STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Earl Ray Tomblin
Governor

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Karen L. Bowling
Cabinet Secretary

Pharmaceutical and Therapeutics Committee

January 27th, 2016

Location: Diamond, Rooms B10 and B11
Time: 2:00 PM – 5:00 PM
Charleston, WV 25301
(304) 558-1700

MINUTES

Committee Members Present:
Robert Stanton, PharmD., Chairman
Bradley Henry, MD, Vice Chairman
Elizabeth Baldwin, RN, MSN, PNP, APRN-BC
Adam Breinig, DO
Scott Brown, RPh
Chris Terpening, PharmD, PhD
Tom Kines, RPh
Heather Jones, PA-C

By Phone:
Kenneth Hilsbos, MD
Steve Neal, PharmD

Absent:
Hazi Nazha, MD

Division of Medicaid Staff Present:
Vicki Cunningham, RPh
Brian Thompson, PharmD, MS
Doug Sorvig

Contract Staff/GHS Staff Present:
Chad Bissell, PharmD, MBA
Jeff Barkin, MD
Brent Breeding, RPh
Matt Pettengill, PMP

Other Contract / State Staff Present:
Steve Small, PharmD, Rational Drug Therapy Program
Eric Sears, PharmD, Molina Medicaid Solutions

I. Call to Order

Dr. Robert Stanton, Chairman, called the meeting to order at 2:08 pm.

II. Welcome and Introductions

P&T committee members introduced themselves and one new member, Health Jones, was welcomed to the Committee.

III. Administrative Items / Updates

Vicki Cunningham provided ground rules for public comment.

A. Approval of the October 28th, 2015 Minutes

Dr. Stanton made a motion to approve the minutes from the October 28, 2015, annual meeting. The motion was seconded, all were in favor and the minutes were approved.

B. PDL Compliance/Generic Percent Report Updates

Dr. Barkin reviewed the Generic Percent and PDL Compliance reports provided by Goold Health Services (GHS) with the Committee. PDL compliance was high overall. In some categories with less generic use, the PDL compliance was high because of the use of preferred brands.

IV. Public Comments

Thomas Joseph, representing Adapt Pharma, spoke on behalf of Narcan Spray.
Daniel Belletti, representing AstraZeneca, spoke on behalf of Movantik.
Christopher Kant, representing Allergan. spoke on behalf of Viberzi / Linzess.
Krista Cavaliere, representing Amgen, spoke on behalf of Repatha.

V. Executive Session

Dr. Stanton asked for a motion to move to executive session. The motion was made by Dr. Henry and seconded by Dr. Breinig.

The Committee adjourned for executive session at 2:35pm.

The Committee reconvened at 3:20pm.

VI. New Business

A. Adjustments to Existing Classes

i. Alzheimer's Agents

ALZHEIMER'S AGENTS[AP]		
CHOLINESTERASE INHIBITORS		
donepezil 5 and 10 mg	ARICEPT (donepezil) donepezil 23 mg* EXELON CAPSULE (rivastigmine) EXELON PATCH (rivastigmine) galantamine galantamine ER RAZADYNE (galantamine) RAZADYNE ER (galantamine) rivastigmine	*Donepezil 23 mg tablets will be authorized if the following criteria are met: 1. There is a diagnosis of moderate-to-severe Alzheimer's Disease **and** 2. There has been a trial of donepezil 10 mg daily for at least three (3) months and donepezil 20 mg daily for an additional one (1) month.
NMDA RECEPTOR ANTAGONIST		
memantine	NAMENDA XR (memantine) NAMENDA (memantine)	

