Ohio | Department of Medicaid

# 30 Day Change Notice
# Effective Date: July 1, 2022

| NEW NON-PREFERRED DRUGS | |
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| **THERAPEUTIC CLASS** | **PA REQUIRED NON-PREFERRED** |
| **Analgesic Agents: NSAIDs** | Elyxyb |
| **Endocrine Agents: Growth Hormone** | Skytrofa |
| **Ophthalmic Agents: Dry Eye Treatments** | Tyrvaya |
| **Dermatological: Oral Acne Products** | Absorica<br>Absorica LD |
| **Cardiovascular Agents: Lipotropics** | Juxtapid |

| NEW PREFERRED DRUGS | |
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| **THERAPEUTIC CLASS** | **NO PA REQUIRED PREFERRED** |
| **Central Nervous System (CNS) Agents: Anticonvulsants** | Eprontia |

| NEW CLINICAL PA REQUIRED PREFERRED DRUGS | |
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| **THERAPEUTIC CLASS** | **CLINICAL CRITERIA REQUIRED PREFERRED** |
| **Dermatological: Oral Acne Products** | Accutane<br>Amnesteem<br>Clavaris<br>Isotretinoin<br>Myorisan<br>Zenatane |

| THERAPEUTIC CATEGORIES WITH CHANGES IN CRITERIA |
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| **Cardiovascular Agents: Lipotropics** |
| **Central Nervous System (CNS) Agents: Anticonvulsants** |
| **Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis** |
| **Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction** |
| **Endocrine Agents: Growth Hormone** |
| **Ophthalmic Agents: Dry Eye Treatments** |
| **Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE** |

| REVISED THERAPEUTIC CATEGORY CRITERIA | |
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| **THERAPEUTIC CLASS** | **SUMMARY OF CHANGE** |
| **Cardiovascular Agents: Lipotropics** | **ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS**<br>□ 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~~ drawn to assess ~~changes~~ response to treatment from baseline and/or attestation of clinical stabilization and will be for 365 days.

Diagnosis of Familial Hypercholesterolemia (includes Heterozygous FH and Homozygous FH) **AND** must meet all:

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)

**ADDITIONAL CRITERIA FOR LOMITAPIDE (JUXTAPID):**

- Age ≥18 years **AND**
- Diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) **AND**
- At least a 90-day trial **AND** unable to reach goal LDL-C (LDL ≤ 100mg/dL) with high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 inhibitor (or a clinical reason that these medications cannot be utilized)

Baseline lab results are required, and initial approval will be for 180 days. Subsequent approvals will require additional levels drawn to assess response to treatment from baseline and/or attestation of clinical stabilization and will be for 365 days.

**ADDITIONAL CRITERIA FOR ATP Citrate Lyase (ACL) Inhibitor:**

All products in this class require clinical prior authorization:

- Age ≥18 years **AND**
- A trial and failure with one PCSK9 inhibitor **AND**
- Documented adherence to prescribed lipid lowering medications for previous 90 days **AND**
- 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

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| | with ezetimibe (Zetia)<br><br>Baseline lab results are required, and initial approval will be for 84 days. Subsequent approvals will require additional levels ~~being done~~ drawn to assess ~~changes~~ response to treatment from baseline and/or attestation of clinical stabilization and will be for 365 days.<br>• ~~Lipid profile required at 56 days for HeFH or ASCVD~~ |
| **Central Nervous System (CNS) Agents: Anticonvulsants** | **NON-PREFERRED MEDICATION:**<br>For a non-preferred medication, there has been a therapeutic failure to no less than two preferred products for a 30-day trial each. Prescriptions submitted with the prescriber NPI of a physician who has registered as a neurology specialty with Ohio Medicaid AND for products that are used only for seizures, require a trial of one preferred product for 30 days. This provision applies only to the standard tablet/capsule dosage form and does not apply to brand products with available generic alternatives.<br><br>AR – Eprontia solution: a PA is required for patients 12 years and older |
| **Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis** | **ADDITIONAL CRITERIA FOR MIGRAINE PROPHYLAXIS:**<br>1. Patient must have one of the following diagnoses:<br>a. **Episodic** migraine with the following frequencies of migraine:<br>I. 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.<br>b. **Chronic** migraine with the following frequencies of migraine:<br>I. 15 or more 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<br>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).<br>3. Initial authorization will be limited to 180 days with objective documentation of severity, frequency, and number of headache days per month (preferably a headache diary).<br>4. Re-authorization for 365 days will be allowed based upon evidence of improved headache control (preferably a headache diary or other objective documentation of severity, frequency, and number of headache days per month).<br><br>**ADDITIONAL INFORMATION**<br>In addition to utilizing a preferred agent when applicable, the number of tablets/doses allowed per 30 days is restricted based on the manufacturer's package insert.<br>* Nurtec ODT quantity limit is 18 per 30 days for prophylactic treatment |

