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

MINUTES

Committee Members Present:
Susan Baker, CNP
Suzanne Eastman, PharmD
Jennifer Gwilym, DO
Jennifer Hauler, DO
Karen Jacobs, DO, Chair
Margaret Scott, RPh

Committee Members Not Present:
Mary Ann Dzurec, PharmD
Melissa Jefferis, MD
Michael Howcroft, RPh
Sandra Hrometz PhD, RPh

ODM Staff Present:
Patricia Nussle, RPh
Zachary Zychowicz, PharmD Candidate

Contract Staff/Goold Health System (GHS) Staff Present:
Jeffrey Barkin, MD
Chad Bissell, PharmD
Jill RK Griffith, BS, PharmD
Ben Link, PharmD
Payal Patel, PharmD
Robyn Satterfield, PharmD

Also present were approximately 55 observers, most representing pharmaceutical manufacturers.

I. Call to Order

Karen Jacobs, DO, called the meeting to order at 10:06 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. One new committee member was introduced, Jennifer Gwilym, DO.

III. Administrative Matters

a) Sovereign States Drug Consortium (SSDC)

Dr. Bissell discussed that the state of Ohio has decided to become a member of the SSDC for the 2017 contract year. Ohio will be the 13th state to join the pool covering approximately 3 million fee-for-service lives. Goold Health Systems (GHS) is both a vendor to ODM as well as the SSDC.

Drs. Bissell and Barkin stressed that GHS negotiates supplemental rebates on behalf of ODM through this process, but all monies are passed directly to the state in a transparent process. All offers are presented in detail and each state has the option to accept or reject any proposal. This allows each member state to be autonomous with their PDL decisions and structure.

A general question and answer session followed the overview. It was noted that while GHS has relationships with the manufacturers, communication between ODM and the manufacturers would continue. Becoming a member state makes sense as more patients (e.g. foster kids) move from the fee-for-service program into the managed care plans. The fee-for-service program will evolve into more of an adult population and disabled adults.

b) Meeting Schedule

Ms. Scott discussed the normal procedure of presenting proposed PDL classes in the meeting prior to the annual review. Since the SSDC timeline is different, presenting proposed classes in June prior to the October annual PDL review would not be possible. It was requested that the June meeting be moved to July or August. Ms. Scott will email the committee members to select the new date in place of June's meeting.

Dr. Jacobs requested the October annual review meeting be moved from October 26th to the first Wednesday in October (5th) due to a conflict.

c) Conflict of Interest policy

Members were reminded to sign the Conflict of Interest form. A form was provided to the newest member, Dr. Gwilym.

IV. Department of Medicaid Update

Ms. Scott noted the move of patient populations from the fee-for-service program into the managed care plans was already discussed. Value-based purchasing with episodic care and patient centered medical home programs is underway. To understand more about these programs, it was encouraged to visit the governor's transformation web site (http://www.healthtransformation.ohio.gov). Additionally, more information on the Healthy Ohio program is available on their web page: http://www.healthy.ohio.gov/default.aspx.

V. Approval of January 13, 2016 Meeting Minutes

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

VI. Drug Class Announcements

Currently, there are no drug class announcements due to the change in the PDL process with joining the SSDC pool.

VII. Interested Party Presentations

Dr. Brian Beesley, DO, AAHIVS for Genvoya

Dr. Beesley is a family practitioner, HIV specialist and Associate Professor with Ohio University Heritage College of Osteopathic Medicine and Assistant Professor with The Ohio State University. He provided commentary on how the treatment of the HIV patient population is shifting more towards co-morbidity management with longer survival rates. The physician discussed the merits of Genvoya having less renal and bone loss complications and the ability to use in patients as young as 12 years. It was requested that the P&T Committee consider using step edits in certain patients that would benefit from this therapy.

Dr. Kevin Ware, MD for the Medicaid Psychiatry Exemption

Dr. Ware is a psychiatrist at Mt. Carmel Medical Center. He discussed several patient cases and outcomes with long-acting injection antipsychotic therapy. Dr. Ware desired to have psychiatrists given open access to all antipsychotic drugs and formulations. Currently, the PDL allows psychiatrists open access to all antipsychotics except orally dissolving tablets (ODT) and Aristada (aripiprazole lauroxil), which require a prior authorization. It was noted that the ODT formulation has similar kinetics as standard tablets. While Aristada requires a prior authorization, all of the other (five) long-acting injectable antipsychotics are covered including Abilify Maintenna (aripiprazole).

Dr. Ware would like psychiatrists to have access to Aristada and Dr. Jacobs was concerned that new products coming to the market would have to face this same access issue. Ms. Scott suggested that a discussion take place internally to look at making policy changes to address this issue. This issue is slated to be discussed in the summer meeting along with other policy changes.

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) Vivlodex

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

b) Belbuca

GHS recommended that Belbuca be made non-preferred in the Analgesic Agents: Opioids category. Clinical discussion ensued. Votes were taken and the approved category follows below.

