Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: January 1, 2022

NEW NON- PREFERRED DRUGS	
THERAPEUTIC CLASS	**PA REQUIRED NON-PREFERRED**
Analgesic Agents: Gout	Colchicine Cap
Analgesic Agents: NSAIDS	Licart Patch
Analgesic Agents: Opioids	Qdolo
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors	Granix Udenyca
Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors	Nuwiq Sevenfact
Cardiovascular Agents: Angina, Hypertension and Heart Failure	Verquvo
Central Nervous System (CNS) Agents: Alzheimer's Agents	Galantamine Sol
Central Nervous System (CNS) Agents: Anti Migraine Agents, Prophylaxis	Nurtec ODT
Central Nervous System (CNS) Agents: Anticonvulsants	Elepsia XR
Central Nervous System (CNS) Agents: Anticonvulsants Rescue	Diazepam Gel
Central Nervous System (CNS) Agents: Atypical Antipsychotics	Zyprexa Relprevv
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	Methylphenidate ER (generic of Aptensio XR, Relexxii) Vyvanse Chewable Tab
Central Nervous System (CNS) Agents: Multiple Sclerosis	Ponvory
Central Nervous System (CNS) Agents: Sedative - Hypnotics, Non-Barbiturate	Ramelteon
Endocrine Agents: Diabetes – Hypoglycemia Treatments	Glucagon Emerg Kit [Labeler 00548 & 63323]
Endocrine Agents: Diabetes-Insulin	Humalog U-200 Humulin R U-100 Novolin 70-30 Novolin R U-100
Endocrine Agents: Diabetes – Non-Insulin	Bydureon Bcise Symlinpen
Endocrine Agents: Growth Hormone	Genotropin
Endocrine Agents: Uterine Fibroids	Myfembree
Gastrointestinal Agents: Anti-Emetics	Bonjesta
Gastrointestinal Agents: Ulcerative Colitis	Zeposia
Genitourinary Agents: Urinary Antispasmodics	Gemtesa Vesicare LS
Infectious Disease Agents: Antibiotics – Inhaled	Kitabis Pak
Infectious Disease Agents: Antibiotics – Macrolides	Eryped Erythrocin Stearate

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NEW NON- PREFERRED DRUGS	
THERAPEUTIC CLASS	**PA REQUIRED NON-PREFERRED**
	Erythromycin
Infectious Disease Agents: Antivirals – HIV	Norvir Cap Norvir Pow Norvir Sol
Respiratory Agents: Antihistamines-Second Generation	Cetirizine Chewable
Respiratory Agents: Cystic Fibrosis	Bronchitol
Respiratory Agents: Inhaled Agents	Albuterol HFA Bevespi Aerosphere Proair Respiclick
Topical Agents: Corticosteroids	Fluocinolone Acetonide Oil 0.01%

NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**NO PA REQUIRED PREFERRED**
Cardiovascular Agents: Angina, Hypertension and Heart Failure	Bystolic Olmesartan Olmesartan/Hydrochlorothiazide Olmesartan/Amlodipine/ Hydrochlorothiazide
Central Nervous System (CNS) Agents: Alzheimer's Agents	Donepezil ODT Exelon Patch
Central Nervous System (CNS) Agents: Anticonvulsants	Banzel
Central Nervous System (CNS) Agents: Anticonvulsants Rescue	Diastat
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	Dextroamphetamine Sol Clonidine ER Focalin XR Concerta Methylphenidate Sol Quillichew ER Quillivant XR Ritalin LA
Central Nervous System (CNS) Agents: Atypical Antipsychotics	Invega Risperdal Geodon
Central Nervous System (CNS) Agents: Medicated Assisted Treatment of Opioid Addiction	Bunavail
Central Nervous System (CNS) Agents: Multiple Sclerosis	Dimethyl Fumarate (excluding labeler 00378 & 69097)
Endocrine Agents: Diabetes – Hypoglycemia Treatments	Gvoke Hypopen Gvoke PFS Zegalogue

