



**OHIO DEPARTMENT OF MEDICAID
Pharmacy & Therapeutics Committee
GoToMeeting**

<https://register.gotowebinar.com/register/702258497457130254>

APRIL 6, 2022

10:00 AM

MEETING MINUTES

Committee Members Present:

Scott Baran, RPh
Michael Dietz, DO
Mary Ann Dzurec, PharmD
Suzanne Eastman, RPh, MS Vice Chair
Stephen Hersey, MD
Karen Jacobs, DO, Chair
Melissa Jefferis, MD
Sherri Sievers, APRN

Ohio Medicaid Staff Present:

Michelle Barger, PharmD
Andrew Chenevey, PharmD
Yana Doughty, PharmD
Sean Eckard, PharmD
Brian Gallow, PharmD
Meghan Nestleroth, PharmD

Contract Staff/Change Healthcare Staff Present:

Kaitlyn Bernard, PharmD, CSP
Laureen Biczak, MD
Jill RK Griffith, BS, PharmD

Also present were approximately 60 observers, most representing pharmaceutical manufacturers.

I. Opening Comments

Scott Baran welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience then explained the virtual arrangements for the meeting.

II. Call to Order

Dr. Jacobs called the meeting to order at 10:04 A.M.

III. Introductions

The Committee members, ODM pharmacy staff, and Change Healthcare staff introduced themselves. Quorum was established.

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IV. Approval of January 12, 2022 Meeting Minutes

The minutes from the prior P&T meeting were reviewed and approved by the Committee.

V. Administrative Matters

The conflict-of-interest statement was reviewed. All members signed this statement for this year.

VI. Ohio Department of Medicaid Policy Update

The Ohio Department of Medicaid (ODM) continues to work with both the Single Pharmacy Benefit Manager (SPBM) and Pharmacy Pricing and Audit Consultant (PPAC) vendors as ODM moves closer to the July 1st, 2022 go live date for Medicaid's Next Generation of Managed Care. Pharmacy stakeholder meetings began on March 11th and will continue to be held. Transparency into the pharmacy program and a smooth transition for members are top ODM priorities.

ODM is working on new DUR interventions. In one intervention, ODM is reaching out to prescribers whose patients are receiving insulin claims without claims for blood glucose strips or continuous glucose monitors. The goal is to encourage providers to prescribe blood glucose strips and continuous glucose monitors for their diabetic patients and to assess adherence in order to prevent diabetes complications. Another intervention is aimed at prescribers whose patients are enrolled in the Coordinated Services Program (CSP) but do not have a pharmacy claim for naloxone. The goal is to ensure these at-risk patients have access to naloxone and encourage prescribers to counsel their patients on the importance of filling their prescription for naloxone, carrying naloxone with them in the event of an emergency, and address patient concerns surrounding naloxone. Finally, the most recent intervention is aimed at prescribers whose asthma patients have pharmacy claims for a non-selective beta-blocker. The goal is to educate prescribers on the potential for the non-selective beta-blocker to exacerbate asthma symptoms and to assess the risk/benefit ratio of changing to a selective beta-blocker where appropriate.

The Centers for Medicare and Medicaid Services (CMS) Federal Fiscal year (FFY) 2021 Annual DUR Report is underway. Managed Care Plans, in addition to Fee-For-Service, submit their reports and results are posted later this year on the Medicaid.gov website.

Over recent months, the ODM pharmacy team has worked to fill vacancies on the Board and Committees. First, ODM received and reviewed Letters of Interest for three vacant DUR Committee positions. The new members have accepted their positions and the final arrangements are in process. Second, pharmacists Dr. Jason Martinez and Dr. Kayla Petkus have been appointed and accepted their new positions on the DUR Board. Finally, for the vacant P&T Committee position, ODM would like to welcome Dr. Michael Dietz on his recent appointment. We congratulate all these new members and look forward to their contributions.

VII. Presentations by Drug Manufacturers

- a. Eprontia – Azurity Pharmaceuticals, Inc.
- b. Skytrofa – Ascendis Pharma, Inc.
- c. Repatha – Amgen, Inc.

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VIII. Presentations by Interested Parties

- a. Lisa Garrity, PharmD, SM, BCPS representing Cincinnati Children's Hospital Medical Center. Eprontia.

