Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

NEW PREFERRED DRUGS	
THERAPEUTIC CLASS	**NO PA REQUIRED PREFERRED**
Central Nervous System (CNS) Agents: Anticonvulsants	VALTOCO® (diazepam)

NEW CLINICAL PA REQUIRED "PREFERRED" DRUGS	
THERAPEUTIC CLASS	**CLINICAL PA REQUIRED PREFERRED**
Blood Formation, Coagulation, and Thrombosis Agents: Colony Stimulating Factors	ZIEXTENZO™ (pegfilgrastim-mez)

NEW STEP THERAPY REQUIRED "PREFERRED"	
THERAPEUTIC CLASS	**STEP THERAPY REQUIRED "PREFERRED"**
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute	NURTEC™ ODT (rimegepant)

NEW NON-PREFERRED DRUGS	
THERAPEUTIC CLASS	**PA REQUIRED NON-PREFERRED**
Analgesic Agents: Gout	GLOPERBA® solution (colchicine)
Blood Formation, Coagulation, and Thrombosis Agents: Hemophilia Factors	ESPEROCT® (antihemophilic factor- recombinant, glycopegylated-exei)
Cardiovascular Agents: Lipotropics	NEXLETOL™ (bempedoic acid) NEXLIZET™ (bempedoic acid and ezetimibe)
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute	REYVOW™ (lasmiditan) UBRELVY™ (ubrogepant)
Central Nervous System (CNS) Agents: Atypical Antipsychotics	CAPLYTA™ (lumateperone) SECUADO® (asenapine)
Central Nervous System (CNS) Agents: Multiple Sclerosis	VUMERITY™ (diroximel fumarate)
Dermatological: Topical Acne Products	AKLIEF® cream (trifarotene) AMZEEQ® foam (minocycline) ARAZLO™ lotion (tazarotene)
Endocrine Agents: Androgens	JATENZO® (testosterone undecanoate)
Endocrine Agents: Diabetes – Non-Insulin	TRIJARDY® XR (empagliflozin/linagliptin/metformin)

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

THERAPEUTIC CATEGORIES WITH CHANGES IN CRITERIA
Analgesic Agents: Gout
Cardiovascular Agents: Lipotropics
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Cluster Headache
Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis

Please see below for the criteria changes

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

Analgesic Agents: Gout

LENGTH OF AUTHORIZATIONS: 365 Days

Is there any reason the patient cannot be changed to an agent not requiring prior approval?
Acceptable reasons include:

- Allergy to medications not requiring prior approval
- Contraindication to or drug-to-drug interaction with medications not requiring prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL INFORMATION

The requested medication may be approved if the following is true:

- Febuxostat will be approved after 30-day trial of maximum allopurinol dose, or intolerance/contraindication to allopurinol.
- Lesinurad will be approved when target serum uric acid levels (<6mg/dL) are not achieved on appropriate dose of xanthine oxidase inhibitor alone for at least 90 days and the treatment plan includes ongoing use of an appropriate dose of xanthine oxidase inhibitor
    - Appropriate dose of xanthine oxidase inhibitors:
        - Allopurinol: 300mg daily (200mg daily in patients with eCrCl <60mL/min)
        - Febuxostat: 80mg daily

  Use of the combination tablet of lesinurad and allopurinol will be limited to those cases where lesinurad has already demonstrated that the patient has reached their target serum uric acid levels
- Colchicine will be approved if any one of the following is true:
    - Diagnosis of Familial Mediterranean Fever (FMF) (180-day approval); OR
    - Trial of one of the following within the last 30 days:
        - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
        - Oral corticosteroid
- Gloperba® will be approved if the member is unable to swallow colchicine tablets or capsules and if all of following are met:
    - Member is using Gloperba for the prevention of gout flares
    - Trial of one of the following within the last 30 days:
        - NSAID (i.e., indomethacin, naproxen, ibuprofen, sulindac, ketoprofen)
        - Oral corticosteroid

ANALGESIC AGENTS: GOUT – Agents to Reduce Hyperuricemia

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALLOPURINOL (generic of Zyloprim®) PROBENECID (generic for Benemid®) PROBENECID-COLCHICINE	ULORIC® (febuxostat)

