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**OHIO DEPARTMENT OF MEDICAID
Pharmacy & Therapeutics Committee
Ohio Department of Medicaid
50 W. Town Street, Room C621A and C621B
Columbus, OH
January 15, 2020
10:00 AM
MEETING MINUTES**

Committee Members Present:

Susan Baker, APN
Scott Baran, RPh
Suzanne Eastman, RPh, MS Vice Chair
Karen Jacobs, DO Chair
Melissa Jefferis, MD
Nathan Samsa, DO, PharmD

Ohio Medicaid Staff Present:

Tracey Archibald, PharmD
Michelle Barger, PharmD
Sean Eckard, Pharm D

Contract Staff/Change Healthcare Staff Present:

Jill RK Griffith, BS, PharmD
Jacqueline Hedlund, MD
Steve Liles, PharmD
Gail Master, RPh
Philip Verret, PharmD

Also present were approximately 75 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Dr. Jacobs called the meeting to order at 10:01 A.M.

II. Introductions

Dr. Jacobs welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. The committee members each introduced themselves.

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III. Approval of the October 2nd, 2019 Meeting Minutes

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

IV. Administrative Matters

Conflict of interest statements were signed and collected.

V. Department of Medicaid Update

S. Baran announced that the Ohio Department of Medicaid (ODM) implemented a Unified Preferred Drug List (Unified PDL) on January 1st, 2020. ODM Pharmacy staff and Managed Care Plan staff continue to collaborate on Clinical and Technical questions in order to ensure a successful transition. ODM is very proud of this accomplishment and could not have done it without the contributions, effort, and support from a number of partners. The Unified PDL marks the culmination of many months of cooperative work aimed at reducing the administrative burden for providers, allowing for a standard process across Ohio Medicaid Fee-for-Service and Managed Care Plans, clinical coordination of care for those covered under Ohio's Medicaid program, and minimizing member movement across our five Managed Care Plans

S. Baran then turned to other pharmacy-related initiatives included in the most recent State Budget. He announced that ODM continues to work towards adopting rules to provide a supplemental dispensing fee under the care management system to retail pharmacies as well as working on efforts to select a single pharmacy benefit manager (SPBM) to be used by all of the State's managed care organizations. The Committee should expect more details on both of these initiatives over the coming months.

S. Baran announced that the ODM Pharmacy unit has resumed pharmacy industry visitation days. This program is an opportunity for drug representatives to present new clinical information to ODM about their approved products.

Back in November 2019, the Centers for Medicare & Medicaid Services (CMS) issued guidance concerning implementation of new Medicaid Drug Utilization Review (DUR) provisions included in Section 1004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act, also referred to as the SUPPORT Act. This guidance was designed to assist States with their State Plan Amendment (SPA) submissions which ODM completed.

The annual CMS DUR Report State responses have been posted to the [Medicaid.gov](https://www.medicicaid.gov) website. This was the first year that Medicaid Managed Care Plans were required to submit reports in addition to Fee-For-Service program reports.

Finally, S. Baran announced that the ODM Pharmacy staff has grown since the last meeting. He asked the committee to please join him in welcoming Pharmacist, Sean Eckard to the team. He

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said that they are excited about this addition and look forward to Sean's clinical contributions to their departmental initiatives.

VI. Interested Party Presentations

- a. Anup D. Patel, MD representing Nationwide Children's Hospital
Epidiolex (cannabidiol oral solution)
- b. Karen J. Brown, LSW representing Epilepsy Alliance Ohio
Nayzilam (midazolam nasal spray)
- c. Karen S. McCoy, MD representing Nationwide Children's Hospital
Trikafta (elexacaftor/tezacaftor/ivacaftor)

VII. Unified Preferred Drug List (PDL) Proposal

- a. **Calcium Channel Blockers-Dihydropyridine: Katerzia™ (amlodipine suspension), Silvergate Pharmaceuticals, Calcium Channel Blockers-Dihydropyridine**

Bruce Wallace, R.Ph presented clinical information on Katerzia on behalf of Azurity Pharmaceuticals. Following the presentation, Dr. Hedlund provided an additional clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the U-PDL. A discussion ensued regarding the clinical criteria concerning age and the inability for a patient to swallow. Following this discussion, votes were taken, and the committee recommended the proposed category as shown below:

Cardiovascular Agents: Angina, Hypertension & Heart Failure

LENGTH OF AUTHORIZATIONS: 365 days

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with preferred medications
 - History of unacceptable/toxic side effects to preferred medications
2. The requested medication may be approved if both of the following are true:
 - If there has been a therapeutic failure to no less than a 30-day trial of at least two medication within the same class not requiring prior approval
 - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

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3. If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication. This medication should be reviewed for need at each request for reauthorization.

