiramate extended-release capsules), brand topiramate extended-release capsules, Spritam (levetiracetam tablets for oral suspension), Sympazan (clobazam oral film), Trokendi XR (topiramate extended-release capsules), and Vimpat (lacosamide) to Anticonvulsants.
12/01/20	Interim Review, approved November 10, 2020. Added Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) to GnRH Receptor Antagonist Products. Added Cayston (aztreonam) to Antibiotics. Updated Cambia (diclofenac potassium for oral solution) criteria to include the indication for migraine treatment. Added Actimmune (interferon gamma-1b) to Interferons. Coverage criteria for Actimmune (interferon gamma-1b) (HCPCS code J9216) becomes effective for dates of service on or after March 3, 2021, following 90-day provider notification. Added HCPCS code J9216.
01/01/21	Interim Review, approved December 8, 2020. Added Apriso (mesalamine), Asacol HD (mesalamine), Colazal (balsalazide), Delzicol (mesalamine), Dipentum (olsalazine), Giazo (balsalazide), Lialda (mesalamine), and Pentasa (mesalamine) to Ulcerative Colitis Agents. Added Viberzi (eluxadoline) to irritable bowel syndrome with Diarrhea (IBS-D) Agents. Added HCPCS code J7352.
02/01/21	Interim Review, approved January 12, 2021. Added Helidac (bismuth subsalicylate, metronidazole, tetracycline) to Brand Oral Antibiotics and their generics. Added new indication to Vimpat (lacosamide) for the treatment of generalized tonic-clonic seizures. Removed Ticanase and Ticaspray from Intranasal Corticosteroid Products, Brands and Tovet from Corticosteroids, Topical Brand as these drugs are not approved by the FDA and have coverage blocked under pharmacy benefit. Removed Adapalene/Benzoyl Peroxide/Clindamycin, Adapalene/Benzoyl Peroxide/Niacinamide, Benzoyl Peroxide/Clindamycin/Niacinamide, Benzoyl Peroxide/Clindamycin/Tretinoin, Clindamycin/Niacinamide, Clindamycin/Niacinamide/Spironolactone/Tretinoin, Dapsone/Niacinamide, Dapsone/Niacinamide/Spironolactone, and Niacinamide/Spironolactone/Tretinoin from Brand Topical Acne or Rosacea Products

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	as these drugs are not approved by the FDA and have coverage blocked under pharmacy benefit. Added coverage for nasal polyps and the drugs Nasonex (mometasone) and Xhance (fluticasone propionate) as brand examples for Intranasal Brand Corticosteroid Products. Added Uceris (budesonide extended-release tablets) to Ulcerative Colitis Agents. Added Entocort EC (budesonide delayed-release capsules) and Ortikos (budesonide extended-release capsules) to Crohn's Disease Agents. Added generic rufinamide to Anticonvulsants and updated criteria for Banzel (rufinamide) to require for Banzel oral suspension the patient has tried generic rufinamide oral suspension first.
03/01/21	Interim Review, approved February 9, 2021. Added Arazlo (tazarotene), Atralin (tretinoin), and Soolantra (ivermectin) to Brand Topical Acne or Rosacea Products. Updated Gralise (gabapentin extended release) criteria to include the indication for neuropathic pain. For the Anticonvulsants drugs updated the initial and re-authorization duration to 3-years. Added coverage criteria for Bronchitol (mannitol) to Cystic Fibrosis.
05/01/21	Interim Review, approved April 13, 2021. Added Noxafil (posaconazole) tablets and Tolsura (itraconazole) capsules to Antifungals. Added Verquvo (vericiguat) to Heart Failure Agents. Added Alinia (nitazoxanide) to Antiprotozoal Agents. Added Retin-A and Retin-A Micro to Brand Topical Acne or Rosacea Products. Added note to Pentasa (mesalamine) to allow exception when used for inflammatory bowel disease of the small intestine.
06/01/21	Interim Review, approved May 11, 2021. Updated Qudexy XR (topiramate extended-release capsules) criteria to 2 years of age and older for treatment of seizures. Added Qelbree (viloxazine extended release) for treatment of ADHD to Brand Drugs for ADHD. Added Azor (amlodipine/olmesartan), Caduet (amlodipine/ atorvastatin), Exforge (amlodipine/valsartan), Exforge HCT (amlodipine/valsartan/ hydrochlorothiazide), Lotrel (amlodipine/benazepril), Prestalia (amlodipine/ perindopril), Tarka (verapamil/trandolapril), Tribenzor (amlodipine/olmesartan/ hydrochlorothiazide), and Twynsta (amlodipine/telmisartan) to Calcium Channel Blockers. Added Elidel (pimecrolimus) and Protopic (tacrolimus) to Atopic Dermatitis. Added Omeclamox-Pak (omeprazole, clarithromycin, amoxicillin) and Talicia (omeprazole, amoxicillin, rifabutin) to Brand Oral Antibiotics and Their Generics. Added Alkindi Sprinkle (hydrocortisone), Cortef (hydrocortisone), Dxevo (dexamethasone), Hemady (dexamethasone), Medrol (methylprednisolone), Orapred ODT (prednisolone), Pediapred (prednisolone), Taperdex (dexamethasone), and Zcort (dexamethasone) to Oral Corticosteroids, Brand.
