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

MINUTES

Committee Members Present:

Mary Ann Dzurec, PharmD
Jennifer Gwilym, DO
Jennifer Hauler, DO
Michael Howcroft, RPh
Karen Jacobs, DO, Chair
Melissa Jefferis, MD
Margaret Scott, RPh

Committee Members Not Present:

Susan Baker, CNP
Suzanne Eastman, PharmD
Sandra Hrometz PhD, RPh

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

Laureen Biczak, DO
Chad Bissell, PharmD
Jill RK Griffith, BS, PharmD
Ben Link, PharmD

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

I. Call to Order

Karen Jacobs, DO, called the meeting to order at 10:09 am.

II. Introductions

Dr. Jacobs 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.

III. Administrative Matters

a) Meeting Location

Ms. Scott addressed the change in the meeting location and confirmed the location of the next meeting to be 50 W. Town Street, Room C621.

IV. Department of Medicaid Update

a) Patient Population

Ms. Scott noted that on January 1, 2017 certain groups would be removed from the fee-for-service (FFS) program and transitioned into the managed care plans. Groups identified included those covered under the Bureau for Children with Medical Handicaps (BCMH) and foster children. This would impact an estimated 15,000 lives. The Ohio Medicaid FFS program will manage approximately 250,000 to 300,000 total lives with these changes.

b) 1634 Eligibility

Ms. Scott noted that as of August 1st, 2016 Ohio is no longer a "spend down" state as it has moved from a 209(b) eligibility option to processing Medicaid applications based upon 1634 eligibility criteria. This change includes a conversion of all Medicaid aged, blind, and disabled (ABD) beneficiaries from CRIS-E (the legacy eligibility system) to *Ohio Benefits* (new eligibility system). Beneficiaries previously eligible under spenddown will remain enrolled for one year or until their re-determination period.

c) Pharmacy Claims Processor

Ms. Scott also noted that Goold Health Systems (GHS) has been processing claims since June 12th, 2016.

V. Approval of April 13, 2016 Meeting Minutes

The minutes from the prior P&T meeting were reviewed. Dr. Gwilym move to approve the minutes, seconded by Dr. Dzurec.

VI. Drug Announcements/Discussion-Flumist® lack of effectiveness

Dr. Biczak presented information regarding the June 22nd, 2016 announcement by the Centers for Disease Control Advisory Committee on Immunization Practices (ACIP) that recommended against the use of live attenuated influenza vaccine (LAIV-nasal flu vaccine) for the 2016-17 season. This recommendation was made as a result of evidence depicting poor effectiveness LAIV over recent influenza seasons. Dr. Biczak advised that the Ohio Department of Medicaid make Flumist a non-preferred product for the upcoming influenza season.

VII. Interested Party Presentations

Patrick Beatty, Esq, Director of the Ohio AIDS Coalition

Mr. Beatty provided testimony to advocate for the use of single tablet HIV regimens on the preferred drug list without prior authorization requirements.

Dave Baker, The Dave Baker Foundation

Mr. Baker spoke as an advocate for single tablet HIV medication regimens with special emphasis placed on the side effects that occur as a result of taking multiple pills per day. Mr. Baker mentioned daily living concerns of patients of HIV.

Dr. Jacobs thanked both presenters and stated that there would be later discussion of HIV medications.

VIII. Preferred Drug List (PDL) Proposal

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

a) Durlaza®

GHS recommended that Durlaza be non-preferred in the Blood Formation, Coagulation and Thrombosis Agents: Oral Anticoagulants due to a lack of superiority to other preferred medications in the drug class. Patients must try one preferred agent before Durlaza would be authorized. Votes were taken and the approved category follows below.

BLOOD AGENTS: ORAL ANTICOAGULANTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ELIQUIS® (apixaban) WARFARIN (generic of Coumadin®) XARELTO® (rivaroxaban) *	DURLAZA® (aspirin ER capsule) PRADAXA® (dabigatran) SAVAYSA® (edoxaban)

b) Prestalia®

GHS recommended that Prestalia be non-preferred in the Cardiovascular Agents: Angina, Hypertension & Heart Failure- ACE Inhibitors/CCB Combination. This recommendation was made following a review of the clinical information for Prestalia and identification of preferred alternatives available to patients. Patients must try two preferred agents before Prestalia would be authorized. Votes were taken and the approved category follows below.