ANALGESIC AGENTS: GOUT – Analgesic Agents*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
COLCHICINE tablets (generic of Colcrys®) COLCHICINE capsules (generic of Mitigare®)	GLOPERBA® solution (colchicine)

* Colchicine quantity limit 6/claim for acute gout, 60/30 days for chronic gout after trial on xanthine oxidase inhibitor, 120/30 days for FMF

* Gloperba quantity limit is 1.2 mg per day

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

Cardiovascular Agents: Lipotropics

LENGTH OF AUTHORIZATIONS: 365 days all Lipotropics except Omega-3 Fatty Acid 60 days for Omega-3 Polyunsaturated Fatty Acid

Trial period	30 days for HMG-CoA Reductase Inhibitors, Niacin derivatives, ezetimibe (Zetia®), 90 days for Fibrates
Number of non-PA agents	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

GENERAL GUIDELINES:

- 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-to-drug interaction with medications not requiring prior approval (pravastatin is the only HMG-CoA not metabolized by the cytochrome P450 liver enzyme system)
  - History of unacceptable/toxic side effects to medications not requiring prior approval
- If there has been a therapeutic failure to no less than two of the HMG-CoA preferred products for a 30-day trial, then a non-preferred HMG-CoA agent will be authorized.

ADDITIONAL CRITERIA FOR OMEGA-3 POLYUNSATURATED FATTY ACID AND ICOSAPENT ETHYL (LOVAZA®, VASCEPA®):

- Prescription only omega-3 polyunsaturated fatty acid and icosapent ethyl are approvable only for adult patients with triglyceride levels equal to or greater than 500 mg/dL who have been unable to lower triglyceride levels with fibrates, niacin, or lifestyle changes including diet and exercise.
- Medications known to increase triglycerides (beta blockers, thiazides, and estrogens) must be discontinued or changed, if clinically appropriate, before the drug is approved. Initial approval will be for 60 days, with evidence of reduced triglycerides required for re-approval.

ADDITIONAL CRITERIA FOR COLESEVELAM (WELCHOL®):

- Colesevelam may be approved as first-line therapy if there is a diagnosis of diabetes
- Will be approved through systematic PA if there is a history of an oral hypoglycemic or insulin in the previous 120 days

ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS:

- All products in this class require clinical prior authorization:
  - Age ≥18 years or Age ≥ 13 years and Homozygous Familial Hypercholesterolemia (HoFH)
  - Documented adherence to prescribed lipid lowering medications for previous 90 days

Baseline lab results are required, and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes.

- Lipid profile required at week 8 for HeFH or ASCVD
- Lipid profile required after 3rd dose for HoFH

Date of Notice: 8/14/2020

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
   - Presence of tendon xanthomas or 1st or 2nd degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290 mg/dL **OR**
   - Confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
   - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease: must meet both:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin and
2. Unable to reach goal LDL-C with maximally tolerated dose of statin
   - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH): must meet all:

1. Total cholesterol and LDL-C >600 mg/dL and TG within reference range or confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia®) 10 mg daily with at least 1 other concurrently administered lipid lowering agent
3. Age ≥ 13 years old

ADDITIONAL CRITERIA FOR ATP Citrate Lyase (ACL) Inhibitor:

- All products in this class require clinical prior authorization:
  - Age ≥18 years
  - Unable to reach goal LDL-C after a trial of 2 or more statins (one must be atorvastatin) at the maximally tolerated dose
    - Nexlizet™ (bempedoic acid and ezetimibe tablet) approval requires one of the previous statin trials to be in combination with ezetimibe (Zetia®)
    - Documented adherence to prescribed lipid lowering medications for previous 90 days Baseline lab results are required, and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes
    - Lipid profile required at week 8 for HeFH or ASCVD

Diagnosis of Heterozygous Familial Hypercholesterolemia (HeFH): must meet both:

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following:
   - Presence of tendon xanthomas or 1st or 2nd degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290 mg/dL **OR**
   - Confirmation of diagnosis by gene or receptor testing