07/01/21	Annual Review, approved June 8, 2021. Removed Soolantra from the Brand Topical Acne and Rosacea products. Added Soolantra (ivermectin) criteria. Removed Contour branded test strips from the Nonpreferred Diabetic Test Strips. Added Gemtesa (vibegron), Myrbetriq (mirabegron), Oxytrol (oxybutynin), and Toviaz (fesoterodine) criteria. Updated Corlanor (ivabradine) criteria to include indication for pediatric heart failure.

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08/01/21	Interim Review, approved July 13, 2021. Added Azstarys (serdexmethylphenidate and dexmethylphenidate) to brand stimulants for ADHD. Added Brexafemme (ibrexafungerp) for the treatment of VVC to Antifungals. Added Farxiga (dapagliflozin) for the treatment of chronic kidney disease. Updated Entresto (sacubitril/valsartan) criteria removing requirement of a reduced ejection fraction of 40% or less. Added quantity limits to Dexcom G6 Sensor, Dexcom G6 Transmitter, Freestyle Libre Sensor, and Freestyle Libre 2 Sensor. Added Aveed (testosterone undecanoate) to Testosterone Replacement Products. Coverage criteria for Aveed (testosterone undecanoate) (HCPCS code J3145) becomes effective for dates of service on or after November 5, 2021, following 90-day provider notification. Added HCPCS code J3145.
09/01/21	Interim Review, approved August 10, 2021. Added Kerendia (finerenone) to Chronic Kidney Disease Treatment. Updated Eucrisa (crisaborole) criteria removing exception for the face involvement with topical calcineurin inhibitors. Added Twyneo (tretinoin and benzoyl peroxide) to Brand Topical Acne or Rosacea Products.
10/01/21	Interim Review, approved September 14, 2021. Added Jardiance (empagliflozin) to Heart Failure Agents. Added Eysuvis (loteprednol etabonate ophthalmic suspension) to Dry Eye Treatment.
12/01/21	Interim Review, approved November 9, 2021. Updated age requirement for Briviact (brivaracetam) for treatment of partial-onset seizures from 4 years or older to 1 month or older. Added new indication to Solosec (secnidazole) for treatment of trichomoniasis. Added Opzelura (ruxolitinib) criteria.
01/01/22	Interim Review, approved December 14, 2021. Added generic ibuprofen + famotidine (two-drug combination) with identical coverage criteria as brand Duexis (ibuprofen + famotidine) to NSAIDs and Combinations. Added Lybalvi (olanzapine and samidorphan) to Antipsychotics, Second Generation. Added quantity limits to help control the off-label use for treatment of COVID-19 to generic ivermectin and Stromectol (ivermectin).
02/01/22	Interim Review, approved January 11, 2022. Added coverage criteria for Korsuva (difelikefalin) for the treatment of pruritus associated with CKD. Removed Orilissa(elagolix) and Oriahnn (elagolix, estradiol, and norethindrone acetate; elagolix) from Policy 5.01.605 as coverage criteria are now listed Policy 5.01.625 GnRH Analogs. Added HCPCS code J3490.
03/01/22	Interim Review, approved February 8, 2022. Added Quviviq (daridorexant) to Hypnotics. Added Ryaltris (olopatadine and mometasone) to Intranasal Brand Corticosteroid Products. Added quantity limit of 1 treatment course every 90 days to molnupiravir and Paxlovid (nirmatrelvir tablets; ritonavir tablets).
04/01/22	Coding update. Added new CPT code J0879.
05/01/22	Interim Review, approved April 25, 2022. Removed from Jardiance (empagliflozin) the requirement for a reduced ejection fraction of 40% or less when being used for the treatment of heart failure. Added brand baclofen oral solution with identical coverage

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	criteria as Ozobax (baclofen oral solution). Added to Fintepla (fenfluramine) coverage for seizures associated with Lennox-Gastaut syndrome.
06/01/22	Annual Review, approved May 23, 2022. Moved the atopic dermatitis drugs Elidel (pimecrolimus), Eucrisa (crisaborole), Opzelura (ruxolitinib), and Protopic (tacrolimus) from Policy 5.01.605 to Policy 5.01.628 Pharmacologic Treatment of Atopic Dermatitis with no changes to the coverage criteria.