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| **Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction** | **BUPRENORPHINE SAFETY EDITS AND DRUG UTILIZATION REVIEW CRITERIA:** In favor of eliminating prior authorization for all forms of oral short acting buprenorphine- containing products, ODM and the Managed Care Plans will implement safety edits and a retrospective drug utilization review process for all brand and generic forms of oral short acting buprenorphine-containing products. Safety edits are in place for dosages over 24mg of buprenorphine equivalents/day. |
| **Endocrine Agents: Growth Hormone** | **LENGTH OF AUTHORIZATIONS**: Varies as listed below.<br><br>**PRIOR AUTHORIZATION CRITERIA:**<br>Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:<br>• Allergy to all medications not requiring prior approval<br>• Contraindication to or drug-to-drug interaction with medications not requiring prior approval.<br>• History of unacceptable/toxic side effects to medications not requiring prior approval<br>~~**NOTE:**~~<br>~~• All products in this class require clinical prior authorization~~<br>~~• Must meet the below clinical criteria for approval~~<br>~~• Must be treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist or gastroenterologist (as appropriate for diagnosis)~~<br>~~• All information and documentation requested on the prior authorization form to justify criteria being met, including height, weight, bone age (children), date of most current x- ray, stimulus test results, IGF-1 levels and a growth chart (children) must be supplied.~~<br><br>**NON-PREFERRED MEDICATION:**<br>• For a non-preferred medication drug, ~~there The requested medication may be approved if the following is true: If~~ there must have ~~has~~ been a therapeutic failure to no less than a 90-day trial of at least one preferred medication or a medically valid reason for not being able to take a preferred medication.<br><br>**CLINICAL CRITERIA**<br>**Pediatric Approvals (under 18 years of age):**<br>Initial Approvals - based on diagnoses below<br>Reauthorization: 365 days - Must provide documentation that the patient's health status has improved since last approval (i.e., height, weight gain, improved body composition)<br><br>~~Children - initial approval for the following diagnoses:~~<br>Patient must have **ONE** of the following diagnoses:<br><br>**1. Growth Hormone Deficiency (GHD)** – 180-day approval:<br>1) Standard deviation of 2.0 or more below mean height for chronological age; AND |

~~2) No expanding intracranial lesion or tumor diagnosed; AND~~
~~3) Growth rate is:~~
~~1. Below five (5) centimeters per year; OR~~
~~2. Below ten (10) centimeters per year in children under 3 years of age or; OR~~
~~3. Below ten (10) centimeters per year during puberty AND~~
4) Failure of any two stimuli test to raise the serum growth hormone level above 10 nanograms/milliliter; ~~AND~~
~~5) Epiphyses must be open; AND~~
~~6) Bone age 15-16 years or less in females and 16-17 years or less in males~~
~~7) Females with bone age >16 and males with bone age >17 may be approved for maintenance therapy (approval for 365 days) upon request by an endocrinologist. (Maintenance dose is typically 50% of dose used to improve height)~~

2. **Growth Retardation of Chronic Kidney Disease** – 365-day approval:
1) Standard deviation of 2.0 or more below mean height for chronological age; AND
~~2) No expanding intracranial lesion or tumor diagnosed; AND~~
~~3) Growth rate below five (5) centimeters per year; AND~~
4) Irreversible renal insufficiency with a glomerular filtration rate less than 75 ml/min per 1.73m$^2$ but pre-renal transplant; ~~AND~~
~~5) Bone age 14-15 years or less in females and 15-16 years or less in males; AND~~
~~6) Epiphyses open~~.

3. **Genetic diagnosis** – 365-day approval:
1) One of the following: (a) Krause-Kivlin Syndrome; ~~or~~ (b) Turner Syndrome; ~~or~~ (c) Prader-Willi Syndrome; ~~or~~ (d) Noonan Syndrome
~~2) Bone age between 14-15 years; **AND**~~
~~3) Epiphyses open; **AND**~~
~~4) Growth rate below five (5) centimeters per year~~

4. **Neurosecretory Growth Retardation** – 180-day approval
1) Standard deviation of 2.0 or more below mean height for chronological age; AND
~~2) No expanding intracranial lesion or tumor diagnosed; AND~~
~~3) Growth rate below five (5) centimeters per year; AND~~
~~4) Bone age 14-15 years or less in females and 15-16 years or less in males; AND~~
~~5) Epiphyses open; AND~~
6) Mixed or normal response to any two (2) stimuli test in raising serum growth hormone above 10 nanograms/milliliter.

