

**Ohio Department of Medicaid (ODM)
Pharmacy & Therapeutics Committee
Quarterly Meeting
January 13, 2016
10:00 am**

MINUTES

Committee Members Present:

Susan Baker, CNP
Mary Ann Dzurec, PharmD
Suzanne Eastman, PharmD
Jennifer Hauler, DO
Karen Jacobs, DO
Melissa Jefferis, MD
Margaret Scott, RPh

Committee Members Not Present:

Jennifer Gwilym, DO
Sandra Hrometz PhD, RPh

ODM Staff Present:

Michael Howcroft, RPh
Patricia Nussle, RPh
Jonathan Thackeray, MD

Contract Staff/Goold Health System (GHS) Staff Present:

Laureen Biczak, DO
Chad Bissell, PharmD
Jill RK Griffith, BS, PharmD
Steve Liles, PharmD

Also present were approximately 40 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Ms. Margaret Scott, ODM Pharmacist, called the meeting to order at 10:08 am.

II. Introductions

Ms. Scott welcomed the Pharmacy & Therapeutics (P&T) Committee and all guests in the audience. All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations. Two new committee members were appointed and introduced, Mary Ann Dzurec, PharmD (present) and Jennifer Gwilym, DO (not present).

III. Administrative Matters

The P&T Committee By-Laws were discussed and unanimously approved. Elections were held for Chair and Vice Chair. Dr. Jacobs was elected Chair and Ms. Eastman Vice Chair. Ms. Scott collected the signed P&T Committee member Conflict of Interest forms.

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IV. Department of Medicaid Update

Ms. Scott stated that implementation with GHS was going well. Ms. Nussle discussed a new drug court program that is being overseen by the Ohio Department of Mental Health and Addiction Services, which requires Medicaid to lift prior authorization for medication assisted treatment for participants of drug court in 15 counties. She discussed her observations of Franklin County drug court. The program appeared to be well-run with Medicaid patients receiving medications without difficulty when needed.

V. Approval of October 14, 2015 Meeting Minutes

Dr. Jacobs asked for additions or corrections to the October 14, 2015 meeting. There were no additions or corrections. The minutes stand approved.

VI. Drug Class Announcements

Dr. Bissell introduced the drugs under consideration and the process for review and approval.

VII. Interested Party Presentations

There were no interested party presentations.

VIII. Preferred Drug List Proposal

Pharmaceutical manufacturers were given the opportunity to present clinical information on their products and respond to questions from committee members.

A. Synjardy

GHS recommended that Synjardy be made non-preferred in the Diabetes-Oral Hypoglycemics, Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitor and Combinations category. Clinical discussion ensued. Votes were taken. The approved category appears below.

DIABETES – ORAL HYPOGLYCEMICS, SODIUM-GLUCOSE COTRANSPORTER 2 (SGLT2) INHIBITOR AND COMBINATIONS

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
		FARXIGA® (dapagliflozin) GLYXAMBI® (empagliflozin/ linagliptin) INVOKAMET® (canagliflozin/ metformin) INVOKANA® (canagliflozin) JARDIANCE® (empagliflozin) SYNJARDY® (empagliflozin and metformin) XIGDUO XR® (dapagliflozin/ metformin)

B. Tivorbex

GHS recommended that Tivorbex be made non-preferred in the Analgesic Agents: NSAIDS category. Patients must try two preferred NSAIDS before Tivorbex would be authorized. Clinical discussion ensued. Votes were taken and the recommendation for non-preferred status approved.

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C. Repatha and Praluent

GHS recommended that Repatha and Praluent require clinical PA and be made non-preferred in the Cardiovascular Agents: Lipotropics-PCSK9 Inhibitors category. Clinical discussion ensued. Votes were taken and the approved category and recommended criteria follows below.

ADDITIONAL CRITERIA FOR PCSK9 INHIBITORS:

- All products in this class require clinical prior authorization:
 - Age ≥ 18 years or Age ≥ 13 years and Homozygous Familial Hypercholesterolemia (HoFH)
 - Documented adherence to prescribed lipid lowering medications for previous 90 days
 - Recommended by cardiologist or lipidologist
 - Baseline lab results are required and approvals will be limited to 12 weeks initially and then annually thereafter. Subsequent approvals will require additional levels being done to assess changes.
 - Lipid profile required at week 8 for HeFH or ASCVD
 - Lipid profile required after 3rd dose for HoFH

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

1. Total Cholesterol > 290 mg/dL or LDL-C > 190 mg/dL and one of the following :
 - Presence of tendon xanthomas or 1st or 2nd degree relative with documented tendon xanthomas, MI at age ≤ 60 years or TC > 290 mg/dL or
 - Confirmation of diagnosis by gene or receptor testing
2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia®) 10 mg daily plus concurrently administered lipid lowering agent
 - A trial of 2 or more statins, at least one must be atorvastatin

Diagnosis of Clinical Atherosclerotic Cardiovascular Disease: must meet both:

1. History of MI, angina, coronary or other arterial revascularization, stroke, TIA or PVD of atherosclerotic origin and
2. Unable to reach goal LDL-C with maximally tolerated dose of statin plus ezetimibe (Zetia®) 10 mg daily
 - A trial of 2 or more statins, at least one must be atorvastatin

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

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

CARDIOVASCULAR AGENTS: LIPOTROPICS PCSK9 INHIBITORS

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

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D. Zecuity

GHS recommended that Zecuity be made non-preferred in the CNS Agents: Anti-Migraine Agents-Serotonin 5-HT₁ Receptor Agonists category. Clinical discussion ensued. Votes were taken and the approved category follows below.