CALCIUM CHANNEL BLOCKERS- DIHYDROPYRIDINE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE (generic of Norvasc®)	ISRADIPINE (generic of Dynacirc®)
FELODIPINE (generic of Plendil®)	KATERZIA® oral suspension (amlodipine)
NICARDIPINE (generic of Cardene®)	NIMODIPINE (generic of Nimotop®)*
NIFEDIPINE ER (generic of Procardia XL®, Adalat CC®)	NYMALIZE oral solution (nimodipine solution) *
NIFEDIPINE IMMEDIATE RELEASE (generic of Procardia®)	NISOLDIPINE (generic of Sular®)

* Note: nimodipine only approvable for 21 days after subarachnoid hemorrhage.

- Anticonvulsants: First Generation: Nayzilam® (midazolam nasal spray), UCB**
Rejena Azad, PharmD, presented clinical information on Nayzilam on behalf of UCB. Following the presentation, Dr. Hedlund provided an additional clinical overview of the medication. ODM recommended a No PA Required "Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

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.

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 thirty days of at least one preferred product.

OTHER APPROVAL CRITERIA

Is there any reason the patient cannot be changed to a preferred medication?
Acceptable reasons include:

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- Allergy to two preferred medications
 - Contraindication to or drug interaction with two preferred medications
 - History of unacceptable/toxic side effects to two preferred medications
 - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated
2. If there has been a therapeutic failure to no less than two preferred products for a 30 days trial each. Prescriptions submitted with the prescriber NPI of a physician who has registered a neurology specialty with Ohio Medicaid, 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.

ANTICONVULSANTS: FIRST GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLONAZEPAM tablet (generic of Klonopin®)	CELONTIN® (methsuximide)
DIAZEPAM rectal gel (generic of Diastat®)	CLONAZEPAM ODT (generic of Klonopin® wafer)
DIVALPROEX (generic of Depakote®)	CLOBAZAM (generic for Onfi®)
DIVALPROEX ER (generic of Depakote® ER)	PEGANONE® (ethotoin)
ETHOSUXAMIDE (generic of Zarontin®)	STAVZOR® (valproic acid delayed-release)
NAYZILAM® (midazolam)	SYMPAZAN™ (clobazam film)
PHENOBARBITAL	
PHENYTOIN (generic of Dilantin®)	
PRIMIDONE (generic of Mysoline®)	
VALPROIC ACID (generic of Depakene®)	

- c. **Central Nervous System Agents: Medication Assisted Treatment Of Opioid Addiction - Chemical Dependency Agents Alpha-2 Adrenergic Agonists: Lucemyra™ (lofexidine tab), US WorldMeds**
Mark Pirner MD, presented clinical information on Lucemyra on behalf of US WorldMeds. Dr. Hedlund provided an additional clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

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

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14-day authorization for Lucemyra® (lofexidine)

Criteria for Lucemyra (lofexidine)

- Indicated for Opioid Withdrawal, must meet all the following criteria:
 - Diagnosis of opioid dependence or opioid use disorder
 - Age ≥ 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

ALPHA-2 ADRENERGIC AGONIST

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CLONIDINE	LUCEMYRA (lofexidine)

d. CNS Agents: Anti-Migraine Agents – Serotonin 5-Ht1 Receptor Agonists –“Fast” Onset: Tosymra™ (sumatriptan nasal spray), Promius Pharma

Dr. Hedlund provided a clinical overview of the medication. ODM recommended a PA Required “Non-Preferred” place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

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

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
 - Has the patient failed a therapeutic trial of at least two weeks with at least two medications not requiring prior approval

CNS AGENTS: ANTI-MIGRAINE AGENTS – SEROTONIN 5-HT₁ RECEPTOR AGONISTS – “Fast”