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NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**NO PA REQUIRED PREFERRED**
Endocrine Agents: Diabetes – Insulin	Apidra Humalog U-100 Novolog 70-30 Novolog U-100 Toujeo
Endocrine Agents: Diabetes – Non-Insulin	Actoplus Met XR Byetta Farxiga Invokamet Invokana Janumet Janumet XR Januvia Jardiance Jentadueto Miglitol Synjardy Tradjenta Trulicity Victoza
Gastrointestinal Agents: Anti-Emetics	Diclegis
Genitourinary Agents: Urinary Antispasmodics	Gelnique Myrbetriq Toviaz Solifenacin
Infectious Disease Agents: Antivirals – HIV	Efavirenz/Emtricitabine/Tenofovir Emtricitabine/Tenofovir Disoproxil Fumarate
Ophthalmic Agents: Glaucoma Agents	Rhopressa Rocklatan
Otic Agents: Antibacterial and Antibacterial/Steroid Combinations	Cortisporin-TC
Respiratory Agents: Inhaled Agents	Advair Diskus Advair HFA Anoro Ellipta Incruse Ellipta ProAir HFA Stiolto Striverdi Respimat Ventolin HFA
Topical Agents: Corticosteroids	Derma-Smoothe/FS Flurandrenolide

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NEW CLINICAL PA REQUIRED PREFERRED DRUGS	
THERAPEUTIC CLASS	**CLINICAL PA REQUIRED "PREFERRED"**
Analgesic Agents: Gout	Probenecid/Colchicine
Blood Agents: Blood Formation, Coagulation, and Thrombosis Agents: Hematopoietic Agents	Mircera
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors	Neupogen
Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors	Adynovate Eloctate Esperoct Idelvion
Cardiovascular Agents: Lipotropics	Praluent Repatha
Endocrine Agents: Growth Hormone	Omnitrope
Immunomodulator Agents for Systemic Inflammatory Disease	Kineret Otezla Xeljanz IR 10 mg
Infectious Disease Agents: Antivirals – HIV	Rukobia ER
Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE	Xolair

NEW STEP THERAPY REQUIRED PREFERRED DRUGS	
THERAPEUTIC CLASS	**STEP THERAPY REQUIRED "PREFERRED"**
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	Qelbree
Immunomodulator Agents for Systemic Inflammatory Disease	Taltz
Topical Agents: Immunomodulators	Elidel

THERAPEUTIC CATEGORIES WITH CHANGES IN CRITERIA
Analgesic Agents: NSAIDs
Analgesic Agents: Gout
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating factors
Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factor
Blood Formation, Coagulation, and Thrombosis Agents: Oral Antiplatelet
Cardiovascular Agents: Angina, Hypertension & Heart Failure
Cardiovascular Agents: Lipotropics
Central Nervous System (CNS) Agents: Alzheimer's Agents
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute
Central Nervous System (CNS) Agents: Anticonvulsant Rescue
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents

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THERAPEUTIC CATEGORIES WITH CHANGES IN CRITERIA
Central Nervous System (CNS) Agents: Medicated Assisted Treatment of Opioid Addiction
Endocrine Agents: Diabetes – Hypoglycemia
Endocrine Agents: Diabetes – Non-Insulin
Endocrine Agents: Uterine Fibroids
Gastrointestinal Agents: Crohn's Disease
Genitourinary Agents: Urinary Antispasmodics
Infectious Disease Agents: Antivirals: HIV
Infectious Disease Agents: Hepatitis C
Respiratory Agents: Antihistamines-Second Generation
Respiratory Agents: Cystic Fibrosis
Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-Ige
Respiratory Agents: Other Agents

Please see below for the criteria changes

<table>
<tr><th colspan="2">CHANGES IN CRITERIA</th></tr>
<tr><th>THERAPEUTIC CLASS</th><th>SUMMARY OF CHANGE</th></tr>
<tr><td>Analgesic Agents: NSAIDs</td><td><u>LENGTH OF AUTHORIZATIONS:</u> Dependent on medication request

<table><tr><th></th><th>Approval Duration Length</th></tr><tr><td>H. Pylori Treatment</td><td>30 days</td></tr><tr><td>Transdermal/Topical</td><td>90 days</td></tr><tr><td>All Other Treatments</td><td>365 days</td></tr></table>
The requested medication may be approved if the member had a 30 day trial and failure with <u>two</u> <u>medications</u> not requiring prior approval</td></tr>
<tr><td>Analgesic Agents: Gout</td><td><u>ADDITIONAL INFORMATION</u>
• Colchicine tablets will be approved if any one of the following is true:
o Diagnosis of Familial Mediterranean Fever (FMF) (180-day approval); OR
o Trial of one of the following within the last 30 days:
▪ NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
▪ Oral corticosteroid
• Colchicine capsules can be approved if the patient had a trial and failure with colchicine tablets</td></tr>
<tr><td>Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors</td><td><u>PRIOR AUTHORIZATION CRITERIA</u>
3. Will the medication be used for an approved FDA indication and duration?</td></tr>
</table>