Dr. Bradley Henry made a motion to approve the change to Alzheimer's Agents as recommended and the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

ii. Antihyperlipidemics – Fibrates

LIPOTROPICS, OTHER (Non-statins)[AP]		
FIBRIC ACID DERIVATIVES		
fenofibrate 40 mg fenofibrate 54, 150 and 160 mg fenofibrate micronized 67mg, 134mg & 200mg gemfibrozil TRICOR (fenofibrate nanocrystallized)	ANTARA (fenofibrate) FENOGLIDE (fenofibrate) FIBRICOR (fenofibric acid) fenofibrate 43, 50, 120 and 130 mg fenofibrate nanocrystallized 48 mg, 145 mg fenofibric acid LIPOFEN (fenofibrate) LOFIBRA (fenofibrate) LOPID (gemfibrozil) TRIGLIDE (fenofibrate) TRILIPIX (fenofibric acid)	
PCSK-9 INHIBITORS		

Dr. Bradley Henry made a motion to approve the change to Lipotropics, Other Non-statins as recommended and the motion was seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

iii. Hypoglycemics, Meglitinides

HYPOGLYCEMICS, MEGLITINIDES		
MEGLITINIDES		
nateglinide repaglinide	PRANDIN (repaglinide) repaglinide/metformin STARLIX (nateglinide)	

Dr. Bradley Henry made a motion to approve the change to Hypoglycemics, Meglitinides as recommended and the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

iv. Macrolides/Ketolides

MACROLIDES/KETOLIDES		
MACROLIDES		
azithromycin clarithromycin suspension erythromycin base	BIAXIN (clarithromycin) clarithromycin tablets clarithromycin ER E.E.S. (erythromycin ethylsuccinate) E-MYCIN (erythromycin) ERYC (erythromycin) ERYPED (erythromycin ethylsuccinate) ERY-TAB (erythromycin) ERYTHROCIN (erythromycin stearate) erythromycin estolate PCE (erythromycin) ZITHROMAX (azithromycin) ZMAX (azithromycin)	Five (5) day trials each of the preferred agents are required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.

A motion was made and seconded to approve the recommended change to the Macrolides/Ketolides category. Elizabeth Baldwin recommended keeping clarithromycin suspension preferred for pediatric patients; but moving clarithromycin tablets to non-preferred. Dr. Adam Breining seconded the motion.

The amendment was discussed by the Committee and there was a motion to approve the amendment. Approval of the motion, with the amendment, was seconded by Dr. Adam Breinig. All members were in favor and the motion was approved as amended.

v. NSAIDS

NSAIDS[AP]		
NON-SELECTIVE		
diclofenac (IR, SR) flurbiprofen ibuprofen (Rx and OTC) INDOCIN SUSPENSION (indomethacin) indomethacin ketoprofen ketorolac nabumetone naproxen (Rx and OTC) piroxicam sulindac	ANAPROX (naproxen) ANSAID (flurbiprofen) CATAFLAM (diclofenac) CLINORIL (sulindac) DAYPRO (oxaprozin) diflunisal DUEXIS (famotidine/ibuprofen) etodolac IR etodolac SR FELDENE (piroxicam) fenoprofen INDOCIN SUPPOSITORIES (indomethacin) indomethacin ER ketoprofen ER meclofenamate mefenamic acid MOTRIN (ibuprofen) NALFON (fenoprofen) NAPRELAN (naproxen) NAPROSYN (naproxen) oxaprozin PONSTEL (meclofenamate) SPRIX (ketorolac) TIVORBEX (indomethacin) tolmetin VOLTAREN (diclofenac) ZIPSOR (diclofenac potassium) ZORVOLEX (diclofenac)	

Dr. Bradley Henry made a motion to approve the change to NSAID Category as recommended and the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

B. Expansion of Existing Drug Classes

i. Immunomodulators, Genital Warts & Actinic Keratosis Agents

IMMUNOMODULATORS, GENITAL WARTS & ACTINIC KERATOSIS AGENTS		
CONDYLOX GEL (podofilox) EFUDEX (fluorouracil) imiquimod	ALDARA (imiquimod) CARAC (fluorouracil) CONDYLOX SOLUTION (podofilox) diclofenac 3% gel fluorouracil 5% cream podofilox SOLARAZE (diclofenac) VEREGEN (sinecatechins) ZYCLARA (imiquimod)*	*Zyclara will be authorized for a diagnosis of actinic keratosis.