Onset

NO PA REQUIRED “PREFERRED”	PA REQUIRED “NON-PREFERRED”
RIZATRIPTAN tablets (generic of Maxalt®)	ALMOTRIPTAN (generic of Axert®)
RIZATRIPTAN ODT (generic of Maxalt-MLT®)	ONZETRA™ XSAIL™ (sumatriptan)
SUMATRIPTAN tablets, nasal spray, injection (generic of Imitrex®)	ELETRIPTAN (generic of Relpax®)
	SUMAVEL DOSEPRO® (sumatriptan)
	TOSYMRA® (sumatriptan)
	ZOLMITRIPTAN (generic of Zomig®)
	ZOLMITRIPTAN ODT (generic of Zomig ZMT®)
	ZOMIG® NASAL SPRAY (zolmitriptan)
	ZECUITY® (sumatriptan)

e. **CNS Agents, Antidepressants: Serotonin-Norepinephrine Reuptake Inhibitors (SNRI): Drizalma Sprinkle™ (duloxetine DR), Sun Pharmaceutical Industries**

Dr. Hedlund provided a clinical overview of the medication. ODM recommended a PA Required ‘Non-Preferred’ place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

Central Nervous System (CNS) Agents: Antidepressants

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

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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.

PSYCHIATRIST EXEMPTION:

Providers (as identified below) are exempt from prior authorization of any non-preferred antidepressant, or step therapy of any preferred brand, in the standard tablet/capsule dosage forms. Other dosage forms may still require prior authorization. The exemption will be processed by the claims system when the pharmacy has submitted the prescriber on the claim using the individual national provider identifier (NPI) for the provider.

- **FFS:** Physicians who are registered with Ohio Medicaid as having a specialty in psychiatry
- **MCOs:** Physicians with a specialty in psychiatry, nurse practitioners certified in psychiatric mental health, or clinical nurse specialists certified in psychiatric mental health, who are credentialed via the Medicaid managed care plan

LENGTH OF AUTHORIZATIONS: 365 days

1. If there has been a therapeutic failure to no less than two preferred products for a 30-day trial each.
2. Is there any reason the patient cannot be changed to a preferred medication? Acceptable reasons include:
 - Allergy to preferred medications
 - Contraindication to or drug interaction with preferred medications
 - History of unacceptable/toxic side effects to preferred medications
 - For orally disintegrating tablet dosage forms, the patient is unable or unwilling to swallow the standard tablet/capsule dosage form.
 - The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated

ANTIDEPRESSANTS: SEROTONIN-NOREPINEPHRINE REUPTAKE INHIBITORS (SNRI)*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DULOXETINE 20mg, 30mg, 60mg (generic of Cymbalta®)	DESVENLAFAXINE ER (generic of Khedezla ER®)
VENLAFAXINE (generic of Effexor®)	DESVENLAFAXINE ER tablet
VENLAFAXINE ER capsule (generic of Effexor XR®)	DESVENLAFAXINE FUMARATE
	DRIZALMA SPRINKLE® (duloxetine DR)
	DULOXETINE 40mg (generic of Irenka®)
	FETZIMA® (levomilnacipran)
	PRISTIQ® (desvenlafaxine)
	VENLAFAXINE ER tablet

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f. CNS Agents: Attention Deficit Hyperactivity Disorder Agents – Long Acting, Solid: Adhansia XR™ (methylphenidate ER cap), Adlon Therapeutics

Dr. Hedlund provided a clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents

LENGTH OF AUTHORIZATIONS: 365 days

Short acting considered separately from Long Acting products

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
 - Preferred long-acting non-solid dosage forms may be approved for a patient over age 12 if the patient is unable to swallow pills
 - Has the patient failed a therapeutic trial of at least 14 days with at least two medications not requiring prior approval?
2. Note: Patients on non-preferred therapies are not required to obtain prior authorization for the use of their product until after June 30th, 2020. Providers may obtain prior authorization before June 30th,

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CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – LONG ACTING, SOLID DOSAGE FORMS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATOMOXETINE (generic of Strattera®) APTENSIO XR™ (methylphenidate) DEXMETHYLPHENIDATE ER (generic of Focalin XR®) DEXTROAMPHETAMINE-AMPHETAMINE XR (generic of Adderall XR®) DEXTROAMPHETAMINE SA (generic of Dexedrine® spansule) GUANFACINE ER (generic of Intuniv®) METHYLPHENIDATE ER (generic of Metadate® ER, Methylin® ER, Ritalin SR®) METHYLPHENIDATE ER (generic of Concerta®) [Labeler 10147] METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA) VYVANSE® (lisdexamfetamine)	ADHANSIA XR® (methylphenidate hydrochloride ER) CLONIDINE ER (generic of Kapvay®) JORNAY PM™ (methylphenidate ER) METHYLPHENIDATE ER (generic of Concerta®) [All other Labelers] MYDAYIS™ (amphetamine-dextroamphetamine ER)

g. CNS Agents: Parkinson's Agents: Nourianz™ (istradefylline tab), Kyowa Kirin

Dr. Hedlund provided a clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

Central Nervous System (CNS) Agents: Parkinson's Agents

LENGTH OF AUTHORIZATIONS: 365 days

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

ADDITIONAL INFORMATION

The requested medication may be approved if both of the following are true:

1. If there has been a therapeutic failure to no less than a 30-day trial of at least one medication not requiring prior approval

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2. The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated.
3. Neupro® may be approved if the patient is unable to swallow.
4. Requests for Inbrija™ and Nourianz® must have documentation of a trial of at least one other medication for the treatment of "off episodes" (dopamine agonist, COMT inhibitor, or MAO-B inhibitor) AND member must currently be taking carbidopa/levodopa.

PARKINSON'S AGENTS –FOR INTERMITTENT TREATMENT OF OFF EPISODES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	APOKYN® (apomorphine) INBRIJA™ (levodopa) NOURIANZ® (istradefylline)

h. Endocrine Agents: Diabetes –Glucagon-Like Peptide-1 Receptor Agonists: Rybelsus® (semaglutide tab), Novo Nordisk

Dr. Hedlund provided a clinical overview of the medication. S. Baran indicated that Mary Ann Dzurec, a committee member who was unable to attend, suggested that the committee consider changing the 90-day requirement of metformin to a 30-day requirement for step therapy. Discussion ensued related to this topic. A vote was taken to table this discussion and to discuss the oral antidiabetic medication class at the April P&T meeting. ODM recommended a PA Required "Non-Preferred" place on the PDL for Rybelsus. Votes were taken, and the committee recommended the proposed category as shown below:

Endocrine Agents: Diabetes – Non-Insulin

LENGTH OF AUTHORIZATIONS: 365 days

STEP THERAPY:

1. For a drug requiring step therapy, there must have been inadequate clinical response to metformin products (either single-ingredient or in a sulfonylurea/ metformin or TZD/metformin combination), including a trial of no less than 90 days of at least one preferred metformin product
2. For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including metformin and a trial of no less than 90 days of at least one preferred or step therapy product

Note: Inadequate clinical response is the inability to reach A1C goal after at least 90 days of recommended therapeutic dose with documented adherence to the regimen.

OTHER APPROVAL CRITERIA:

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Is there any reason the patient cannot be changed to a medication within the same class 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

ENDOCRINE AGENTS: DIABETES –GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	VICTOZA* (liraglutide) TRULICITY* (dulaglutide)	ADLYXIN™ (lixisenatide) BYDUREON* (exenatide) BYDUREON* BCISE (exenatide) BYETTA™ (exenatide) OZEMPIC* (semaglutide) RYBELSUS* (semaglutide)

i. Immunomodulator Agents for Systemic Inflammatory Disease - Janus Kinase Inhibitor:

Rinvoq™ (upadacitinib ER tab), AbbVie

Justin Simmons, PharmD presented clinical information on Rinvoq, on behalf of AbbVie. Dr. Hedlund provided an additional clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

Immunomodulator Agents for Systemic Inflammatory Disease

LENGTH OF AUTHORIZATIONS:

DEPENDENT ON DIAGNOSIS

All products in this class require Clinical Prior Authorization:

- No current infection; and
- Prior first-generation therapy appropriate for diagnosis; and
- Diagnosis of one of the following: 365 days approval
 - Rheumatoid Arthritis
 - Plaque Psoriasis
 - Psoriatic Arthritis
 - Polyarticular Juvenile Idiopathic Arthritis
 - Crohn's Disease
 - Ankylosing Spondylitis
 - Psoriasis

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- Uveitis
- Cryopyrin-Associated Periodic Syndrome
- Giant Cell Arteritis
- Hidradenitis Suppurativa
- Diagnosis of Moderate to Severe Ulcerative Colitis (UC) (Humira, Simponi, and Xeljanz only): initial approval 56 days, reapprovals 365 days
Humira may be approved if there is an inadequate clinical response to at least 90 days of therapy with both 5-ASA and immunosuppressants.
Initial approval for Humira will be for 56 days. If clinical response is not seen in 56 days, further therapy with TNF inhibitors will not be approved. If there is an initial clinical response to Humira after 56 days of therapy, but no improvement in the progression of ulcerative colitis symptoms after 180 days, Simponi or Xeljanz may be approved.
 - Quantity limits for UC diagnosis:
Humira – 7 pens/syringes during month one, then 2 pens/syringes per month
Simponi – 3 pens/syringes during month one, then 1 pen/syringe per month
Xeljanz – 60 pills per month