5. **Idiopathic Short Stature** – 180-day approval
1) A standard deviation of 2.25 or more below mean height for chronological age; AND
~~2) No expanding intracranial lesion or tumor diagnosed; AND~~
~~3) Growth rate is below five (5) centimeters per year; AND~~
~~4) Bone age is 14-15 years or less in females and 15-16 years or less in males and epiphyses are open; AND~~

5) A mixed or normal response to any two stimuli tests in raising serum growth hormone above 10 nanograms/milliliter~~; AND~~
~~6) The child is proportionally shorter than the predicted rate of growth from the parent's height; AND~~
~~7) Requests must come from a pediatric endocrinologist.~~

6. **Small for Gestational Age (SGA)** – 365-day approval
~~1) Request must come from a pediatric endocrinologist; AND~~
2) Documentation to support diagnosis defined as birth weight or length 2 or more standard deviations below the mean for gestational age AND
3) Child fails to manifest catch up growth before 2 years of age, defined as height 2 or more standard deviations below the mean for age and gender.
~~4) Note:~~ Review must include evaluation of growth curves from birth

**AND ALL** of the following:

1. Must be treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist, or gastroenterologist (as appropriate for diagnosis)
2. Must provide documentation to justify criteria being met, including height, weight, bone age (children), date and results of most current x- ray, stimulus test results, IGF-1 levels and a growth chart (children).
3. The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)
4. Not being used in combination with another somatropin agent

~~Reauthorization: The patient health status has improved since last approval (weight gain, improved body composition) 1-year approval~~

~~Adults - initial approval for 180 days:~~
**Adult Approvals (18 years of age or older):**
Initial Approvals: 180 days
Reauthorization: 365 days – must provide documentation by endocrinologist that discontinuing agent would have a detrimental effect on body composition or other metabolic parameters.

~~Adult patients with growth hormone deficiency may be approved for replacement of endogenous growth hormone upon documentation of medical necessity from an endocrinologist. Requests will be reviewed and approved based upon the following conditions:~~
Patients must have ONE of the following diagnoses along with documentation of medical necessity from an endocrinologist:

1) Childhood Onset - Patients who were growth hormone deficient during childhood and who have a continued deficiency which is confirmed by provocative testing.
2) Adult Onset - Patients who have growth hormone deficiency, either alone or with multiple pituitary hormone deficiencies, such as hypopituitarism, as

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| | a result of pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma.<br><br>~~Criteria for Approval for both conditions listed above:~~<br>**AND ALL** of the following:<br>1) Biochemical diagnosis of growth hormone deficiency by means of a negative response to an appropriate stimulation test ordered by the endocrinologist (Clonidine test is not acceptable for adults.)<br>~~2) No evidence of malignancy or other contraindication; AND~~<br>2) Base-line evaluation of the following clinical indicators: (1) insulin-like growth factor (IGF-1); (2) fasting lipid profile; (3) BUN; (4) fasting glucose; (5) electrolyte levels; (6) evaluation of any new osteoarthritis and joint pain; (7) bone density test<br>3) The patient does not have any FDA labeled contraindication(s) to therapy with the requested agent (i.e., closed epiphyses, no expanding intracranial lesion or tumor diagnosed, etc)<br>4) Other hormonal deficiencies addressed with adequate replacement therapy;~~ AND~~<br>~~4) Base-line evaluation of the following clinical indicators~~<br>~~a. Insulin-like growth factor-1 (IGF-1) also required following dosage change~~<br>~~b. Fasting lipid profile~~<br>~~c. BUN~~<br>~~d. Fasting glucose~~<br>~~e. Electrolyte levels~~<br>~~f. Evaluation of any new osteoarthritis and joint pain~~<br>~~g. Bone density test~~<br>Maximum dose – less than or equal to 0.025mg/kg daily (up to 35 years of age)<br>Maximum dose – less than or equal to 0.0125mg/kg daily (35 years of age or older)<br>~~Reauthorization: documentation by endocrinologist that for the indication, discontinuing GH would have a detrimental effect on body composition or other metabolic parameters 1-year approval.~~ |
| **Ophthalmic Agents: Dry Eye Treatments** | **LENGTH OF AUTHORIZATIONS**: ~~365 Days for Cequa, Restasis, Tyrvaya, and Xiidra~~<br>~~14 Days for Eysuvis~~<br>14 Days for Eysuvis; 365 Days for all other agents |
| **Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE** | **PRIOR AUTHORIZATION CRITERIA:**<br>Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:<br>- Allergy to all medications not requiring prior approval<br>- Contraindication to or drug-to-drug interaction with medications not requiring prior approval<br>- History of unacceptable/toxic side effects to medications not requiring prior approval<br><br>**NON-PREFERRED MEDICATION:** |