IX. Unified Preferred Drug List (Unified PDL) Proposals

- a. **Analgesic Agents: NSAIDs. Elyxyb (celecoxib solution), Dr. Reddy's Laboratories, Inc.** Dr. Biczak provided a clinical overview of Elyxyb. ODM recommended Elyxyb as "Non-Preferred, PA required". The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Celecoxib	Diclofenac/Misoprostol
Diclofenac	Diclofenac Patch 1.3%
Diclofenac DR	Diclofenac ER
Diclofenac ER	Elyxyb
Diclofenac Gel 1%	Fenoprofen 400mg
Etodolac	Ibuprofen/Famotidine
Fenoprofen 600mg	Ketorolac Tromethamine Nasal Spray
Flurbiprofen	Ketoprofen
Ibuprofen	Licart Patch
Indocin	Meloxicam Cap
Indomethacin	Naproxen CR
Ketoprofen ER	Naproxen DR
Ketorolac	Naproxen ER
Meclofenamate	Naproxen EC
Mefenamic Acid	Naproxen/Esomeprazole
Meloxicam Tab	Pennsaid
Nabumetone	Qmiiz ODT
Naproxen IR	Relafen DS
Naproxen Susp ^{AR}	Zipsor
Oxaprozin	Zorvolex
Piroxicam	
Sulindac	

Link to Criteria: Analgesic Agents: NSAIDS

UPDL Legend

- AR** (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
- BvG** (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
- PA** (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
- QL** (Quantity Limit) - A limit on the quantity that can be covered within a given time frame
- ST** (Step Therapy) - Medications require a trial with one or more preferred products before approval

Analgesic Agents: NSAIDs

LENGTH OF AUTHORIZATIONS:

Dependent on medication request

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	Approval Duration
H. Pylori Treatment	30 days
Transdermal/Topical	90 days
All Other Treatments	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 all 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

The requested medication may be approved if the member had a 30-day trial and failure with two medications not requiring prior approval.

AR – Naproxen Suspension: a PA is required for patients over 12 years old

- b. **Central Nervous System (CNS) Agents: Anticonvulsants. Eprontia (topiramate solution), Azurity Pharmaceuticals, Inc.** Dr. Biczak provided a clinical overview of Eprontia. ODM recommended Eprontia as “Non-Preferred, PA required”. Discussion ensued and a motion carried recommending Eprontia as a Preferred product with an age restriction limiting use to members less than 12 years of age. The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Banzel ^{BvG}	Aptiom
Carbamazepine	Briviact
Clobazam	Celontin
Clonazepam	Clonazepam ODT
Diacomit ^{PA QL}	Elepsia XR
Divalproex	Felbamate
Divalproex ER	Fintepla
Epidiolex ^{PA QL}	Lamotrigine ER
Eprontia ^{AR}	Lamotrigine ODT
Ethosuximide	Levetiracetam ER Tab
Fycompa ST	Oxtellar XR
Gabapentin	Peganone
Lamotrigine	Rufinamide
Levetiracetam IR Tab	Spritam
Levetiracetam Sol	Sympazan
Oxcarbazepine	Tiagabine
Phenobarbital	Topiramate ER
Phenytoin	Topiramate ER Sprinkle Cap
Pregabalin	Topiramate Sprinkle Cap
Primidone	Trokendi XR

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PREFERRED

Topiramate
Valproic Acid
VimpatST
Zonisamide

NON-PREFERRED

Vigabatrin
Vigabatrin Powder^{AR}
Xcopri

Link to Criteria: Central Nervous System (CNS) Agents: Anticonvulsants

UPDL Legend

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QL (Quantity Limit) - A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

Central Nervous System (CNS) Agents: Anticonvulsants*

LENGTH OF AUTHORIZATIONS:

365 Days

GRANDFATHERING:

Patients who have a claim for a non-preferred drug in the previous 120 days will be automatically approved to continue the drug through the automated PA system. Patients who have taken the drug in the previous 120 days, but do not have claims history (e.g., new to Medicaid), will be approved for PA after prescriber contact.

PRIOR AUTHORIZATION CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication?
Acceptable reasons include:
 - Allergy to two preferred medications
 - Contraindication to or drug interaction with two preferred medications
 - History of unacceptable/toxic side effects to two preferred medications

STEP THERAPY: all agents listed

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 one preferred product.

NON-PREFERRED MEDICATION:

- 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.