07/01/22	Interim Review, approved June 14, 2022. Added Camzyos (mavacamten) for the treatment of symptomatic NYHA class II-III obstructive HCM. Added Tlando (testosterone capsules) to Testosterone Replacement Products. Added Lymepak (doxycycline) to Brand Oral Antibiotics and Their Generics. Added Epsolay (benzoyl peroxide cream) for the treatment of inflammatory lesions of rosacea. Added Impavido (miltefosine) to Antiprotozoal Agents. Added Fleqsuvy (baclofen oral solution) to Muscle Relaxants. Added Cuvrior (trientine tetrahydrochloride) for the treatment of adult patients with stable Wilson's disease to Chelating Agents. Added Igalmi (dexmedetomidine sublingual film) for the acute treatment of agitation associated with schizophrenia or bipolar I or II disorder.
10/01/22	Interim Review, approved September 13, 2022. Added Freestyle Libre 3 Sensor to CGM Supplies Quantity Limits. Updated Qelbree (viloxazine extended release) to include patients 6 years of age or older. Added Lyvispah (baclofen oral granules) to Muscle Relaxants. Updated note for Pentasa to specify Crohn's disease that affects the small intestine. Added brand quetiapine and Lybalvi (olanzapine and samidorphan) to Antipsychotics, Second Generation. Added Armonair Digihaler (fluticasone propionate) and brand fluticasone propionate inhalation aerosol to Inhaled Corticosteroids. Added Konvomep (omeprazole/sodium bicarbonate) to Proton Pump Inhibitors. Updated Vimpat (lacosamide) criteria to require patient has tried generic lacosamide and at least one additional generic anti-seizure medication. Updated Xifaxan (rifaximin) criteria for SIBO to include exception for patients with documented allergies or contraindications to using two other antibiotics. Updated Angiotensin II Receptor Blockers (ARBs), Brand criteria from tried one generic ARB to tried 2 generic ARBs and added coverage criteria for brand valsartan solution. Added Atacand HCT (candesartan/HCTZ), Avalide (irbesartan/HCTZ), Benicar HCT (olmesartan/HCTZ), Diovan HCT (valsartan/HCTZ), Edarbyclor (azilsartan/chlorthalidone), Hyzaar (losartan/HCTZ), Micardis HCT (telmisartan/HCTZ), and Tekturna HCT (aliskiren/HCTZ) to Angiotensin II Receptor Blocker (ARB) Combinations, Brand. Removed HCPCS code J3490. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/22	Interim Review, approved October 11, 2022. Updated Fintepla (fenfluramine) criteria to require the individual has tried four anti-seizure medications and changed dosing limit to state concomitant clobazam plus Diacomit (stiripentol). Added to Qudexy XR, brand topiramate extended-release capsules, and Trokendi XR that when used for the preventive treatment of migraine a requirement the individual has first tried generic topiramate and a dose limit of 100 mg per day. Added Zonisamide (zonisamide oral

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	suspension) to Anticonvulsants. Updated Camzyos (mavacamten) to require the patient is receiving concurrent therapy with a BB or a CCB.
01/01/23	Interim Review, approved December 13, 2022. Removed all coverage criteria for Nayzilam (midazolam nasal spray) and Valtoco (diazepam nasal spray). Updated Diacomit (stiripentol) criteria to include individuals 6 months of age and older. Added Ztalmy (ganaxolone) to Anticonvulsants for the treatment of seizures associated with CDKL5 deficiency disorder. Updated the Xofluza (baloxavir marboxil) quantity limits to reflect the 40 mg tablet, 80 mg tablet, and 40 mg/20 mL oral suspension. Added quantity limit to ketorolac 10 mg tablet. Added quantity limit to Auvi-Q, Epinephrine auto-injector, EpiPen, EpiPen Jr, and Symjepi. Updated drug category from "All Single-Source Brand Oral NSAIDs" to "All Brand Oral NSAIDs". Added Accupril (quinapril), Altace (ramipril), Epaned (enalapril solution), Lotensin (benazepril), Qbrelis (lisinopril solution), Vasotec (enalapril), and Zestril (lisinopril) to Angiotensin-Converting Enzyme Inhibitors (ACEIs), Brand. Added Accuretic (quinapril/HCTZ), Lotensin HCT (benazepril/HTCZ), Lotrel (amlodipine/benazepril), Prestalia (amlodipine/perindopril), Vaseretic (enalapril/HCTZ), and Zestoretic (lisinopril/HCTZ) to Angiotensin-Converting Enzyme Inhibitor (ACEI) Combinations, Brand. Added Azor (amlodipine/olmesartan), Exforge (amlodipine/valsartan) and Teveten HCT (eprosartan/HCTZ) to Angiotensin II Receptor Blocker (ARB) Combinations, Brand. Added Ciclodan (ciclopirox/urea), Ecoza (econazole), Ertaczo (sertaconazole), Exelderm (sulconazole), Extina (ketoconazole), Loprox (ciclopirox), Luliconazole, Luzu (luliconazole), Mentax (butenafine), Miconazole/Zinc Oxide/Petrolatum, Naftin (naftifine), Oxistat (oxiconazole), Sulconazole nitrate, Vusion (miconazole/zinc/petrolatum), and Xolegel (ketoconazole) to Antifungals, Topical Brand. Added Ala-Scalp HP, Analpram-HC, Clobex, Diprolene, Halobetasol proprionate, Hydrocortisone/pramoxine, Locoid, Luxiq, Neo-Synalar, Pramosone, Proctocort, Psorcon, Temovate, Tridesilon, and Vanos to Corticosteroids, Topical Brand. Added Gloperba (colchicine), Mitigare (colchicine), Uloric (febuxostat), and Zyloprim (allopurinol) to Gout Agents, Brand. Added Gimoti (metoclopramide nasal spray) to Gastrointestinal Stimulants. Added brand diclofenac epolamine, Flector (diclofenac epolamine), and Licart (diclofenac epolamine) to Nonsteroidal Anti-inflammatory Drugs (NSAIDs) and Combinations. Added Avar, Avar LS, Avar-E, Avar-E LS, Benzamycin, Clenia Plus, Cleocin T, Evoclin, Metrocream, Metrogel, Noritate, Plexion, Rosanil, Rosula, Sodium sulfacetamide-sulfur, Sumadan, Sumaxin, Sumaxin TS, Vanoxide-HC, and Ziana to Brand Topical Acne or Rosacea Products. Added Methitest (methyltestosterone tablets) to Testosterone Replacement Products. Added Denavir (penciclovir), Xerese (acyclovir and hydrocortisone), Zovirax (acyclovir cream), and Zovirax (acyclovir ointment) to Topical Antivirals, Brand. Added Klaron (sulfacetamide), Ovace Plus Cream (sulfacetamide), Ovace Plus Lotion (sulfacetamide), Ovace Plus Shampoo (sulfacetamide), Ovace Plus Wash (sulfacetamide), Ovace Plus Wash Cleansing Gel (sulfacetamide), Ovace Wash (sulfacetamide), Plexion NS (sulfacetamide), Selrx (selenium sulfide), and Tersi (selenium sulfide) to Topical Seborrheic Dermatitis Agents, Brand. Added Condylox (podofilox) and Veregen (sinecatechins) to Topical Wart Agents, Brand.

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02/01/23	Interim Review, approved January 10, 2023. Added Adderall, Adderall XR, Concerta, Desoxyn, Dexedrine, Evekeo ODT, Focalin, Focalin XR, Intuniv, Kapvay, Methylin, Ritalin, and Strattera to ADHD Drugs, Brands. Added Iyuzeh (latanoprost ophthalmic solution), Omlonti (omidenepag isopropyl ophthalmic solution), and Xalatan (latanoprost ophthalmic solution) to Ophthalmic Prostaglandin Analogs. Removed a duplicate policy criteria entry for Gimoti (metoclopramide nasal spray). Added brand diclofenac potassium for oral solution to NSAIDs and Combinations. Updated Horizant and Gralise coverage criteria to include generic pregabalin as an alternative qualifier to generic gabapentin. Added coverage criteria for Tyrvaya (varenicline solution nasal spray) for treatment of dry eye disease.
03/01/23	Interim Review, approved February 14, 2023. Added brand minocycline ER to Brand Oral Antibiotics and Their Generics. Added brand colchicine to Gout Agents, Brand. For Qelbree (viloxazine extended release) updated the dose prescribed limit from 400 mg per day to 600 mg per day. Updated Kerendia (finerenone) criteria removing the requirement individual has tried and failed either eplerenone or spironolactone. Added Dexcom G7 Sensor to CGM Supplies Quantity Limits.
05/01/23	Annual Review, approved April 11, 2023. Added Austedo XR (deutetrabenazine extended release) to Austedo criteria. Added requirement to try and fail generic lurasidone to Latuda (lurasidone) for treatment of bipolar depression criteria. Added criteria for Nexobrid (anacaulase-bcdb). Added criteria for Emverm (mebendazole) to Antifungals. Added criteria for Chemet (succimer) to Chelating Agents. Added criteria for Patanase (olopatadine) to Brand Intranasal Antihistamine products. Added criteria for Dhivy (carbidopa-levodopa), Duopa (carbidopa-levodopa), Lodosyn (carbidopa), Rytary (carbidopa-levodopa), Sinemet (carbidopa-levodopa), Stalevo (carbidopa-levodopa-entacapone), and Xadago (safinamide) to Parkinson's Disease Agents. Added criteria for TobraDex (tobramycin-dexamethasone) and tobramycin-vancomycin to Brand Ophthalmic Corticosteroids. Updated Corlanor (ivabradine) criteria to require previous therapy with the maximum tolerated dose of a beta blocker for adults and added a prescriber requirement to adult and pediatric criteria. Updated Farxiga (dapagliflozin) criteria to require an eGFR of 25 mL/min/1.73m^2 or greater to initiate therapy. Updated Jardiance (empagliflozin) criteria to require an eGFR of 20 mL/min/1.73m^2 or greater to initiate therapy. Added Zyprexa (olanzapine), Zyprexa Zydis (olanzapine), brand clozapine ODT, Abilify (aripiprazole), Geodon (ziprasidone), Invega (paliperidone), Risperdal (risperidone), Seroquel (quetiapine), and Vraylar (cariprazine) to Brand Second Generation Antipsychotics. Effective date removed from Korsuva.