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CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factor	**PRIOR AUTHORIZATION CRITERIA:** 2. Has the patient failed one preferred medication? 3. For extended half-life factors, prescribing physician attests that patient is not a suitable candidate for treatment with shorter-acting half-life product. 4. If Rebinyn is requested, confirmation that it is not being used for routine prophylaxis 5. Approval based upon diagnosis and dosage appropriate to weight, patient pharmacokinetic factors, and presence of inhibitors.
Blood Formation, Coagulation, and Thrombosis Agents: Oral Antiplatelet	**INDICATION AND LENGTH OF AUTHORIZATION:** Requested medication must be used for an approved FDA indication and duration **PRIOR AUTHORIZATION CRITERIA:** 1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: ○ Allergy to medications not requiring prior approval ○ Contraindication to all medications not requiring prior approval ○ History of unacceptable/toxic side effects to medications not requiring prior approval 2. Has the patient failed a 14 day trial with two medications not requiring prior approval?
Cardiovascular Agents: Angina, Hypertension & Heart Failure	**ENTRESTO CRITERIA:** 2. Reduced left ventricular ejection fraction **VERQUVO CRITERIA:** 1. Patient must meet all the following criteria: ○ Diagnosis of symptomatic chronic heart failure (NYHA Class II-IV), and ○ Left ventricular ejection fraction less than 45%, and ○ Patient has been hospitalized for the treatment of heart failure within the previous 180 days or needs treatment with an outpatient intravenous diuretic within the previous 90 days, and ○ Patient must be treated with an agent from ALL the following medication classes unless contradicted: ○ Angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, or an angiotensin receptor neprilysin inhibitor ○ Beta-blocker ○ Aldosterone antagonist and/or SGLT2 inhibitor as appropriate for renal function
Cardiovascular Agents: Lipotropics	**LENGTH OF AUTHORIZATIONS:** 365 days all Lipotropics **ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS:** ○ Age ≥18 years or Age ≥ 13 years and Homozygous Familial Hypercholesterolemia (HoFH) ○ Documented adherence to prescribed lipid lowering medications for previous 90 days

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CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Central Nervous System (CNS) Agents: Alzheimer's Agents	Has the patient failed a therapeutic trial of at least 30 days with at least two medications not requiring prior approval?
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute	Nurtec ODT quantity limit is 8 per 34 days
Central Nervous System (CNS) Agents: Anticonvulsant Rescue	**LENGTH OF AUTHORIZATIONS**: 365 Days **PRIOR AUTHORIZATION CRITERIA:** 1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include: ○ Allergy to medications not requiring prior approval ○ Contraindication to or drug interaction with medications not requiring prior approval ○ History of unacceptable/toxic side effects to medications not requiring prior approval AR - Valtoco: a PA is required for patients younger than 6 years old AR - Nayzilam: a PA is required for patients who are younger than 12 years old
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	**STEP THERAPY:** 1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days of at least two preferred products. Note: Patients on non-preferred therapies are not required to obtain prior authorization for the use of their product until after June 30th, 2022. Providers may obtain prior authorization before June 30th, 2022. AR - Dextroamphetamine Solution: a PA is required for patients over 12 years old AR - Methylphenidate Solution: a PA is required for patients over 12 years old
Central Nervous System (CNS) Agents: Medicated Assisted Treatment of Opioid Addiction	**Criteria for SUBCUTANEOUS BUPRENORPHINE INJECTION (SUBLOCADE™)** ○ Provider will attest that the patient is receiving or planning to receive counseling.
Endocrine Agents: Diabetes - Hypoglycemia	**PA REQUIRED NON-PREFERRED:** A non-preferred medication will be approved after a trial with a preferred medication not requiring prior approval or the inability of the member and/or caregiver to administer a preferred glucagon product in a timely fashion.
Endocrine Agents: Diabetes – Non-Insulin	**NON-PREFERRED:** There must have been a therapeutic failure of at least a 60-day trial and failure with three preferred products. Note: Inadequate clinical response after at least 60 days of recommended therapeutic dose with documented adherence to the regimen.