ADDITIONAL CRITERIA FOR EPIDIOLEX**LENGTH OF AUTHORIZATIONS:**

Initial Authorization 180 days
Subsequent Authorizations 365 days

- Patient has a diagnosis of Lennox-Gastaut syndrome, Dravet syndrome or tuberous sclerosis

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- complex
- Patient has trialed and failed (inadequate seizure control or intolerance) 3 prior anticonvulsant therapies for 30 days each (**Note:** not required to be met for a diagnosis of Dravet Syndrome)
- Prescriber has obtained serum transaminases (ALT and AST) and total bilirubin levels prior to starting therapy
- Prescriber must submit documented average number of seizure days per month (measured monthly or quarterly)
 - Maximum daily dose (QL) not to exceed 20 mg/kg/day (titration based on response/tolerability) for Lennox-Gastaut syndrome or Dravet syndrome and not to exceed 25 mg/kg/day (titration based on response/tolerability) for tuberous sclerosis complex

Epidiolex excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per month (measured monthly or quarterly).

ADDITIONAL CRITERIA FOR DIACOMIT

LENGTH OF AUTHORIZATIONS:

Initial Authorization 180 days
Subsequent Authorizations 365 days

- Medication is prescribed by a neurologist or in consultation with a neurologist
- Patient has Dravet Syndrome
- Patient has baseline hematologic testing (CBC)
 - Prescribers must include management plans for patients with neutrophil counts <1500 cells/mm³ or platelet count less than 150,000/ μ L
- Address any co-morbid conditions
 - Patients with phenylketonuria (PKU) will not be authorized for suspension dosage form without evidence of total daily amount of phenylalanine
- Patient must be concurrently managed with clobazam.
- Dose will be restricted based upon patient weight to 50 mg/kg/day. Requested dose not to exceed 3,000mg/day
- Prescriber must submit documented average number of seizure days per 30 days (measured monthly or quarterly)

Diacomit excluded from Grandfathering. Re-authorization requires documented reduction in average number of seizure days per 30 days (measured monthly or quarterly).

AR - Vigabatrin Powder: a PA is required for patients over 2 years old

AR – Eprontia Solution: a PA is required for patients 12 years and older

- c. **Endocrine Agents: Growth Hormone. Skytrofa (lonapegsomatropin-tcgd injection), Ascendis Pharma, Inc. & Criteria administrative reorganization.** Dr. Biczak provided a clinical overview of Skytrofa. ODM recommended Skytrofa as “Non-Preferred, PA required”. Discussion ensued and the committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Norditropin ^{PA}	Genotropin

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PREFERRED	NON-PREFERRED
Omnitrope ^{PA}	Humatrope Nutropin Saizen Serostim Skytrofa Zomacton

Link to Criteria: Endocrine Agents: [Growth Hormone](#)

UPDL Legend

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PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate

QL (Quantity Limit) - A limit on the quantity that can be covered within a given time frame

ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

Endocrine Agents: Growth Hormone

LENGTH OF AUTHORIZATIONS:

Varies as listed below.

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 prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval

NOTE:

- All products in this class require clinical prior authorization
- Must meet the below clinical criteria for approval
- Must be treated and followed by a pediatric endocrinologist, pediatric nephrologist, clinical geneticist, endocrinologist or gastroenterologist (as appropriate for diagnosis)
- 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.

NON-PREFERRED MEDICATION:

- For a non-preferred medication drug, there The requested medication may be approved if the following is true: If 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.

CLINICAL CRITERIA

Pediatric Approvals (under 18 years of age):

Initial Approvals - based on diagnoses below

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)

Children – initial approval for the following diagnoses:

Patient must have **ONE** of the following diagnoses:

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1. **Growth Hormone Deficiency (GHD) – 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 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 1.73m² 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

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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 a result of pituitary disease, surgery, hypothalamic disease, radiation therapy, or trauma.

Criteria for Approval for both conditions listed above:

AND ALL of the following:

- 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.)
- 2) No evidence of malignancy or other contraindication; AND

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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

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) Other hormonal deficiencies addressed with adequate replacement therapy;
AND

4) Base-line evaluation of the following clinical indicators

- a. Insulin-like growth factor-1 (IGF-1) also required following dosage change
- b. Fasting lipid profile
- c. BUN
- d. Fasting glucose
- e. Electrolyte levels
- f. Evaluation of any new osteoarthritis and joint pain
- g. Bone density test

Maximum dose – less than or equal to 0.025mg/kg daily (up to 35 years of age)

Maximum dose – less than or equal to 0.0125mg/kg daily (35 years of age or

older) 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.