07/01/23	Interim Review, approved June 13, 2023. Added coverage criteria for Veozah (Fezolinetant) for the treatment of moderate to severe vasomotor symptoms due to menopause. Added brand baclofen oral suspension to brand baclofen oral solution criteria.
08/01/23	Interim Review, approved July 11, 2023. Added coverage criteria for Linzess (linaclotide) for the treatment of functional constipation in pediatric individuals 6 to 17 years old. Added coverage criteria for Vevye (cyclosporin Ophthalmic solution) for the

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	signs and symptoms of dry eye disease. Added Xelstrym (dextroampetamine) to the list of brand ADHD medications.
09/01/23	Interim Review, approved August 8, 2023. Added coverage criteria for Zylet (tobramycin-loteprednol). Zylet may be considered medically necessary when the individual has tried and failed generic ophthalmic tobramycin and generic ophthalmic loteprednol.
10/01/23	Interim Review, approved September 12, 2023. Added coverage criteria for Opvee (nalmefene) for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric individuals aged 12 years and older, as manifested by respiratory and/or central nervous system depression. Added coverage criteria for Ingrezza for the treatment of chorea associated with Huntington's disease. Removed Farxiga requirement of a reduced ejection fraction of 40% or less. Added coverage criteria for Jesduvroq (daprodustat) for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. Added new HCPCS codes J0889 and J7353.
11/01/23	Interim Review, approved October 10, 2023. Added new indication to Rexulti for the treatment of agitation associated with dementia due to Alzheimer's disease. Added Osmolex ER (amantadine) for the treatment of Parkinson's disease and drug-induced extrapyramidal reactions to Parkinson's Disease Agents. Added Gocovri (amantadine) for the treatment of dyskinesia and treatment of "off" episodes in Parkinson's disease to Parkinson's Disease Agents. Added Lokelma (sodium zirconium cyclosilicate) and Veltassa (patiromer) for the treatment of hyperkalemia to Potassium Binders. Added Humatin (paromomycin) for the treatment of intestinal amebiasis and management of hepatic coma to Antiparasitic Agents. Added Miebo (perfluorohexyloctane ophthalmic solution) to Dry Eye Treatment. Updated criteria for Cequa, Tyrvaya, Vevye, Xiidra to require individual has tried and failed generic cyclosporine ophthalmic emulsion 0.05%. Added Thiola (tiopronin), Thiola EC (tiopronin delayed-release), and generic tiopronin for the prevention of cystine stone formation to Cystine Binding Drugs. Added requirement to use generic lisdexamfetamine dimesylate first prior to brand Vyvanse for the treatment of ADHD. Updated Vyvanse criteria for BED adding requirement individual has tried and failed or is intolerant to generic lisdexamfetamine dimesylate. Removed Vyvanse exception to use of a generic stimulant when the individual has a history of drug abuse or dependence due to the available use of generic lisdexamfetamine dimesylate. Updated criteria for Trulance, Motegrity, Pizensy, Linzess, Movantik, and Amitiza to require the individual has tried and failed or is intolerant to generic lubiprostone. Added Pancreaze (pancrelipase) and Pertzye (pancrelipase) for the treatment of exocrine pancreatic insufficiency to Digestive Enzymes.
12/01/23	Interim Review, approved November 14, 2023. Added Motpoly XR (lacosamide) for the treatment of partial-onset seizures to Anticonvulsants. Updated molnupiravir in the policy to Lagevrio (molnupiravir).
01/01/24	Interim Review. Added Lovenox (enoxaparin) and Fragmin (dalteparin) to Low Molecular Weight Heparins, approved December 12, 2023. Updated preferred

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	alternative for Inhaled Corticosteroid criteria from Flovent HFA/Flovent Diskus to fluticasone propionate HFA/fluticasone propionate Diskus because Flovent HFA and Flovent Diskus have been removed from the market, approved December 28, 2023.