ACE INHIBITORS/CCB COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMLODIPINE/BENAZEPRIL (generic of Lotrel®) TARKA® (verapamil/trandolapril)	PRESTALIA® (perindopril-amlodipine tablet) VERAPAMIL/TRANDOLAPRIL (generic of Tarka®)

c) Vraylar™

GHS recommended that Vraylar be non-preferred in the Central Nervous System (CNS) Agents: Antipsychotics, Second Generation, Oral category with grandfathering and psychiatrist exemption. Patients must try two preferred agents before Vraylar would be authorized. Votes were taken and the approved category follows below.

ANTIPSYCHOTICS, SECOND GENERATION, ORAL *

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) VRAYLAR™ (cariprazine capsule)

d) Adzenys XR-ODT™

George Kehner presented on behalf of Neo Therapeutics. GHS recommended Adzenys XR-ODT be added as an alternative with a prior authorization requirement, specifically for patients that cannot swallow, in the Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents, Long-acting category. Votes were taken and the approved category follows below.

LENGTH OF AUTHORIZATIONS: 1 year

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
   - Daytrana®, Quillivant XR®, Adzenys XR-ODT™, Dyanavel™ XR, Quillichew ER™ may be approved if the patient is unable to swallow pills.

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® (atomexetine) VYVANSE™ (lisdexamfetamine)	ADZENYS XR-ODT™ (amphetamine tablet, ODT) APTENSIO XR™ (methylphenidate) CLONIDINE ER (generic of Kapvay®) DAYTRANA® (methylphenidate) DEXMETHYLPHENIDATE ER (generic of Focalin XR®) DEXTROAMPHETAMINE-AMPHETAMINE (generic of Adderall XR®) DYANAVEL™ XR (amphetamine ER oral suspension) METHYLPHENIDATE LA (generic of Metadate® CD, Ritalin® LA) QUILLICHEW ER™ (methylphenidate tablet, chewable, extended release) QUILLIVANT XR® suspension (methylphenidate)

e) Dyanavel™ XR

Heidi Belden, presented on behalf of Tris Pharma. GHS recommended that Dyanavel XR be added as an alternative with a prior authorization requirement, in the Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents, Long-acting category specifically for patients that cannot swallow. Votes were taken and the approved category is as shown under Adzenys XR-ODT.

f) Quillichew ER™

Eric Millheim, presented on behalf of Pfizer. GHS recommended that Quillichew ER be added as an alternative with a prior authorization requirement, in the Central Nervous System (CNS) Agents: Attention Deficit Hyperactivity Disorder Agents, Long-acting category specifically for patients that cannot swallow. Votes were taken and the approved category is as shown under Adzenys XR-ODT.

g) Taltz®

Steve Babineaux presented on behalf of Eli Lilly and Company. GHS recommended Taltz be non-preferred land require a prior authorization after 3 months of unsatisfactory results from other alternatives, in the Immunomodulator Agents for Systemic Inflammatory Disease category. Votes were taken and the approved category follows below.

ANTI-INFLAMMATORY INTERLEUKIN RECEPTOR ANTAGONIST

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	ACTEMRA® syringe (tocilizumab) COSENTYX™ (secukinumab) KINERET® syringe (anakinra) TALTZ® (ixekizumab injection)

h) Xeljanz® XR

Eric Millheim presented on behalf of Pfizer. GHS recommended Xeljanz XR be non-preferred and require a prior authorization after 3 months of unsatisfactory results from other alternatives, in the Immunomodulator Agents for Systemic Inflammatory Disease category. Votes were taken and the approved category follows below.

JANUS KINASE INHIBITOR

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	XELJANZ® tablet (tofacitinib citrate) XELJANZ® XR (tofacitinib tablet, film coated, extended release)

i) Zepatier™

Steven Smith presented on behalf of Merck. GHS recommended that Zepatier be added to the preferred drug list in the Infectious Disease Agents: Antivirals- Hepatitis C Agents category. Votes were taken and the recommendation approved.