- d. **Ophthalmic Agents: Dry Eye Treatments. Tyrvaya (varenicline tartrate nasal spray), Oyster Point Pharma.** Dr. Biczak provided a clinical overview of Tyrvaya. ODM recommended Tyrvaya as “Non-Preferred, PA required”. The committee voted and recommended the proposed category and clinical criteria as shown below:

PREFERRED	NON-PREFERRED
Restasis Trays ST	Cequa Eysuvis Restasis Multi-Dose Tyrvaya Xiidra

Link to Criteria: Ophthalmic Agents: Dry Eye Treatments

UPDL Legend

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QL (Quantity Limit) – A limit on the quantity that can be covered within a given time frame

ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

Ophthalmic Agents: Dry Eye Treatments

LENGTH OF AUTHORIZATIONS: 365 Days for Cequa, Restasis, Tyrvaya, and Xiidra

14 Days for Eysuvis

14 Days for Eysuvis; 365 Days for all other agents

PRIOR AUTHORIZATION CRITERIA:

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Acceptable reasons include:

- Allergy to all 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

All drugs in this class require step therapy: Patient must have a claim for an artificial tear or OTC dry eye drop in the previous 120 days.

X. Drug Class Announcements

- a. **Dermatologic Agents: Oral Retinoids.** Dr. Biczak provided a therapeutic class overview for the oral retinoids. ODM proposed a new UPDL category with the below placement of drugs in the preferred and non-preferred status. Discussion ensued and the committee voted and recommended the proposed category and clinical criteria as shown below:

XI. Dermatological: Oral Acne Products	
PREFERRED	NON-PREFERRED
Accutane ^{PA}	Absorica
Amnesteem ^{PA}	Absorica LD
Clavaris ^{PA}	
Isotretinoin ^{PA}	
Myorisan ^{PA}	
Zenatane ^{PA}	

Link to Criteria: [Dermatological: Oral Acne Products](#)

UPDL Legend

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QL (Quantity Limit) - A limit on the quantity that can be covered within a given time frame
ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

Dermatologic Agents: Oral Acne Products

LENGTH OF AUTHORIZATIONS: 150 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-to-drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval

ADDITIONAL PRIOR AUTHORIZATION CRITERIA:

- Prescribed in accordance with its FDA approved labeling AND
- Patient must be registered and meet all of the requirements of the iPLEDGE program AND
- 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
- Must be absent oral tretinoin in the past 56 days

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Authorization provided for no more than 150 days at a time then must take 56 days off

XII. Other Business

- a. **Cardiovascular Agents: Lipotropics.** Dr. Biczak provided a brief clinical overview of Juxtapid. ODM recommended the addition of Juxtapid as “Non-Preferred, PA required” along with clinical criteria. Discussion ensued and the committee voted and recommended the proposed category and clinical criteria as shown below:

Cardiovascular Agents: Lipotropics	
PREFERRED	NON-PREFERRED
Atorvastatin	Altoprev
Cholestyramine, Light	Amlodipine/Atorvastatin
Colestipol Tab	Colesevelam
Ezetimibe	Colestipol Granules
Fenofibrate 48 and 145mg Tab	Ezetimibe/Simvastatin
Gemfibrozil	Ezallor
Lovastatin	Fenofibrate 30, 43, 50, 67, 90, 130, 134 and 150mg Cap
Omega-3-Acid Ethyl Esters	Fenofibrate 40, 54, 120 and 160mg Tab
Niacin OTC	Fenofibric Acid
Niacin ER OTC	Fluvastatin
Praluent ^{PA}	Juxtapid
Pravastatin	Livalo
Prevalite	Nexletol
Repatha ^{PA}	Nexlizet
Rosuvastatin	Niacin ER Tab
Simvastatin	Vascepa
	Zypitamag

Link to Criteria: Cardiovascular Agents: [Lipotropics](#)

UPDL Legend

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- PA** (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
- QL** (Quantity Limit) – A limit on the quantity that can be covered within a given time frame
- ST** (Step Therapy) - Medications require a trial with one or more preferred products before approval

Cardiovascular Agents: Lipotropics

LENGTH OF AUTHORIZATIONS: 365 days all Lipotropics

Trial period	30 days for HMG-CoA Reductase Inhibitors, Niacin derivatives, ezetimibe (Zetia), 90 days for Fibrates, and 84 days for ATP Citrate Lyase (ACL) Inhibitors
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

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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-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

ADDITIONAL PRIOR AUTHORIZATION CRITERIA:

- If there has been a 30-day trial with no less than two of preferred HMG-CoA products, then a non-preferred HMG-CoA agent can be approved.