02/01/24	Annual Review, approved January 9, 2024. Removed brand fluticasone propionate HFA from the policy. Updated Denavir, Xerese, and Zovirax cream criteria to require trial and failure with generic penciclovir. Added generic penciclovir criteria to Topical Antivirals, Brand. Added Lodoco (colchicine) criteria to Heart Disease Prevention Agents. Added Xdemvy (lotilaner) to Brand Blepharitis Agents. Added requirement to try and fail generic oral baclofen solution to Muscle Relaxants. Added Ozobax DS to Muscle Relaxants. Added requirement to try and fail generic oral spironolactone suspension to Carospir. Added brand trientine hydrochloride to Chelating Agents. Removed Omlonti (omidenepag isopropyl) from Ophthalmic Prostaglandin Analogs and prescription Lastacaft (alcaftadine) and prescription Pataday (olopatadine) as they were removed from the market. Added requirement that Xiidra is not used concurrently with a cyclosporine ophthalmic, Miebo or Tyrvaya. Added requirement that Cequa and Vevye are not used concurrently with another cyclosporine ophthalmic, Miebo, Tyrvaya or Xiidra. Added requirement that Miebo is not used concurrently with a cyclosporine ophthalmic, Tyrvaya, or Xiidra. Added requirement that Tyrvaya is not used concurrently with a cyclosporine ophthalmic, Miebo, or Xiidra. Added Cabtreo to Brand Topical Acne or Rosacea Products. Removed Xyosted from Nonpreferred Testosterone Replacement Agents. Added Xyosted specific criteria to Testosterone Replacement Products.
03/01/24	Interim Review, approved February 13, 2024. Added Inpefa (sotagliflozin) to Heart Failure Agents. Added Gelnique (oxybutynin) to Overactive Bladder Agents. Updated Helidac (bismuth subsalicylate-metronidazole-tetracycline), Omeclamox-Pak (omeprazole-clarithromycin-amoxicillin), Pylera (bismuth subcitrate potassium-metronidazole-tetracycline), and Talicia (omeprazole-amoxicillin-rifabutin) criteria to the following: Individual is 18 years or older, diagnosed with *H. pylori* infection, and has tried two generic medication regimens. Added Voquezna Dual Pak (amoxicillin-vonoprazan) and Voquezna Triple Pak (amoxicillin-clarithromycin-vonoprazan) to Brand Oral Antibiotic Agents. Added Voquezna (vonoprazan) to Acid Blocker Agents. Updated Brand Topical Antivirals to Brand Antivirals. Added Valtrex (valacyclovir) to Brand Antivirals. Added Betoptic S (betaxolol), Istalol (timolol), Timoptic (timolol), and Timoptic-XE (timolol) to Brand Ophthalmic Beta Blockers. Added Ycanth (cantharidin) to Brand Molluscum Contagiosum Agents. Added generic Vigpoder (vigabatrin) as a preferred alternative for Sabril (vigabatrin) criteria. Added Jardiance (empagliflozin) to Chronic Kidney Disease Treatment. Added Zonisade to Anticonvulsants. Added iDose TR (travoprost intracameral implant) to Brand Ophthalmic Prostaglandin Analogs. Updated age requirement for Cresemba (isavuconazonium) from 18 years to 6 years of age or older. Updated Brexafemme (ibrexafungerp) to include coverage criteria for the reduction of recurrent vulvovaginal candidiasis. Removed ProAir HFA (albuterol) from Short-Acting Beta Agonists as it has been discontinued from the market. Removed Zelnorm (tegaserod) from Constipation Agents as it has been withdrawn from the market. Updated Solosec (secnidazole) age requirement from 18 years to 12 years of

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	age or older. Added Vivjoa (oteseconazole) to Antifungals. Added Vigpoder (vigabatrin) to Anticonvulsants. Added HCPCS codes C9164 and J3490.
04/01/24	Interim Review, approved March 12, 2024. Updated Ycanth (cantharidin) step therapy requirement. Added Zelsuvmi (berdazimer) and brand cantharidin to Brand Molluscum Contagiosum Agents. Added Zoryve (roflumilast) foam to Topical Seborrheic Dermatitis Agents, Brand. Added new HCPCS code J7354 and termed HCPCS code C9164.
05/01/24	Interim Review, approved April 9, 2024. Added Tryvio (aprocitentan) to Hypertensive Agents, Brand. Updated Condylox (podofilox) to clarify the step therapy requirement should be limited to the solution version of generic topical podofilox. Added Nascobal (cyanocobalamin nasal spray) and generic cyanocobalamin nasal spray to Vitamin Agents. Added Vfend (voriconazole) tablets and oral suspension to Antifungals. Added Ambien (zolpidem), Lunesta (eszopiclone), Rozerem (ramelteon), Silenor (doxepin), and brand zolpidem tartrate to Hypnotics. Added Verkazia (cyclosporine ophthalmic emulsion) to Dry Eye Treatments. Rezdiffra (resmetirom) added to MASH Agents. Added Xhance (fluticasone proprionate) for the treatment of chronic rhinosinusitis without nasal polyps to Intranasal Corticosteroid Products, Brands. Elmiron (pentosan polysulfate sodium) added to Cystitis Agents.
06/01/24	Interim Review, approved May 14, 2024. Added Dymista (azelastine-fluticasone) to Intranasal Corticosteroid Products, Brands. Added Qlosi (pilocarpine) and Vuity (pilocarpine) to Ophthalmic Cholinergic Agonists.