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

CARDIOVASCULAR AGENTS: LIPOTROPICS - ATP Citrate Lyase (ACL) Inhibitor

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	NEXLETOL™ (bempedoic acid) NEXLIZET™ (bempedoic acid and ezetimibe)

CARDIOVASCULAR AGENTS: LIPOTROPICS – BILE ACID SEQUESTRANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CHOLESTYRAMINE LIGHT POWDER (generic of Questran Light®) CHOLESTYRAMINE POWDER (generic of Questran®) COLESTIPOL tablets (generic of Colestid® tablets) PREVALITE® POWDER (cholestyramine)	COLESTIPOL granules (generic of Colestid® granules) WELCHOL® packets (colesevelam) WELCHOL® tablets (colesevelam)

CARDIOVASCULAR AGENTS: LIPOTROPICS - STATINS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATORVASTATIN (generic of Lipitor®) LOVASTATIN (generic of Mevacor®) PRAVASTATIN (generic of Pravachol®) ROSUVASTATIN (generic of Crestor®) SIMVASTATIN (generic of Zocor®)	ALTOPREV® (lovastatin) EZALLOR™ SPRINKLE (rosuvastatin) FLUVASTATIN (generic of Lescol®, Lescol XL®) LIVALO® (pitavastatin) ZYPITAMAG™ (pitavastatin)

CARDIOVASCULAR AGENTS: LIPOTROPICS - FIBRIC ACID DERIVATIVES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FENOFIBRATE TABLETS (generic of Tricor®) GEMFIBROZIL (generic of Lopid®)	ANTARA® (fenofibrate micronized capsules) FENOFIBRATE CAPSULES (generic of Lipofen®) FENOFIBRIC ACID CAPSULES (generic of Trilipix®) FENOFIBRIC ACID TABLETS (generic of Fibricor®) LOFIBRA® (fenofibrate micronized capsules) TRIGLIDE® (fenofibrate tablets)

CARDIOVASCULAR AGENTS: LIPOTROPICS - NICOTINIC ACID DERIVATIVES

NO PA REQUIRED PREFERRED"	PA REQUIRED "NON-PREFERRED"
NIACIN	NIACIN ER (generic of Niaspan®)

CARDIOVASCULAR AGENTS: LIPOTROPICS - OMEGA-3 POLYUNSATURATED FATTY ACIDS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
OMEGA 3-ACID ETHYL ESTERS (generic of Lovaza®)	VASCEPA® (icosapent ethyl)

CARDIOVASCULAR AGENTS: LIPOTROPICS - SELECTIVE CHOLESTEROL ABSORPTION INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EZETIMIBE (generic of ZETIA®)	SIMVASTATIN/EZETIMIBE (generic for Vytorin®)

CARDIOVASCULAR AGENTS: LIPOTROPIC/HYPERTENSION COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Inability to utilize agents separately	AMLODIPINE/ATORVASTATIN (generic of Caduet®)

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

CARDIOVASCULAR AGENTS: LIPOTROPICS PCSK9 INHIBITORS*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	PRALUENT® (alirocumab) REPATHA™ (evolocumab)

* Note: Clinical criteria must be met

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Acute

LENGTH OF AUTHORIZATIONS: 180 Days

APPROVAL 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 all preferred medications
  - History of unacceptable/toxic side effects to at least two preferred medications
- **STEP THERAPY APPROVAL CRITERIA:**
  - For a drug requiring step therapy, there must have been inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least two medications not requiring prior approval
  - For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of at least two weeks with at least one medication requiring step therapy

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

CNS AGENTS: ANTI-MIGRAINE AGENTS – ACUTE MIGRANE TREATMENT

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
NARATRIPTAN (generic of Amerge®) RIZATRIPTAN tablets (generic of Maxalt®) RIATRIPTAN ODT (generic of Maxalt-MLT®) SUMATRIPTAN tablets, nasal spray, injection (generic of Imitrex®)	NURTEC™ ODT (rimegepant)	ALMOTRIPTAN (generic of Axert®) CAFERGOT® (ergotamine w/caffeine) ELETRIPTAN (generic of Relpax®) ERGOMAR® (ergotamine) FROVA® (frovatriptan) MIGERGOT® (ergotamine w/caffeine) MIGRANAL® (dihydroergotamine) ONZETRA™ XSAIL™ (sumatriptan) REYVOW™ (lasmiditan) SUMAVEL DOSEPRO® (sumatriptan) TOSYMRA® (sumatriptan) TREXIMET® (sumatriptan/naproxen) UBRELVY™ (ubrogepant) ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan)