Chad Bissell recommended the listed additions be made to this category. Additionally, he noted that Aldara was listed as Preferred on the Draft PDL, however, part of the overall recommendation was to move Aldara to non-preferred and move imiquimod to preferred.

Dr. Henry suggested that brand Efudex be preferred. Dr. Stanton asked about the cost difference between brand and generic versions of fluorouracil. Chad Bissell indicated that for Fee for Service patients, the generic would be significantly more expensive than the brand.

Dr. Bradley Henry made a motion to approve the change to the category as amended; seconded by Tom Kines. All members were in favor and the motion was approved as amended.

ii. Irritable Bowel Syndrome/Short Bowel Syndrome/Selected GI Agents

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS		
CATEGORY PA CRITERIA: Thirty (30) day trial of the preferred agent is required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present.		
AMITIZA (lubiprostone)CL* LINZESS (linaclotide) CL**	FULYZAQ (crofelemer) LOTRONEX (alosetron) MOVANTIK (naloxegol) RELISTOR (methylnaltrexone)	*Amitiza will be prior authorized for patients if the following criteria are met: 1. Diagnosis of chronic idiopathic constipation, with less than three spontaneous bowel movements per week **or** 2. Female with a diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C) **or** 3. Diagnosis of opioid induced constipation accompanied by a diagnosis of non-cancer chronic pain (Diagnosis of chronic pain must be documented with diagnostic studies, if appropriate.) **and each of the following:** 1. Greater than 18 years of age 2. Documentation of change in diet 3. Documented failure of at least fourteen (14) days of therapy each with osmotic and bulk forming laxatives 4. Negative pregnancy test prior to starting therapy if at risk 5. Capable of complying with effective contraceptive measures if at risk

		6. Be appropriately screened for colon cancer, history of bowel obstruction, hepatic or renal disease, hypothyroidism, pelvic floor abnormalities, and spinal cord abnormalities. **Linzess will be authorized if the following criteria are met: 1. Diagnosis of chronic idiopathic constipation, with less than three spontaneous bowel movements per week; **or** 2. Diagnosis of Irritable Bowel Syndrome with Constipation (IBS-C); **and** 3. Patient is eighteen (18) years of age or older **and** 4. Documented failure of at least one month of therapy with osmotic or bulk forming laxatives **and** 5. Appropriate screening for colon cancer, history of bowel obstruction, hepatic or renal disease, hypothyroidism, pelvic floor abnormalities, and spinal cord abnormalities.

Chad Bissell noted the change in the category name.

Dr. Bissell explained the financial considerations around the recommendations for the IBS/SBS/Select GI agents. He further explained that there was not yet a recommendation for Viberzi for this meeting, but that it would be included for consideration during the April meeting.

Dr. Bradley Henry made a motion to approve the change to the IBS/SBS/Select GI Agents category as recommended; the motion was seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