07/01/24	Interim Review, approved June 11, 2024. Added Vafseo (vadadustat) to Hypoxia-Inducible Factor Prolyl Hydroxylase (HIF PH). Removed Armonair Digihaler from Inhaled Corticosteroids as it has been withdrawn from the market. Removed ProAir Digihaler from Short-Acting Beta Agonists as it has been withdrawn from the market. Added Libervant (diazepam) to Anticonvulsants. Added HCPCS code C9399. Added HCPCS code J7355 effective 7/1/2024.
08/01/24	Interim Review, approved July 9, 2024. Added Eohilia (budesonide oral suspension) to Eosinophilic Esophagitis Agents. Updated Vyvanse (lisdexamfetamine dimesylate) binge eating disorder criteria to include an age requirement. Added generic bismuth subcitrate potassium-metronidazole-tetracycline to Brand Oral Antibiotics and Their Generics. Removed Beconase AQ, Nasonex, and Veramyst from Intranasal Brand Corticosteroid Products as they have been withdrawn from the market. Removed statement that Scenesse (afamelanotide) for the treatment of vitiligo is not medically necessary as treatment of vitiligo is considered a cosmetic exclusion. Updated Rezdiffra (resmetirom) to include treatment of certain individuals with MASH who have F2 fibrosis. Updated Rezdiffra (resmetirom) drink limit from 21 drinks per week if male to 15 drinks per week if male. Updated Rezdiffra (resmetirom) drink limit from 14 drinks per week if female to 10 drinks per week if female. Added generic mirabegron as a step therapy option for Overactive Bladder Agents. Added generic mirabegron, Vesicare, and Vesicare LS to the Overactive Bladder Agents.

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09/01/24	Interim Review, approved August 13, 2024. Added Opill (norgestrel) to the Quantity Limits. Added Envarsus XR (tacrolimus extended-release) to Transplant Agents. Added Anaprox (naproxen), Arthrotec (diclofenac-misoprostol), Daypro (oxaprozin), Feldene (piroxicam), Lodine (etodolac), Mobic (meloxicam), Naprosyn (naproxen), Voltaren (diclofenac), and Celebrex (celecoxib) to the Brand Oral NSAIDs. Added Durysta (bimatoprost) to Brand Ophthalmic Prostaglandin Analogs. Updated Motpoly XR (lacosamide) coverage criteria to include treatment of certain individuals with generalized tonic-clonic seizures. Updated Palforzia (peanut [*Arachis hypogaea*] allergen powder) coverage criteria age requirement from 4 years to 1 year of age or older. Updated Sirturo (bedaquiline) coverage criteria to update diagnosis requirement to pulmonary tuberculosis due to *Mycobacterium tuberculosis* resistant to at least rifampin and isoniazid. Added Vigafyde (vigabatrin) to the Anticonvulsants.
10/01/24	Interim Review, approved September 10, 2024. Added Restasis (cyclosporine ophthalmic emulsion) to the Dry Eye Treatments.
11/01/24	Interim Review, approved October 8, 2024. Added Ambien CR to Hypnotics. Added generic apomorphine and Crexont (carbidopa-levodopa) to Parkinson's Disease Agents. Added Pivya (pivmecillinam) to Brand Oral Antibiotics and Their Generics. Added Sofdra (sofpironium) to Hyperhidrosis Agents. Added Onyda XR (clonidine) to Brand ADHD Drugs. Added generic ivabradine to Heart Failure Agents. Updated Corlanor (ivabradine) to require trial with generic ivabradine first. Added generic oxcarbazepine ER to Anticonvulsants. Updated Oxtellar XR (oxcarbazepine extended release) from trial and failure with another generic antiseizure medication to trial with generic oxcarbazepine ER. Added Neffy (epinephrine nasal spray) to Epinephrine Agents. Updated Xepi (ozenoxacin) from trial with mupirocin to generic mupirocin. Added Centany (mupirocin) to Topical Antibiotics. Added Cortifoam (hydrocortisone) and Dexonto (dexamethasone) to Brand Topical Corticosteroids. Added Neuac (benzoyl peroxide-clindamycin) Brand Topical Acne or Rosacea Products. Added Anusol-HC (hydrocortisone), brand hydrocortisone-pramoxine, Proctocort (hydrocortisone), and Zypram (hydrocortisone-pramoxine) to Brand Suppository Corticosteroids. Added brand esomeprazole and brand rabeprazole to Proton Pump Inhibitors. Added Oravig (miconazole) to Antifungals. Updated Qbrexza (glycopyrronium) diagnostic criteria.