PDL 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

ADDITIONAL CRITERIA:

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

- If there has been a therapeutic failure to no less than a 90-day trial of at least one preferred medication AND one step therapy product.
- Step therapy: secukinumab (Cosentyx®) may be approved for labeled indications after a trial of adalimumab (Humira®) or etanercept (Enbrel®).
- For patients with a diagnosis of moderate to severe plaque psoriasis receiving phototherapy, initial authorization for Humira® or Enbrel® will only be approved if there is inadequate clinical response to at least 90 days of phototherapy.

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JANUS KINASE INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	OLUMIANT® (baricitinib) RINVOQ® (upadacitinib) XELJANZ® tablet (tofacitinib citrate) XELJANZ® XR (tofacitinib tablet, extended release)

j. Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting: ProAir® Digihaler™ (albuterol DPI), Teva

Dr. Hedlund provided a clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

Agents: Beta-Adrenergic Agonists – Inhaled, Short Acting

LENGTH OF AUTHORIZATIONS: 365 DAYS

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? 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
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 14-day trial of at least one medication not requiring prior approval within the same class and formulation. (i.e., nebulizers for nebulizers).

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING METERED DOSE INHALERS OR OTHER DEVICES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALBUTEROL HFA (authorized generics Proair®, Proventil®, Ventolin®) PROAIR RESPICLICK® (albuterol)	XOPENEX HFA® (levalbuterol) PROAIR DIGIHALER® (albuterol sulfate)

k. Respiratory Agents: Beta-Adrenergic-Muscarinic Combinations (LABA/LAMA): Duaklir® Pressair® (aclidinium bromide and formoterol fumarate DPI), Circassia Pharmaceuticals

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Dr. Hedlund provided a clinical overview of the medication. ODM recommended a PA Required "Non-Preferred" place on the PDL. Votes were taken, and the committee recommended the proposed category as shown below:

Respiratory Agents: Beta-Adrenergic Agonists – Inhaled, Long Acting

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? 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
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 14 day trial of at least one medication not requiring prior approval

RESPIRATORY AGENTS: BETA-ADRENERGIC-MUSCARINIC COMBINATIONS (LABA/LAMA)

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BEVESPI AEROSPHERE™ (glycopyrrolate/formoterol) † UTIBRON™ NEOHALER® (indacaterol/glycopyrrolate)†	ANORO™ ELLIPTA (umeclidinium/vilanterol)† STIOLTO™ (tiotropium/olodaterol) DUAKLIR PRESSAIR™ (aclidinium bromide/formoterol fumarate)†

†Denotes breath actuated inhaler

VIII. Drug Class Announcement

ODM announced a new UPDL class, Respiratory Agents, Cystic Fibrosis. Dr. Hedlund provided a clinical overview of the medications. ODM recommended a Clinical PA Required "Preferred" place on the PDL for all four agents. Votes were taken, and the committee recommended the proposed category as shown below:

Respiratory Agents: Cystic Fibrosis

LENGTH OF AUTHORIZATIONS: Initial authorization 90 days
Subsequent authorization 365 days

Initial Authorization

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- KALYDECO® (ivacaftor), ORKAMBI® (lumacaftor/ivacaftor), SYMDEKO® (tezacaftor/ivacaftor) and TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor and ivacaftor) may be approved if the patient meets all the following criteria:
 - Diagnosis of cystic fibrosis
 - The prescriber is, or has consulted with a pulmonologist or infectious disease specialist
 - Patient has documentation (must include with PA request) of the genetic mutation(s) that the FDA approved the requested medication to treat
 - Patient meets the FDA-approved age minimum for the requested medication

Reauthorization Criteria:

- Patient may be approved for reauthorization if they meet all the following criteria:
 - Patient must meet all initial criteria
 - Patient's adherence to medication is confirmed by claim history
 - Chart notes submitted with one or more of the following:
 - Lung function improvement as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
 - Improvement in sweat chloride
 - Decrease in pulmonary exacerbations
 - Decrease in pulmonary infections
 - Increase in weight-gain
 - Decrease in hospitalizations
 - Increased Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

RESPIRATORY AGENTS: CYSTIC FIBROSIS

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
KALYDECO® (ivacaftor) ORKAMBI® (lumacaftor/ivacaftor) SYMDEKO® (tezacaftor/ivacaftor) TRIKAFTA® (elexacaftor/tezacaftor/ivacaftor)	

- a. S. Baran announced that pediatric strengths of Harvoni and Sovaldi are now available.
- b. S. Baran reviewed the Respiratory Category with the Committee. There were no clinical criteria changes or drug status changes, only cosmetic changes to make the category easier to navigate. The Committee agreed with these updates.