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

- 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 ≤ 100 mg/dL for adults or LDL ≤ 110 mg/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 ≤ 70 mg/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 ≤ 100 mg/dL) with high-potency statin therapy (atorvastatin or rosuvastatin), ezetimibe and PCSK9 inhibitor (or a clinical reason that these medications cannot be utilized)

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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 with ezetimibe (Zetia)

Baseline lab results are required, and initial approval will be for 84 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.

- Lipid profile required at 56 days for HeFH or ASCVD

- b. **Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis.** ODM recommended a quantity limit to be added to Nurtec ODT in the anti-migraine, prophylaxis category. The committee voted and recommended the proposed category and clinical criteria as shown below:

Central Nervous System (CNS) Agents: Anti-Migraine Agents, Prophylaxis	
PREFERRED	NON-PREFERRED
Aimovig ^{QL ST}	Emgality
Ajovy ST	Nurtec ODT ^{QL}
Cardiovascular Agents: Beta-Blockers	Qulipta
CNS Agents: Anticonvulsants	
CNS Agents: Serotonin-Norepinephrine Reuptake Inhibitors	
CNS Agents: Tricyclic Antidepressants	

Link to Criteria: [Central Nervous System \(CNS\) Agents: Anti-Migraine Agents, Prophylaxis](#)

UPDL Legend

- AR** (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
- BvG** (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
- PA** (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
- QL** (Quantity Limit) - A limit on the quantity that can be covered within a given time frame
- ST** (Step Therapy) - Medications require a trial with one or more preferred products before approval

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

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LENGTH OF AUTHORIZATIONS:

Initial Authorization 180 days
Subsequent 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 preferred medications
 - Contraindication to three preferred medications
 - History of unacceptable/toxic side effects to at least three preferred medications

STEP THERAPY REQUIRED PREFERRED MEDICATION:

- For a drug requiring step therapy, there must have been inadequate clinical response to 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).

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 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) AND an inadequate clinical response to a trial of at least 30 days of one step therapy required preferred medication

ADDITIONAL CRITERIA FOR MIGRAINE PROPHYLAXIS:

1. Patient must have one of the following diagnoses:
 - a. **Episodic** migraine with the following frequencies of migraine:
 - 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.
 - b. **Chronic** migraine with the following frequencies of migraine:
 - 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
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 with objective documentation of severity, frequency, and number of headache days per month (preferably a headache diary).
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).

ADDITIONAL INFORMATION

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.

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* Nurtec ODT quantity limit is 18 per 30 days for prophylactic treatment

* Aimovig Initial Dose is limited to 70mg once per 30 days; may request dose increase if 70mg fails to provide adequate relief over 60 consecutive days.

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

- c. **Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction.** ODM explained the administrative change to remove Bunavail as it is no longer on the market. ODM announced that the DUR Board recommended and voted that Sublocade will no longer require PA effective 4/15/22. ODM recommended the buprenorphine equivalent safety limit to be increased from 16 mg/day to 24mg/day. The committee voted and recommended the proposed category as shown below:

PREFERRED	NON-PREFERRED
Bunavail	Buprenorphine
Buprenorphine/Naloxone	Lucemyra ^{QL}
Clonidine	
Sublocade ^{PA QL}	
Suboxone	
Vivitrol	
Zubsolv	

[Link to Criteria: Central Nervous System \(CNS\) Agents: Medication Assisted Treatment of Opioid Addiction](#)

UPDL Legend

AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization

BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent

PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate

QL (Quantity Limit) - A limit on the quantity that can be covered within a given time frame

ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

Central Nervous System (CNS) Agents: Medication Assisted Treatment of Opioid Addiction

LENGTH OF AUTHORIZATIONS: No PA required for short-acting, buprenorphine containing, oral agents
30 days for initial authorization of injectable not to exceed 180 days for subsequent authorizations of injectable; length depending upon patient status and compliance to treatment plan
14-day authorization for Lucemyra[®] (lofexidine)

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 prior approval.
- History of unacceptable/toxic side effects to medications not requiring prior approval

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Criteria for Lucemyra (lofexidine)