ANALGESIC AGENTS: OPIOIDS – Long-Acting Oral

NO PA REQUIRED "PREFERRED GENERIC"	STEP THERAPY REQUIRED "PREFERRED BRAND"	PA REQUIRED
Extended Release Buprenorphine Products		
		BELBUCA™ (Buprenorphine buccal film)
Extended Release Hydrocodone Products		
		ZOHYDRO ER® (hydrocodone)

Extended Release Morphine Products		
MORPHINE SULFATE ER tablet (generic of MS Contin®)		EMBEDA® (morphine sulfate/ naltrexone) MORPHINE SULFATE ER capsule (generic of Avinza®, Kadian®)
Extended Release Oxycodone Products		
		HYSINGLA ER® (oxycodone) OXYCODONE ER (generic of Oxycontin®) OXYCONTIN® (oxycodone) XARTEMIS XR® (oxycodone/ acetaminophen)
Extended Release Tramadol Products		
		CONZIP® (tramadol) TRAMADOL ER (generic of Ryzolt ER®, Ultram ER®)
Extended Release Oxymorphone Products		
		OPANA ER tablets (oxymorphone abuse-deterrent) OXYMORPHONE HCL ER tablets (generic of Opana® ER non-abuse-deterrent)
Extended Release Hydromorphone Products		
		HYDROMORPHONE ER (generic of Exalgo® ER)
Extended Release Tapentadol Products		
	NUCYNTA ER® (tapentadol)	

c) Uptravi

David Catanzano, PharmD, presented on behalf of Actelion. GHS recommended that Uptravi be made non-preferred in the Cardiovascular Agents: Pulmonary Arterial Hypertension (PAH) category. Clinical discussion ensued. Votes were taken and the approved category follows below.

CARDIOVASCULAR AGENTS: PULMONARY ARTERIAL HYPERTENSION,
Prostacyclin Receptor Agonist, Oral*

CLINICAL PA REQUIRED "PREFERRED"	PA REQUIRED
	UPTRAVI® (selexipag)

*Patients on current regimens will be grandfathered.

d) Tresiba Flextouch

Kristen Dial, PharmD, presented on behalf of Novo Nordisk. GHS recommended that Tresiba be made non-preferred in the Endocrine Agents: Diabetes- Insulin category. Clinical discussion ensued. Votes were taken and the approved category follows below with a re-review of the class and criteria during the October annual review.

ENDOCRINE AGENTS: DIABETES - INSULINS - Long Acting*

NO PA REQUIRED "PREFERRED"	PA REQUIRED
LANTUS® (insulin glargine)	LEVEMIR® (insulin detemir) ** TOUJEO® (insulin glargine) TRESIBA FLEXTOUCH® (insulin degludec)

* Patients on current insulin regimens will be grandfathered.

** Levemir (pregnancy category B) may be approved for pregnant women through the estimated due date.

e) Varubi

GHS recommended that Varubi be made non-preferred in the Gastrointestinal Agents: Anti-emetics category. Clinical discussion ensued. Votes were taken and the approved category follows below.

GASTROINTESTINAL AGENTS: ANTI-EMETIC AGENTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED
EMEND® tablets, trifold (aprepitant) ONDANSETRON tablets, solution, ODT (generic of Zofran®)	ANZEMET® (dolasetron) GRANISETRON tablet, solution (generic of Kytril®) SANCUSO® patch (granisetron) VARUBI™ (rolapitant) ZUPLENZ® film (ondansetron)

f) Genvoya

Paul Miner, PharmD, presented on behalf of Gilead. GHS recommended that Genvoya be made non-preferred in the Infectious Disease: Antivirals- HIV category. Clinical discussion ensued. Votes were taken and the approved category follows below with a change to the criteria allowing authorization in patients with renal impairment and bone mineral loss.

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 (new to Medicaid, samples, etc.), will be approved for PA after prescriber contact.

OTHER APPROVAL CRITERIA:

1. Is there any reason the patient cannot be changed to a medication not requiring prior approval? Acceptable reasons include:
2. Allergy to medications not requiring prior approval
3. Contraindication to all medications not requiring prior approval
4. History of unacceptable/toxic side effects to medications not requiring prior approval
5. Has the patient failed a therapeutic trial of at least one month with at least one medication not requiring prior approval?
6. Approval will be given for Genvoya if the patient has had renal or bone mineral density issues.

HIV INTEGRASE INHIBITOR & RTI COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED
TRIUMEQ® (dolutegravir/abacavir/lamivudine)	GENVOYA® (elvitegravir/cobicistat/emtricitabine/ tenofovir alafenamide) STRIBILD® (elvitegravir/cobicistat/emtricitabine/ tenofovir)

IX. Other Business

No other items discussed.

X. Next Meeting Dates:

Summer meeting to be determined- specific date will be ascertained through P&T Committee member email communication with ODM.

October 5, 2016

XI. Adjournment

Meeting was adjourned at 11:33am

ODM Actions: Following the meeting, ODM accepted all recommendations of the P&T Committee