Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: April 1, 2022

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**PA REQUIRED NON-PREFERRED**
Cardiovascular Agents: Angina, Hypertension, and Heart Failure	Kerendia
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute	Trudhesa
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis	Qulipta
Central Nervous System (CNS) Agents: Atypical Antipsychotics*	Lybalvi
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	Azstarys
Central Nervous System (CNS) Agents: Skeletal Muscle Relaxants, Non-Benzodiazepine	Ozobax
Dermatological: Topical Acne Products	Winlevi
Gastrointestinal Agents: Unspecified GI	Aemcolo
Genitourinary Agents: Urinary Antispasmodics	Myrbetriq Granules
Infectious Disease Agents: Antifungals	Brexafemme
Topical Agents: Immunomodulators	Opzelura

NEW CLINICAL PA REQUIRED PREFERRED DRUGS	
THERAPEUTIC CLASS	**CLINICAL CRITERIA REQUIRED PREFERRED**
Central Nervous System (CNS) Agents: Atypical Antipsychotics*	Invega Hafyera ER

NEW STEP THERAPY PREFERRED DRUGS	
THERAPEUTIC CLASS	**STEP THERAPY REQUIRED PREFERRED**
Gastrointestinal Agents: Hepatic Encephalopathy	Xifaxan
Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea	Xifaxan
Gastrointestinal Agents: Unspecified GI	Xifaxan

THERAPEUTIC CATEGORIES WITH CHANGES IN CRITERIA
Cardiovascular Agents: Angina, Hypertension, and Heart Failure
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis
Central Nervous System (CNS) Agents: Atypical Antipsychotics*
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents
Dermatological: Topical Acne Products
Genitourinary Agents: Urinary Antispasmodics
Topical Agents: Immunomodulators

Dąte of Notice: 3/1/2022

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CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Cardiovascular Agents: Angina, Hypertension, and Heart Failure	**KERENDIA CRITERIA:** 1. Patient must meet all the following criteria: ○ A diagnosis of Chronic Kidney Disease due to Type 2 Diabetes ○ Be on maximum tolerated dose of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker ○ Allergy, intolerance, or inadequate response to an SGLT2 Inhibitor
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute	Nurtec ODT quantity limit is 8 per 30 days
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis	**AUTHORIZATION CRITERIA:** □ Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: ○ Allergy to preferred medications ○ Contraindication to three preferred medications ○ History of unacceptable/toxic side effects/intolerance to at least three preferred medications **NON-PREFERRED MEDICATION:** □ For a non-preferred medication drug there must have been inadequate clinical response to a trial of at least 30 days each to at least three controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors) AND an inadequate clinical response or intolerance to a trial of at least 30 days of one step therapy required preferred medication Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control (such as headache diary or attestation of ongoing efficacy from provider).
Central Nervous System (CNS) Agents: Atypical Antipsychotics*	**ADDITIONAL CRITERIA FOR INVEGA HAFYERA ER:** 1. Treatment with 4 months of Invega Sustenna or 3 months of Invega Trinza before starting Invega Hafyera. **ADDITIONAL CRITERIA FOR LYBALVI:** 1. Patient must not be using opioids. 2. Patient must not be undergoing acute opioid withdrawal.
Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents	**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 at least two medications not requiring prior approval □ Contraindication to all medications not requiring prior approval □ History of unacceptable/toxic side effects to at least two medications not requiring prior approval □ Has the patient failed a therapeutic trial of at least 14 days with at least two medications not requiring prior approval?

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CHANGES IN CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Dermatological: Topical Acne Products	**PRIOR AUTHORIZATION CRITERIA:** Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include: • Allergy to all medications not requiring prior approval • Contraindication to or drug-to-drug interaction with medications not requiring pri approval • History of unacceptable/toxic side effects to medications not requiring prior approval • Inadequate response to no less than a 30-day trial of at least three (3) medications not requiring prior approval
Genitourinary Agents: Urinary Antispasmodics	AR – Vesicare LS: PA is not required for patients 2-5 years of age. AR – Myrbetriq Sol: PA is not required for patients that are 3-5 years of age.