- Indicated for Opioid Withdrawal, must meet all the following criteria:
 - Diagnosis of opioid dependence or opioid use disorder
 - Age \geq 18 years
 - Patient is currently undergoing or is scheduled to undergo abrupt opioid discontinuation
 - Medical justification supports why an opioid taper (such as with buprenorphine or methadone) cannot be used
 - Does the patient meet one or more of the following criteria:
 - Therapeutic failure of clonidine due to intolerable adverse effects or inability to reach maximal doses of clonidine due to adverse effects
 - Documented history of intolerance to clonidine (ex: hypotension, bradycardia)
 - Contraindication to clonidine as specified in FDA labeling
 - Lofexidine has already been initiated in an inpatient setting
 - Dose will not exceed 2.88 mg (16 tablets) per day

Prescribing for buprenorphine products must follow the requirements of Ohio Administrative Code rule 4731-33-03 *Office based treatment for 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.**

Buprenorphine SL tablets (Generic of Subutex) use restricted to pregnancy or breastfeeding; or contraindication to preferred products.

Vivitrol may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered by the pharmacist, the drug must be released only to the administering provider or administering provider's staff, following all regulations for a Prescription Pick-Up Station as described by the Ohio Board of Pharmacy.

Criteria for SUBCUTANEOUS BUPRENORPHINE INJECTION (SUBLOCADE™)

- Indicated for opioid dependence:
 - Patient \geq 18 years
 - Currently established on a dose of at least 8mg of oral buprenorphine for at least 7 days
 - Medical justification supports inability to continue to use oral formulation and Vivitrol
 - Urine drug screen result obtained within the last 7 days with no illicit substances or non-prescribed therapies detected (initially). Subsequent authorization dependent upon UDS results indicating compliance to treatment plan.
 - Provider will attest that the patient is receiving or planning to receive counseling.
 - The physician has reviewed OARRS within 7 days prior to the PA request. If the patient has received controlled substances since the previous authorization:
 - The physician has coordinated with all other prescribers of controlled substances and has determined that the patient should continue treatment; **AND**

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- ☐ If the patient has received other controlled substances for 84 or more continuous days, the physician has consulted with a board-certified addictionologist or addiction psychiatrist who has recommended the patient receive substance abuse treatment (consultation not necessary if the prescriber is a board-certified addictionologist or addiction psychiatrist).
- Dose does not exceed 300mg per 30 days in the first 60 days and 100mg thereafter. Providers may request a maintenance dose increase beyond 100mg by submitting additional clinical documentation supporting the need for a higher dose
- ☐ Re-authorization requires adherence to specified treatment plan inclusive of adherence to counseling, OARRS and urine drug screening requirements

Sublocade Drug Utilization Review Criteria:

- Dosing schedule will be limited to 300mg/30 days.

Additional Sublocade Information

Sublocade may be billed by the pharmacy if it is not dispensed directly to the patient. If not administered at the pharmacy, the drug must be released only to the administering provider or administering provider's staff, following all applicable regulations.

- d. **Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE.** ODM proposed an administrative reorganization of the criteria for this category. The committee voted and recommended the proposed category as shown below:

PREFERRED	NON-PREFERRED
Fasenra ^{PA}	Dupixent
Nucala ^{PA}	
Xolair ^{PA}	

Link to Criteria: [Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE](#)

UPDL Legend

- AR (Age Restriction) - An age edit allows claims for members within a defined age range to adjudicate without authorization
- BvG (Brand Preferred Over the Generic) - The brand name medication is preferred over the generic equivalent
- PA (Clinical Prior Authorization) - A prior authorization is required before the medication will adjudicate
- QL (Quantity Limit) - A limit on the quantity that can be covered within a given time frame
- ST (Step Therapy) - Medications require a trial with one or more preferred products before approval

Respiratory Agents: Monoclonal Antibodies-Anti-IL/Anti-IgE

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 all 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

NON-PREFERRED MEDICATION:

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- 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 Fasenna
- ~~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, 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

Clinical Criteria for Moderate to Severe Atopic Dermatitis

- ~~Indicated for~~ Patient must have a diagnosis of **moderate to severe atopic dermatitis** if: AND
- Patient has minimum body surface area (BSA) involvement of at least 10% AND
- Prescribed by or in consultation with a dermatologist or allergist/immunologist AND
- Prescribed in accordance with its FDA approved labeling AND
- ~~Patient is 6 years of age or older~~
- 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™]

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unless atopic dermatitis is severe and involves greater than 25% of BSA.

□ 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).

☐ 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

XIII. 2022 Meeting Dates

- a. Quarter 3 – Wednesday, July 13, 2022
- b. Quarter 4 – Wednesday, September 28, 2022.

XIV. Adjournment

Dr. Jacobs adjourned the meeting at 12:07 PM EST.