C. New Generics

iii. Paliperidone ER

ANTIPSYCHOTICS, ATYPICAL		
SINGLE INGREDIENT		
ABILIFY (aripiprazole)* AP ABILIFY MAINTENA (aripiprazole)** CL clozapine clozapine ODT INVEGA SUSTENNA (paliperidone)** CL INVEGA TRINZA (paliperidone)*** CL LATUDA (lurasidone)**** AP olanzapine olanzapine ODT quetiapine***** AP for the 25 mg Tablet Only RISPERDAL CONSTA (risperidone) ** CL risperidone ziprasidone	ADASUVE (loxapine) aripiprazole CLOZARIL (clozapine) FANAPT (iloperidone) FAZACLO (clozapine) GEODON (ziprasidone) GEODON IM (ziprasidone) INVEGA (paliperidone) olanzapine IM** paliperidone ER REXULTI (brexipiprazole) RISPERDAL (risperidone) SAPHRIS (asenapine) SEROQUEL (quetiapine) SEROQUEL XR (quetiapine) VERSACLOZ (clozapine) ZYPREXA (olanzapine) ZYPREXA IM (olanzapine)** ZYPREXA RELPREVV (olanzapine)	*Abilify will be prior authorized via electronic PA for MDD if the following criteria are met: 1. The patient is eighteen (18) years of age or older **and** 2. Diagnosis of Major Depressive Disorder (MDD) **and** 3. Prescribed as adjunctive therapy with buproprion, an SSRI agent or an SNRI agent **and** 4. The daily dose does not exceed 15 mg **All injectable antipsychotic products require clinical prior authorization and will be approved on a case-by-case basis. ***Invega Trinza will be authorized after four months' treatment with Invega Sustenna ****Latuda will be authorized for patients only after a trial of one other preferred drug *****Quetiapine 25 mg will be authorized: 1. For a diagnosis of schizophrenia **or** 2. For a diagnosis of bipolar disorder **or**

		3. When prescribed concurrently with other strengths of Seroquel in order to achieve therapeutic treatment levels. *****Quetiapine 25 mg will not be authorized for use as a sedative hypnotic.

Dr. Bradley Henry made a motion to approve the change to the Antipsychotics, Atypical category as recommended; the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

iv. Dutasteride-Tamsulosin

BPH TREATMENTS		
5-ALPHA-REDUCTASE (5AR) INHIBITORS/ALPHA BLOCKER COMBINATION		
	dutasteride/tamsulosin JALYN (dutasteride/tamsulosin)	**Substitute for Category Criteria**: Concurrent thirty (30) day trials of dutasteride and tamsulosin are required before the non-preferred agent will be authorized.

Dr. Bradley Henry made a motion to approve the change to the BPH Treatments category as recommended; the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

v. Repaglinide-Metformin HCL

HYPOGLYCEMICS, MEGLITINIDES		
MEGLITINIDES		
nateglinide repaglinide	PRANDIN (repaglinide) repaglinide/metformin STARLIX (nateglinide)	

Dr. Bradley Henry made a motion to approve the changes to the Hypoglycemics, Meglitinides category as recommended; the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

vi. Fenofibrate 40 mg tablet

LIPOTROPICS, OTHER (Non-statins)[AP]		
FIBRIC ACID DERIVATIVES		
fenofibrate 40 mg fenofibrate 54, 150 and 160 mg fenofibrate micronized 67mg, 134mg & 200mg gemfibrozil TRICOR (fenofibrate nanocrystallized)	ANTARA (fenofibrate) FENOGLIDE (fenofibrate) FIBRICOR (fenofibric acid) fenofibrate 43, 50, 120 and 130 mg fenofibrate nanocrystallized 48 mg, 145 mg fenofibric acid LIPOFEN (fenofibrate) LOFIBRA (fenofibrate) LOPID (gemfibrozil) TRIGLIDE (fenofibrate) TRILIPIX (fenofibric acid)	

Dr. Bradley Henry made a motion to approve the changes to the Lipotropics, Other (non-statins) category as recommended and the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