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CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Endocrine Agents: Uterine Fibroids	**LENGTH OF AUTHORIZATIONS** Patients who have been treated with Oriahnn or Myfembree for 720 days or more are not eligible for additional authorizations
Gastrointestinal Agents: Crohn's Disease	**LENGTH OF AUTHORIZATIONS**: 365 Days **PRIOR AUTHORIZATION CRITERIA:** Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: ○ Allergy to medications not requiring prior approval ○ Contraindication to or drug interaction with medications not requiring prior approval ○ History of unacceptable/toxic side effects to medications not requiring prior approval For a non-preferred agent, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred products.
Genitourinary Agents: Urinary Antispasmodics	AR – Vesicare LS: PA is not required for patients less than 5 years of age
Infectious Disease Agents: Antivirals: HIV	**ADDITIONAL CRITERIA FOR RUKOBIA ER** 1. Patient has been diagnosed with multidrug-resistant HIV-1 infection
Infectious Disease Agents: Hepatitis C	**The following documentation must be submitted with initial request for consideration of approval:** ❑Active HCV infection verified by viral load within 180 days HCV RNA: million IU/mL Date ❑HCV Genotype verified by lab Genotype ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 Hepatitis fibrosis stage:_____ Date:_____ Method(s) used:_____ ❑Patients scheduled to receive an HCVNS3 protease inhibitor (i.e. grazoprevir, voxilaprevir, glecaprevir) should be assessed for a history of decompensated liver disease and liver disease severity using the Child-Turcotte-Pugh (CTP) score if cirrhosis is determined to be likely present (as evidenced by clinical findings, radiology, Metavir fibrosis score of F4, pathology findings or other laboratory markers (FibroTest/FibroSure/FIB-4 index). ❑Prescriber has discussed the importance of adherence to treatment plan, office visits, lab monitoring, imaging, procedures and to taking requested regimen as prescribed. ❑Patient does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions. **Ribavirin (RBV)-ineligible:**
Respiratory Agents: Antihistamines-Second Generation	**ADDITIONAL INFORMATION** ○ Fexofenadine is indicated for patients 6 years of age and older ○ Loratadine is indicated for patients 2 years of age and older ○ Cetirizine and desloratadine are indicated for patients 6 months of age and older
Respiratory Agents: Cystic Fibrosis	**INITIAL AUTHORIZATION CRITERIA FOR BRONCHITOL, KALYDECO, ORKAMBI, SYMDEKO AND TRIKAFTA:** Patient must meet all the following criteria: ○ Diagnosis of cystic fibrosis ○ The prescriber is, or has consulted with a pulmonologist or infectious disease specialist

CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
	○ Patient meets the FDA-approved age minimum for the requested medication **ADDITIONAL CRITERIA FOR BRONCHITOL** ○ Bronchitol must be used as an add-on maintenance therapy ○ Patients must have passed the Bronchitol Tolerance Test **ADDITIONAL CRITERIA FOR KALYDECO, ORKAMBI, SYMDEKO AND TRIKAFTA** ○ Patient has documentation (must include with PA request) of the genetic mutation(s) that the FDA approved the requested medication to treat **REAUTHORIZATION CRITERIA:** Chart notes submitted with stabilization OR improvement of FEV1 AND with one or more of the following: ○ Stabilization or improvement of weight gain ○ Stabilization or improvement in sweat chloride ○ Decrease in the number of pulmonary exacerbations or their severity ○ Decrease in the number or severity of pulmonary infections ○ Decrease in the number of hospitalizations ○ Increased Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score ○ Other documentation by the physician clearly explaining the ongoing benefit of continuing the drug based on stated and documented objective evidence of improvement or a clear stabilization in a previous decline in one of the above parameters
Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-Ige	**ADDITIONAL CRITERIA FOR OMALIZUMAB (XOLAIR)** Indicated for **chronic urticaria** if: o Patient has tried and failed two 14-day trials with two different antihistamines ○ Prescribed by or in consultation with a dermatologist or allergist/immunologist o Prescribed in accordance with its FDA approved labeling Indicated for **chronic rhinosinusitis with nasal polyposis** if: ○ Patient is 18 years of age or older ○ Patient had an inadequate response, intolerance or contraindication to one oral corticosteroid ○ Patient had a 30-day trial and experienced an inadequate response, intolerance or contraindication to one nasal corticosteroid spray
Respiratory Agents: Other Agents	**LENGTH OF AUTHORIZATIONS**: For the date of service only; Daliresp evaluated with each refill **PRIOR AUTHORIZATION CRITERIA:** 1. Daliresp must be used with a long-acting beta agonist or long-acting muscarinic antagonists 2. Daliresp evaluated with each refill

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REVISED THERAPEUTIC CATEGORIES
Blood Formation, Coagulation, and Thrombosis Agents: Oral Anticoagulants
Blood Formation, Coagulation, and Thrombosis Agents: Oral Antiplatelet
Gastrointestinal Agents: Crohn's Disease