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Respiratory Agents: Antihistamines – Second Generation

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there have been therapeutic failures after courses of treatment (e.g., 30 days for allergic rhinitis) with medication not requiring prior approval, then may approve the requested medication.

ADDITIONAL INFORMATION

- Fexofenadine is indicated for patients 6 years of age and older
- Loratadine is indicated for patients 2 years of age and older
- Cetirizine and desloratadine are indicated for patients 6 months of age and older

RESPIRATORY AGENTS: ANTIHISTAMINES: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CETIRIZINE chewable, syrup (generic of Zyrtec®) (no PA required for age 6 or under)	CETIRIZINE chewable, syrup (generic of Zyrtec®) (PA required for over age 6)
CETIRIZINE tablets (generic of Zyrtec®)	CLARINEX® syrup (desloratadine)
LORATADINE rapid dissolve (generic of Claritin® Redi-tabs)	CLARITIN REDITABS® 5mg (loratadine)
LORATADINE tablets, syrup (generic of Claritin®)	DESLOLATADINE tablets, ODT (generic of Clarinex®)
	FEXOFENADINE tablets, suspension (generic of Allegra®)
	LEVOCETIRIZINE tablets, oral solution (generic of Xyzal®)

RESPIRATORY AGENTS: ANTIHISTAMINE/DECONGESTANT COMBO: SECOND GENERATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CETIRIZINE/PSEUDOEPHEDRINE (generic of Zyrtec- D®)	CLARINEX-D 12, 24 HOUR® (desloratadine/pseudoephedrine)
LORATADINE/PSEUDOEPHEDRINE (generic of Claritin-D®)	

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Respiratory Agents: Epinephrine Auto-Injectors

LENGTH OF AUTHORIZATIONS: 365 days

The requested medication may be approved if there has been therapeutic failure using the product(s) not requiring prior approval.

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

- Intolerance to medication(s) not requiring prior approval
- Contraindication to or drug interaction with medication(s) not requiring prior approval
- History of unacceptable/toxic side effects to medication(s) not requiring prior approval

RESPIRATORY AGENTS: EPINEPHRINE AUTO-INJECTORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
EPINEPHRINE manufactured by labeler 49502 (authorized generic of EpiPen®) SYMJEPI™ (epinephrine)	EPINEPHRINE not manufactured by labeler 49502 (generic of Adrenaclick®, EpiPen®) EPIPEN® (epinephrine) EPIPEN JR® (epinephrine)

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Respiratory Agents: Hereditary Angioedema

LENGTH OF AUTHORIZATIONS: 365 days

All products in this class require clinical prior authorization:

- Diagnosis of hereditary angioedema
- History of recurrent angioedema (without urticaria) within the past 6 months
- History of recurrent episodes of abdominal pain and vomiting within the past 6 months
- History of laryngeal edema within the past 180 days
- Positive family history of angioedema

PDL 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

ADDITIONAL INFORMATION

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

- If there has been one episode of angioedema during use of a preferred medication

RESPIRATORY AGENTS: HEREDITARY ANGIOEDEMA

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
HAEGARDA® (C1 esterase inhibitor, plasma derived) RUCONEST® (C1 esterase inhibitor, recombinant) TAKHZYRO™ (lanadelumab-flyo)	BERINERT® (C1 esterase inhibitor, plasma derived) CINRYZE® (C1 esterase inhibitor, plasma derived) ICATIBANT ACETATE (Generic for Firazyr®) KALBITOR® (ecallantide)

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Respiratory Agents: Inhaled Agents

LENGTH OF AUTHORIZATIONS:

365 DAYS

- Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? 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
- The requested medication may be approved if there has been a therapeutic failure to no less than a 14-day trial of at least one medication not requiring prior approval within the same class and formulation (must try two medications if anticholinergic).