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) ZEPATIER™ (elbasvir and grazoprevir tablet)	DAKLINZA™ (daclatasvir) SOVALDI® (sofosbuvir)

j) Descovy®

Stuart O'Brochta presented on behalf of Gilead Sciences, Inc. Mr. O'Brochta discussed both Descovy and Odefsey together with an emphasis on tenofovir alafenamide (TAF) data. GHS recommended that Descovy remain in non-preferred status in the Infectious Disease Agents: Antivirals- HIV and require prior authorization with criteria updated that products containing TAF will be given approval in patients that have renal or bone mineral density issues. Votes were taken and the approved category follows below.

OTHER APPROVAL CRITERIA:

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

a) Allergy to medications not requiring prior approval
b) Contraindication to all medications not requiring prior approval
c) History of unacceptable/toxic side effects to medications not requiring prior approval
d) Has the patient failed a therapeutic trial of at least one month with at least one medication not requiring prior approval?
e) Approval will be given for products containing tenofovir alafenamide (TAF) if the patient has had renal or bone mineral density issues.

HIV RTI, NUCLEOSIDE-NUCLEOTIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
TRUVADA® (emtricitabine/tenofovir)	DESCOVY® (emtricitabine/ tenofovir alafenamide)

k) Odefsey®

GHS recommended that Odefsey remain on the non-preferred status in the Infectious Disease Agents: Antivirals- HIV and require prior authorization with criteria updated that products containing TAF will be given approval in patients that have renal or bone mineral density issues as shown above with Descovy. Votes were taken and the approved category follows below.

HIV RTI, NUCLEOSIDE, NUCLEOTIDE, & NON-NUCLEOSIDE ANALOGS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
ATRIPLA® (emtricitabine/efavirenz/tenofovir) COMPLERA® (emtricitabine/rilpivirine/tenofovir)	ODEFSEY® (emtricitabine/rilpivirine/tenofovir alafenamide)

l) Sernivo™

GHS presented clinical data and recommended that Sernivo be non-preferred. Sernivo may be approved following trials of at least two preferred medications. Votes were taken and the approved category follows below.

TOPICAL AGENTS: CORTICOSTEROIDS – HIGH POTENCY

NO PA REQUIRED "PREFERRED"	PA REQUIRED
AMCINONIDE ointment, cream, lotion BETAMETHASONE VALERATE ointment (generic of Valisone®) DIFLORASONE DIACETATE cream, ointment (generic of Florone®) FLUOCINONIDE cream, gel, ointment, solution (generic of Lidex®, Lidex-E®)	APEXICON-E® (diflorasone diacetate emollient base) cream BETAMETHASONE DIPROPIONATE cream, ointment (generic of Diprolene®) FLUOCINONIDE (generic of Vanos® cream) HALOG® cream, ointment (halcinonide) KENALOG® aerosol spray (triamcinolone acetonide) SERNIVO™ (betamethasone dipropionate spray)

IX. Other Business

a) New Drug Classes for the annual Preferred Drug List (PDL) review to be discussed at the October P&T meeting.

Dr. Bissell presented information regarding the annual PDL review in October. In an effort to condense the amount of time spent reviewing the Preferred Drug List, GHS recommended category extraction for approval and review utilizing a consent agenda as outlined in *Robert's Rules of Order*. New drug classes to be added to the PDL are as follows:

i. NSAIDs class expanded to include all NSAIDs and all dosage forms (oral, topical/transdermal, and injectable)
ii. IBS category expanded to include SBS and otherSelected GI products

Dr. Jacobs raised a question on how long the committee would have to review the PDL prior to the October meeting. With a response indicating that the meeting agenda would be distributed 30 days prior to the meeting occurrence. It was additionally noted that process for information dissemination would be formalized.

X. Next Meeting Dates:

a. Wednesday, October 5, 2016 Location: Ohio Department of Medicaid, 50 W. Town Street, Room C621

XI. Adjournment
   a. Dr. Jacobs adjourned the meeting at 11:42 a.m.

Following the meeting, ODM agreed with the recommendations of the P&T Committee and all changes will be implemented by October 1.