Topical Agents: Immunomodulators	**CLINICAL INFORMATION**
	• Indicated for short-term and intermittent long-term treatment of atopic dermatitis if:
	  ○ Alternative, conventional therapies (such as topical corticosteroids) are deemed inadvisable because of potential risks, or
	  ○ There has been inadequate response or intolerance to alternative, conventional therapies (such as topical corticosteroids)
	• Elidel and Protopic 0.03% are indicated in patients 2 years old or older. Protopic 0.1% is indicated in adults only.
	• Opzelura is contraindicated for use in immunocompromised patients

REVISED THERAPEUTIC CATEGORY CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Cardiovascular Agents: Lipotropics	<table><tr><td>**Trial period**</td><td>30 days for HMG-CoA Reductase Inhibitors, Niacin derivatives, ezetimibe (Zetia), 90 days for Fibrates, and 84 days for ATP Citrate Lyase (ACL) Inhibitors</td></tr><tr><td>**Number of non-PA agents**</td><td>1 medication – The assumption is that the medication must be in the same class of the medication requested, if available, except for HMG-CoA reductase inhibitors- see specific criteria</td></tr></table> **ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS** • For Repatha: Age ≥18 years with ASCVD or Age ≥10 years and Familial Hypercholesterolemia (FH) **OR** for Praluent: Age ≥18 years with ASCVD or FH **AND** • Documented adherence to prescribed lipid lowering medications for previous 90 days Baseline lab results are required, and approvals will be for 365 days. Subsequent approvals will require additional levels being done to assess changes. Diagnosis of Familial Hypercholesterolemia (includes Heterozygous [HeFH] and Homozygous [HoFH]) **AND** must meet all:

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REVISED THERAPEUTIC CATEGORY CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
	1. Unable to reach goal LDL-C (LDL ≤ 100mg/dL for adults or LDL ≤ 110mg/dL for those < 18 years of age) with maximally tolerated dose of statin and ezetimibe (Zetia) o A trial of 2 or more high potency statins (atorvastatin or rosuvastatin) Diagnosis of Clinical Atherosclerotic Cardiovascular Disease (ASCVD) **AND** must meet both: 1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD or atherosclerotic origin and 2. Unable to reach goal LDL-C (LDL ≤ 70mg/dL) with maximally tolerated dose of statin and ezetimibe (Zetia) o A trial of 2 or more high potency statins (atorvastatin or rosuvastatin)

NEW THERAPEUTIC CATEGORIES
Gastrointestinal Agents: Hepatic Encephalopathy
Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea
Gastrointestinal Agents: Unspecified GI

NEW THERAPEUTIC CATEGORY CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
Gastrointestinal Agents: Hepatic Encephalopathy	**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 medication not requiring prior approval - Contraindication to or drug interaction with medication not requiring prior approval - History of unacceptable/toxic side effects to medication not requiring prior approval **STEP THERAPY:** all agents listed 1. For a drug requiring step therapy, there must have been inadequate clinical response to a preferred alternative 2. XIFAXAN requires a diagnosis of hepatic encephalopathy and may be approved for monotherapy or add on therapy if there has been a therapeutic failure (defined as a recurrent episode) while on lactulose
Gastrointestinal Agents: Irritable Bowel Syndrome (IBS) with Diarrhea	**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

NEW THERAPEUTIC CATEGORY CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
	▯ History of unacceptable/toxic side effects to medications not requiring prior approval **STEP THERAPY:** all agents listed 1. For a drug requiring step therapy, there must have been inadequate clinical response to a preferred alternative 2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 14-days of at least one step therapy product
Gastrointestinal Agents: Unspecified GI	**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 **STEP THERAPY:** all agents listed 1. For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including no less than a 14-day trial of at least two medications not requiring prior approval 2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including no less than 14-day trial of at least three preferred products including one step therapy product **ADDITIONAL INFORMATION:** 1. Patient must be 18 years or older 2. ZORBTIVE and GATTEX require a diagnosis of short bowel syndrome (SBS) and evidence of specialize nutritional support a. GATTEX requires evidence of parenteral nutrition support at least three times per 7 days and appropriate colonoscopy and lab assessment (bilirubin, alkaline phosphatase, lipase, and amylase) 180 days prior to initiation b. Re-authorization of these therapies requires evidence of improved condition (i.e. as measured by total volume, total calories, or decreased frequency of specialized nutrition support) 3. MYTESI requires a diagnosis of non-infectious diarrhea and evidence of concurrent HIV antiviral therapy a. MYTESI will be limited to no more than 2 tablets per day 4. RELISTOR and SYMPROIC require a history of chronic pain requiring continuous opioid therapy for 84 days or longer. Electronic PA will approve with a history of 90 days of opioid therapy in the previous 90 days, in addition to trials of preferred products 5. AEMCOLO initial approval criteria for Travelers' Diarrhea (TD) (must meet all):

NEW THERAPEUTIC CATEGORY CRITERIA	
THERAPEUTIC CLASS	**SUMMARY OF CHANGE**
	a. Diagnosis of TD b. Inability to take, or failure of, any of the following: ○ Azithromycin (generic Zithromax) ○ Ciprofloxacin (generic Cipro) ○ Levofloxacin (generic Levaquin) ○ Ofloxacin (generic Floxin) ○ Xifaxan (rifaximin) c. Approval duration is 3 days