RESPIRATORY AGENTS: BETA-ADRENERGIC, SHORT-ACTING (SABA)

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ALBUTEROL HFA (authorized generics Proair®, Proventil®, Ventolin®) ALBUTEROL nebulizer solution (generic of Proventil®, Ventolin®) 0.083% Premixed nebulizers, 0.5% Concentrated Solution) ALBUTEROL nebulizer solution (generic of Accuneb®) 0.42mg/ml, 0.63mg/ml (no PA required for ages 12 and under) PROAIR RESPICLIK® (albuterol)	ALBUTEROL nebulizer solution (generic of Accuneb®) 0.42mg/ml, 0.63mg/ml (PA required for over age 12) LEVALBUTEROL NEBULIZER SOLUTION (generic of Xopenex®) XOPENEX HFA® (levalbuterol)

RESPIRATORY AGENTS: BETA-ADRENERGIC, LONG-ACTING (LABA)

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SEREVENT DISKUS®(salmeterol)†	ARCAPTA NEOHALER® (indacaterol)† STRIVERDI RESPIMAT® (olodaterol) BROVANA™ (arformoterol) PERFOROMIST® (formoterol)

†Denotes breath actuated inhaler

RESPIRATORY AGENTS: BETA-ADRENERGIC-STEROID COMBINATIONS (LABA/ICS)

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SALMETEROL/FLUTICASONE (generic of Advair Diskus®) + [Labeler 66993] DULERA® (formoterol/mometasone) SYMBICORT® (formoterol/budesonide)	ADVAIR® HFA (salmeterol/fluticasone) AIRDUO™ RESPICLIK® (salmeterol/fluticasone) + BREO® ELLIPTA® (vilanterol/fluticasone)† SALMETEROL/FLUTICASONE (generic of Advair Diskus®) + [All other labelers] WIXELA™ Inhub™ (salmeterol/fluticasone) †

†Denotes breath actuated inhaler

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RESPIRATORY AGENTS: BETA-ADRENERGIC-MUSCARINIC COMBINATIONS (LABA/LAMA)

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BEVESPI AEROSPHERE™ (formoterol/glycopyrrolate) † UTIBRON™ NEOHALER® (indacaterol/glycopyrrolate) †	ANORO™ ELLIPTA (vilanterol/ umeclidinium)† STIOLTO™ (olodaterol/tiotropium)

†Denotes breath actuated inhaler

RESPIRATORY AGENTS: ANTICHOLINERGICS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATROVENT HFA® (ipratropium) COMBIVENT Respimat® (ipratropium/albuterol) IPRATROPIUM nebulizer solution IPRATROPIUM/ALBUTEROL nebulizer solution (generic of Duoneb®) SPIRIVA® Handihaler® (tiotropium)† SPIRIVA® Respimat® (tiotropium)	INCRUSE ELLIPTA® (umeclidinium)† LONHALA™ MAGNAIR™ (glycopyrrolate) SEEBRI™ NEOHALER® (glycopyrrolate)† TUDORZA® (aclidinium bromide)† YUPELRI™ (revefenacin)

†Denotes breath actuated inhaler

ADDITIONAL INFORMATION TO AID IN THE FINAL PA DECISION- GLUCOCORTICOIDS

If there have been therapeutic failures to no less than 30-day trials of at least two medications not requiring prior approval, then may approve the requested medication.

Requested medication may be approved if the patient is:

- Under 13 years old and is unable to use an inhaler not requiring prior approval
- Disabled and unable to use a preferred inhaler
- Non-compliant on a preferred inhaler due to taste, dry mouth, or infection
- Clinically unstable, as defined in current guidelines in terms of oral steroid use or patient's current symptomatology

RESPIRATORY AGENTS: GLUCOCORTICOIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ASMANEX® Twisthaler (mometasone) BUDESONIDE nebulizer solution (generic of Pulmicort®) (no PA required for age 6 or under) FLOVENT DISKUS™ and HFA (fluticasone) PULMICORT FLEXHALER® (budesonide)†	AEROSPAN® HFA (flunisolide) ALVESCO® (ciclesonide) ARMONAIR™ RESPICLICK® (fluticasone) † ARNUITY ELLIPTA® (fluticasone furoate)† ASMANEX® HFA (mometasone) BUDESONIDE nebulizer solution (generic of Pulmicort®) (PA required for over age 6) QVAR® (beclomethasone)