- Non-preferred medications will be approved for patients with uncontrolled ~~eosinophilic~~ asthma symptoms and/or exacerbations despite at least 90 days adherence to therapy with a preferred agent

**Clinical Criteria for Asthma**

 ~~Indicated for~~ Patient must have a diagnosis of **moderate to severe asthma** ~~if:~~ AND

 Prescribed by or in consultation with an allergist/immunologist or pulmonologist AND

 Prescribed in accordance with its FDA approved labeling AND

 Preferred medications will be approved for patients with uncontrolled ~~eosinophilic~~ asthma symptoms and/or exacerbations despite at least 30 days adherence to therapy with:

- Medium dose preferred ICS/LABA inhaler (patients 6-11 years old) ~~–~~ ~~Nucala~~
- Medium dose preferred ICS/LABA inhaler with tiotropium or high dose preferred ICS/LABA inhaler (patients 12 years and older) ~~– Nucala or Fasenra~~
  - ~~Non-preferred medications will be approved for patients with uncontrolled eosinophilic asthma symptoms and/or exacerbations despite at least 90 days adherence to therapy with a preferred agent~~

*Initial authorization is limited to 180 days
*Re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. improvement in PFTs).

**Clinical Criteria for Chronic Rhinosinusitis With Nasal Polyposis**

 ~~Indicated for~~ Patient must have a diagnosis of **chronic rhinosinusitis with nasal polyposis** ~~if:~~ AND

 Prescribed by or in consultation with an allergist/immunologist, ~~or~~ pulmonologist, or otolaryngologist AND

 Prescribed in accordance with its FDA approved labeling AND

 Patient had an inadequate response, intolerance or contraindication to one oral corticosteroid AND ~~Patient had a~~ 30-day trial ~~and experienced an inadequate response, intolerance or contraindication~~ to one nasal corticosteroid spray

  - ~~Patient is 18 years of age or older~~

**Clinical Criteria for Chronic Urticaria**

 ~~Indicated for~~ Patient must have a diagnosis of **chronic urticaria** ~~if:~~ AND

 Prescribed by or in consultation with a dermatologist or allergist/immunologist AND

 Prescribed in accordance with its FDA approved labeling AND

 Patient has tried and failed two 14-day trials with two different antihistamines

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| | **Clinical Criteria for Moderate to Severe Atopic Dermatitis**<br>~~Indicated for~~ Patient must have a diagnosis of **moderate to severe atopic dermatitis** ~~if:~~ AND<br>Patient has minimum body surface area (BSA) involvement of at least 10% AND<br>Prescribed by or in consultation with a dermatologist or allergist/immunologist AND<br>Prescribed in accordance with its FDA approved labeling AND<br>~~Patient is 6 years of age or older~~<br>Patient has had inadequate response or contraindication to two of the following: topical corticosteroids, topical calcineurin inhibitors [e.g. Elidel], or topical PDE-4 inhibitors [e.g. Eucrisa™] unless atopic dermatitis is severe and involves greater than 25% of BSA.<br>Initial authorization is limited to ~~112~~ 180 days with re-authorization of up to 365 days granted following demonstration of improvement in patient condition with therapy (e.g. reduced BSA affected).<br><br>~~Indicated for **chronic rhinosinusitis with nasal polyposis** if:~~<br>~~o Patient is 18 years of age or older~~<br>~~o Patient had an inadequate response, intolerance or contraindication to one oral corticosteroid~~<br>~~o Patient had a 30-day trial and experienced an inadequate response, intolerance or contraindication to one nasal corticosteroid spray~~ |

| NEW THERAPEUTIC CATEGORIES |
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| **Dermatological: Oral Acne Products** |

| NEW THERAPEUTIC CATEGORY CRITERIA | |
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| **THERAPEUTIC CLASS** | **SUMMARY OF CHANGE** |
| **Dermatological: Oral Acne Products** | **LENGTH OF AUTHORIZATIONS:** 150 days<br><br>**PRIOR AUTHORIZATION CRITERIA:**<br>Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:<br>Allergy to medications not requiring prior approval<br>Contraindication to or drug-to-drug interaction with medications not requiring prior approval<br>History of unacceptable/toxic side effects to medications not requiring prior approval<br><br>**ADDITIONAL PRIOR AUTHORIZATION CRITERIA:**<br><br>Prescribed in accordance with its FDA approved labeling AND |

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| | • Patient must be registered and meet all of the requirements of the iPLEDGE program AND<br>• Patient must have had at least a 30-day trial and failure with at least 1 topical and 1 oral FDA-approved anti-acne product AND<br>• Must be absent oral tretinoin in the past 56 days<br><br>Authorization provided for no more than 150 days at a time then must take 56 days off |