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

NO PA REQUIRED “PREFERRED”	PA REQUIRED
IMITREX® Injection (sumatriptan) IMITREX® Nasal spray (sumatriptan) RIZATRIPTAN tablets (generic of Maxalt®) RIZATRIPTAN ODT (generic of Maxalt-MLT®) Sumatriptan tablets (generic of Imitrex®)	ALMOTRIPTAN (generic of Axert®) RELPAX® (eletriptan) Sumatriptan injection (generic of Imitrex®) Sumatriptan nasal spray (generic of Imitrex®) Sumavel Dosepro® (sumatriptan) ZOLMITRIPTAN (generic of Zomig®) ZOLMITRIPTAN ODT (generic of Zomig ZMT®) ZOMIG® NASAL SPRAY (zolmitriptan) ZECUITY® (sumatriptan)

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

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
Naratriptan (generic of Amerge®)	FROVA® (frovatriptan)	

E. Rexulti

GHS recommended that Rexulti be made non-preferred in the Antipsychotics, Second Generation category. Clinical discussion ensued. Votes were taken and the approved category follows below.

ANTIPSYCHOTICS, SECOND GENERATION *

NO PA REQUIRED “PREFERRED GENERIC”	STEP THERAPY REQUIRED “PREFERRED BRAND”	PA REQUIRED
QUETIAPINE (generic of Seroquel®) Risperidone (generic of Risperdal®) ZIPRASIDONE (generic of Geodon®)	Abilify® tablet (aripiprazole) aripiprazole solution LATUDA® (lurasidone) Seroquel XR® (quetiapine)	Aripiprazole tablet (generic of Abilify®) Abilify Discmelt® (aripiprazole) CLOZAPINE (generic of Clozaril®) Fanapt® (iloperidone) Fazaclo® (clozapine) Invega® (paliperidone) olanzapine (generic of Zyprexa®) olanzapine ODT (generic of Zyprexa® Zydis) REXULTI® (brexpiprazole) Saphris® (asenapine) Versacloz® (clozapine oral suspension)

*Patients on current regimens will be grandfathered.

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F. Aristada

GHS recommended that Aristada be made non-preferred in the Antipsychotics, Second Generation, Long-Acting Injectables category. Clinical discussion ensued. Votes were taken and the approved category follows below.

ANTIPSYCHOTICS, SECOND GENERATION LONG-ACTING INJECTABLES * +

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ABILIFY MAINTENA® (aripiprazole) INVEGA SUSTENNA® (paliperidone) INVEGA TRINZA® (paliperidone) RISPERDAL CONSTA® (risperidone) ZYPREXA RELPREVV® (olanzapine)	ARISTADA™ (aripiprazole lauroxil)

*Patients on current regimens will be grandfathered.

+ Long-Acting Injectable Antipsychotics may be billed by the pharmacy if they are not dispensed directly to the patient. 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.

G. Aptensio XR

GHS recommended that Aptensio XR be made non-preferred in the CNS Agents: Attention Deficit Hyperactivity Disorder Agents-Long-Acting category. Clinical discussion ensued. Votes were taken and the approved category follows below.

CNS AGENTS: ATTENTION DEFICIT HYPERACTIVITY DISORDER AGENTS – LONG ACTING

NO PA REQUIRED "PREFERRED"	PA REQUIRED
Adderall XR® (amphetamine/dextroamphetamine) Dextroamphetamine SA (generic of Dexedrine® spansule) FOCALIN® XR (dexmethylphenidate) GUANFACINE ER (generic of Intuniv®) METADATE® CD (methylphenidate) METADATE® ER (methylphenidate) METHYLIN® ER (methylphenidate) METHYLPHENIDATE ER (generic of Concerta®) METHYLPHENIDATE ER (generic of Ritalin SR®) STRATTERA® (atomoxetine) VYVANSE™ (lisdexamfetamine)	APTENSIO XR™ (methylphenidate) Clonidine ER (generic of Kapvay®) DAYTRANA® (methylphenidate) DEXMETHYLPHENIDATE ER (generic of Focalin XR®) Dextroamphetamine-Amphetamine (generic of Adderall XR®) METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA) QUILLIVANT XR® suspension (methylphenidate)

H. Daklinza

GHS recommended that Daklinza be made non-preferred in the Infectious Disease Agents: Hepatitis C – Direct-Acting Antiviral category. Clinical discussion ensued. Votes were taken and the approved category follows below.

I. Technivie

GHS recommended that Technivie be made preferred in the Infectious Disease Agents: Hepatitis C –Direct-Acting Antiviral category. Clinical discussion ensued. Votes were taken and the approved category follows below.

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INFECTIOUS DISEASE AGENTS: HEPATITIS C – DIRECT-ACTING ANTIVIRAL

CLINICAL PA REQUIRED “PREFERRED”	PA REQUIRED
Harvoni® (ledipasvir/sofosbuvir) tablets TECHNIVIE™ (ombitasvir/paritaprevir and ritonavir) VIEKIRA PAK™ (ombitasvir/paritaprevir and ritonavir tablets/dasabuvir tablets)	DAKLINZA™ (daclatasvir) SOVALDI® (sofosbuvir)

IX. Other Business

No other business was discussed.

X. Next Meeting Dates

The next P&T Committee meetings will be held on: Wednesday, April 13, 2016 at 10am, location to be announced; Wednesday, June 8, 2016 at 9am, location to be announced; and Wednesday, October 26, 2016 at 10am, location to be announced.

XI. Adjournment

Dr. Jacobs adjourned the meeting at 12:02pm.

ODM Actions: Following the meeting, ODM accepted all recommendations of the P&T Committee and will implement the recommendations by April 1, 2016.