01/01/25	Interim Review, approved December 10, 2024. Farxiga and Jardiance moved from Policy 5.01.605 to 5.01.646. Entresto moved from Policy 5.01.605 to 5.01.547 with no changes to coverage criteria. Added step therapy criteria to Airsupra (albuterol sulfate-budesonide), brand albuterol sulfate HFA, brand levalbuterol tartrate HFA, ProAir RespiClick (albuterol sulfate), Ventolin HFA (albuterol sulfate), and Xopenex HFA (levalbuterol tartrate). Added Airsupra to Short-Acting Beta Agonists Quantity Limit. Clarified that brand and generic albuterol sulfate HFA are included in Short-Acting Beta Agonists Quantity Limit. Added Myhibbin (mycophenolate mofetil oral suspension) to Transplant Agents. Added Lithostat (acetohydroxamic acid) to Miscellaneous Infectious Disease Agents. Added a new indication to Voquezna (vonoprazan) for the relief of heartburn associated with non-erosive gastroesophageal

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	reflux disease. Added generic gabapentin extended release (generic of Gralise) for the treatment of neuropathic pain. Added Orlynvah (sulopenem etzadroxil and probenecid) to Brand Oral Antibiotics and Their Generics. Added Vivlodex (meloxicam) to Brand Oral NSAIDs. Added Ohtuvayre (ensifentrine) to COPD medications. Added Karbinal ER (carbinoxamine), Ryclora (dexchlorpheniramine), and Ryvent (carbinoxamine) to Antihistamines, Oral. Added brand quazepam and Doral (quazepam) to Hypnotics. Added Mestinon (pyridostigmine) to Myasthenia Gravis Agents. Added Norgesic (orphenadrine, aspirin, and caffeine) and Norgesic Forte (orphenadrine, aspirin, and caffeine) to Muscle Relaxants. Added Zemplar (paricalcitol) to Vitamin Agents. Updated Pivya (pivmecillinam) criteria to require a trial of 3 generic antibiotics first. Added a prescribed dose limit to Qbrexza (glycopurronium cloth) and to Sofdra (sofpironium). Updated Xdemvy (lotilaner) criteria to specify initial approval is for 6 weeks and that re-authorization beyond 6 weeks is investigational. Added Emrosi (minocycline) to Brand Oral Antibiotics and Their Generics. Removed Xyrosa (doxycycline) as the product has been discontinued. Updated Humatin (paromomycin) criteria removing requirement to use generic paromomycin first due to generic paromomycin no longer being available. Added generic dexlansoprazole to Proton Pump Inhibitors. Added brand levamlodipine, Cardizem (diltiazem), Cardizem CD (diltiazem extended-release), Cardizem LA (diltiazem extended-release), Katerzia (amlodipine suspension), Norliqva (amlodipine solution) Norvasc (amlodipine), Procardia XL (nifedipine extended-release), Sular (nisoldipine extended-release), Tiazac (diltiazem extended-release), and Verelan PM (verapamil extended-release) to Calcium Channel Blockers. Removed Azor and Exforge names from ARB Combination, Brand as Azor and Exforge have coverage criteria under CCBs. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information. Added new HCPCS code J0901.
02/01/25	Annual Review, approved January 14, 2025. Rezdiffra (resmetirom) moved from Policy 5.01.605 to Policy 5.01.615 Pharmacologic Treatment of Chronic Non-Infectious Liver Diseases with no changes to the coverage criteria. Moved the gout drugs brand colchicine, Gloperba (colchicine), Mitigare (colchicine), Uloric (febuxostat), and Zyloprim (allopurinol) from Policy 5.01.605 to Policy 5.01.616 Pharmacologic Treatment of Gout with no changes to the coverage criteria. Added TobraDex ST (tobramycin and dexamethasone ophthalmic suspension) to Brand Ophthalmic Corticosteroids. Updated Apokyn (apomorphine) criteria to require a trial and inadequate response to generic apomorphine first. Updated Zemplar (paricalcitol) criteria to require a trial and inadequate response to generic paricalcitol first. Added coverage criteria for Cobenfy (xanomeline and trospium chloride) to Antipsychotics, Second Generation. Added coverage criteria for Opipza (aripiprazole oral film) to Antipsychotics, Second Generation. Added coverage criteria for Arikayce (amikacin liposome) for the treatment of *Mycobacterium avium* complex lung disease. Added Zelapar (selegiline) to Parkinson's Disease Agents. Updated criteria for Xadago (safinamide) to include selegiline as a qualifying prerequisite drug. Updated re-authorization criteria for Xdemvy (lotilaner) to allow for retreatment of Demodex blepharitis after ≥ 1-year since completing a prior treatment course. Added coverage criteria for Akynzeo (netupitant

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	and palonosetron), Emend (aprepitant), Sancuso (granisetron transdermal system), and Varubi (rolapitant) to Cancer Related Antiemetics. Added Kyzatrex (testosterone capsules) and Undecatrex (testosterone capsules) to Testosterone Replacement Products. Updated all Testosterone Replacement Products to limit use to individuals assigned male at birth or for the treatment of gender dysphoria. Policy changes for Aveed (testosterone undecanoate) and Testopel (testosterone pellets) will be effective May 6, 2025, following 90-day provider notification. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.