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Cluster Headache

LENGTH OF AUTHORIZATIONS: 180 Days

APPROVAL 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 all preferred medications
  - History of unacceptable/toxic side effects to at least one preferred medication

ADDITIONAL CRITERIA FOR EPISODIC CLUSTER HEADACHE

1. At least 5 attacks within 30 days
2. Attacks characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes when untreated; during part (but less than half) of the time-course of cluster headache, attacks may be less severe and/or of shorter or longer duration
3. Patient must have one or more of the following symptoms:
   a) At least one of the following ipsilateral to the headache:
      I. Conjunctival injection and/or lacrimation
      II. Nasal congestion and/or rhinorrhea
      III. Eyelid edema
      IV. Forehead and facial sweating
      V. Miosis and/or ptosis
   b) A sense of restlessness or agitation
4. Attacks have a frequency between one every other day and eight per day; during part (but less than half) of the active time-course of cluster headache, attacks may be less frequent
5. Not better accounted for by another ICHD-3 diagnosis
6. At least two cluster periods lasting from seven days to one year (when untreated) and separated by pain-free remission periods of 90 days or more
7. Failure or intolerance to verapamil titrated at least to a dose of 480 mg daily (may need to be combined with glucocorticoids as adjunctive therapy for more rapid relief until verapamil is titrated)

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

CNS AGENTS: ANTI-MIGRAINE AGENTS – CLUSTER HEADACHE TREATMENT

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
VERAPAMIL (Generic of Calan®) VERAPAMIL SR/ER (Generic of Calan SR®, Isoptin SR®, Verelan®)	EMGALITY™ (galcanezumab)

Date of Notice: 8/14/2020

Ohio | Department of Medicaid

30 Day Change Notice
Effective Date: October 1st, 2020

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis

LENGTH OF AUTHORIZATIONS: Initial Authorization 180 days
Subsequent Authorizations 365 days

APPROVAL 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 to at least three preferred medications

ADDITIONAL CRITERIA FOR EPISODIC MIRGRAINE PROPHYLAXIS:

1. Patient must have a diagnosis of episodic migraine with the following frequencies of migraine:
   - 4-15 headaches per 30 days measured over 90 consecutive days and headache duration of longer than 4 hours per day or longer during an attack on average.
2. Prior Authorization may be approved if the patient has failed a trial of at least 30 days each to at least 3 controller migraine medications or has experienced contraindications or intolerance to them (i.e., beta-blockers, anticonvulsants, tricyclic antidepressants, and/or serotonin-norepinephrine reuptake inhibitors).
3. Initial authorization will be limited to 180 days. Re-authorization for 365 days will be allowed based upon evidence of improved headache control. Re-authorization requests may be managed in consultation with a specialist.

ADDITIONAL INFORMATION

In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per month is restricted based on the manufacturer's package insert.

CNS AGENTS: ANTI-MIGRAINE AGENTS – PROPHYLAXIS TREATMENT

NO PA REQUIRED "PREFERRED" (Trails of at least 3 controller medications)	PA REQUIRED "NON-PREFERRED"
Cardiovascular Agents: Beta-blockers CNS Agents: Anticonvulsants CNS Agents: Serotonin-norepinephrine reuptake inhibitors CNS Agents: Tricyclic antidepressants	AIMOVIG™ (erenumab-aooe) † AJOVY™ (fremanezumab-vfrm) * EMGALITY™ (galcanezumab)

†Initial Dose is limited to 70mg once monthly; may request dose increase if 70mg fails to provide adequate relief over two consecutive months.

* 675mg doses (quarterly administration) will not be authorized until patient has demonstrated efficacy of medication for at least 90 days.

Date of Notice: 8/14/2020