†Denotes breath actuated inhaler

RESPIRATORY AGENTS: GLUCOCORTICOID-MUSCARINIC-BETA-ADRENERGIC COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	TRELEGY ELLIPTA (fluticasone, umeclidinium and vilanterol) †

†Denotes breath actuated inhaler

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Respiratory Agents: Leukotriene Receptor Modifiers and Inhibitors

LENGTH OF AUTHORIZATIONS: 365 days

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
 - Allergy to medications not requiring prior approval
 - Contraindication to or drug interaction with medications not requiring prior approval
 - History of unacceptable/toxic side effects to medications not requiring prior approval
2. If there has been a therapeutic failure to 90 days of one preferred agent not requiring prior approval, then may approve the requested medication.

RESPIRATORY AGENTS: LEUKOTRIENE RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
MONTELUKAST tablets, chewable tablets, granules (generic of Singulair®)	ZAFIRLUKAST (generic of Accolate®)	ZILEUTON extended-release (generic of Zyflo CR®) ZYFLO® (zileuton)

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Respiratory Agents: Nasal Preparations

LENGTH OF AUTHORIZATIONS: 365 days

For a non-preferred drug, there must have been inadequate clinical response to preferred alternatives, including a trial of no less than 30 days each of at least two preferred or step therapy products

OTHER APPROVAL 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

RESPIRATORY AGENTS: NASAL PREPARATIONS - GLUCOCORTICOIDS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
FLUNISOLIDE FLONASE OTC® (fluticasone) FLUTICASONE (generic of Flonase®)	BECONASE®AQ (beclomethasone) BUDESONIDE (generic of Rhinocort Aqua®) DYMISTA® (fluticasone/azelastine) MOMETASONE (generic of Nasonex®) OMNARIS® (ciclesonide) QNASL® (beclomethasone) VERAMYST™ (fluticasone furoate) XHANCE™ (fluticasone) ZETONNA® (ciclesonide)

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTIHISTAMINES

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AZELASTINE (generic of Astelin®, Astepro®) OLOPATADINE (generic of Patanase®)	

RESPIRATORY AGENTS: NASAL PREPARATIONS - ANTICHOLINERGICS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
IPRATROPIUM (generic of Atrovent®)	

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Respiratory Agents: Other Agents

LENGTH OF AUTHORIZATIONS:

365 DAYS

DALIRESP EVALUATED WITH EACH REFILL

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval within the same class and formulation? 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
2. The requested medication may be approved if there has been a therapeutic failure to no less than a 14-day trial of at least one medication not requiring prior approval within the same class and formulation. (i.e., nebulizers for nebulizers).

RESPIRATORY AGENTS: PHOSPHODIESTERASE-4 INHIBITORS *

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DALIRESP® (roflumilast)

* Concurrent therapy with long-acting beta agonist required.

DUPIXENT® (dupilumab) may be approved if:

- Indicated for moderate to severe asthma if:
 - Patient is 12 years of age or older
 - Patient has poor symptom control as demonstrated by a validated asthma control questionnaire (i.e. ACQ)
 - Patient has had asthma-related emergency treatments within the last 180 days
 - Patient has eosinophilic phenotype (please include supporting documentation) or with oral corticosteroid dependent asthma.
 - Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 365 days
 - Please identify which asthma-control treatments will continue with dupilumab use
- Indicated for chronic rhinosinusitis with nasal polyposis if:
 - Patient is 18 years of age or older
 - Patient has had an inadequate response, intolerance or contraindication to one medication in each of the following categories:
 - Nasal corticosteroid spray
 - Oral corticosteroid

ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST

STEP THERAPY REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	DUPIXENT® (dupilumab)

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- c.* The committee determined that a presentation regarding the use of diabetes drugs for the treatment of cardiovascular disease will be tabled for discussion during the April P&T meeting.
- d.* S. Baran announced that a new therapeutic category which will include primarily the monoclonal antibodies for respiratory disease is being prepared for review at the next P&T Committee meeting.

X. Next Meeting Dates

S. Baran announced that ODM has a conflict with the April 8, 2020 meeting date. The committee agreed to change this date to **April 15, 2020**.

April 15th, 2020

July 8th, 2020

September 30th, 2020

T. Archibald reminded attendees to check the ODM Pharmacy website for future meeting information and to please arrive no earlier than 1 hour prior to the start of the meetings.

XI. Adjournment

Dr. Jacobs adjourned the meeting at 11:27 A.M.