D. New Drug Reviews

i. Cresemba

ANTIFUNGALS, ORAL		
clotrimazole fluconazole* nystatin terbinafine CL	ANCOBON (flucytosine) CRESEMBA (isovuconazonium) DIFLUCAN (fluconazole) flucytosine GRIFULVIN V TABLET (griseofulvin) griseofulvin GRIS-PEG (griseofulvin) itraconazole ketoconazole** LAMISIL (terbinafine) MYCELEX (clotrimazole) MYCOSTATIN Tablets (nystatin) NIZORAL (ketoconazole) NOXAFIL (posaconazole) ONMEL (itraconazole) ORAVIG (miconazole) SPORANOX (itraconazole) VFEND (voriconazole) voriconazole suspension voriconazole tablets	*PA is required when limits are exceeded. PA is not required for griseofulvin suspension for children up to six (6) years of age for the treatment of tinea capitis. **Ketoconazole will be authorized if the following criteria are met: 1. Diagnosis of one of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidioidomycosis **and** 2. Documented failure or intolerance of all other diagnosis-appropriate antifungal therapies, i.e. itraconazole, fluconazole, flucytosine, etc **and** 3. Baseline assessment of the liver status including alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, alkaline phosphatase, prothrombin time, and international normalized ration (INR) before starting treatment **and** 4. Weekly monitoring of serum ALT for the duration of treatment (If ALT values increase to a level above the upper limit of normal or 30% above baseline, or if the patient develops symptoms of abnormal liver function, treatment should be interrupted and a full set of liver tests be obtained. Liver tests should be repeated to ensure normalization of values.) **and** 5. Assessment of all concomitant medications for potential adverse drug interactions with ketoconazole. Ketoconazole will not be authorized for treatment for fungal infections of the skin and nails.

Dr. Barkin cited clinical trials regarding Cresemba, as well as additional clinical details in relation to the recommendation.

Dr. Bradley Henry made a motion to approve the addition to the Antifungals, Oral category as recommended and the motion was seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

ii. Repatha

LIPOTROPICS, OTHER (Non-statins)[AP]		
PCSK-9 INHIBITORS		
	PRALUENT (alirocumab) REPATHA (evolocumab)	Praluent PA criteria is available at the BMS Website by clicking on this hyperlink.

Dr. Barkin described Repatha's clinical uses, benefits, and additional details regarding the recommendation to add the drug as non-preferred. Dr. Barkin cited and described four (4) clinical studies.

Dr. Bradley Henry made a motion to approve the addition to the Lipotropics, Other (Non-statins) as recommended and the motion was seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

iii. Tivorbex

NSAIDS[AP]		
NON-SELECTIVE		
diclofenac (IR, SR) flurbiprofen ibuprofen (Rx and OTC) INDOCIN SUSPENSION (indomethacin) indomethacin ketoprofen ketorolac nabumetone naproxen (Rx and OTC) piroxicam sulindac	ANAPROX (naproxen) ANSAID (flurbiprofen) CATAFLAM (diclofenac) CLINORIL (sulindac) DAYPRO (oxaprozin) diflunisal DUEXIS (famotidine/ibuprofen) etodolac IR etodolac SR FELDENE (piroxicam) fenoprofen INDOCIN SUPPOSITORIES (indomethacin) indomethacin ER ketoprofen ER meclofenamate mefenamic acid MOTRIN (ibuprofen) NALFON (fenoprofen) NAPRELAN (naproxen) NAPROSYN (naproxen) oxaprozin PONSTEL (meclofenamate) SPRIX (ketorolac) TIVORBEX (indomethacin) tolmetin VOLTAREN (diclofenac) ZIPSOR (diclofenac potassium) ZORVOLEX (diclofenac)	

Dr. Barkin provided background information regarding the recommendation for Tivorbex, citing two (2) related studies.

Dr. Bradley Henry made a motion to approve the addition to the NSAIDs category as recommended and the motion was seconded by Dr. Chris Terpening. All members were in favor and the motion was approved.

iv. Narcan Nasal Spray

OPIATE DEPENDENCE TREATMENTS		
SUBOXONE FILM (buprenorphine/naloxone)[CL] VIVITROL (naltrexone) [CL] naloxone NARCAN NASAL SPRAY (naloxone)	EVZIO (naloxone) buprenorphine/naloxone tablets BUNAVAIL (buprenorphine/naloxone) ZUBSOLV (buprenorphine/naloxone)	Suboxone PA criteria is available at the BMS Website, by clicking the hyperlink. Vivitrol PA criteria is available at the BMS Website, by clicking the hyperlink. Evzio PA criteria is available at the

		BMS Website, by clicking the hyperlink.

Dr. Barkin described the purpose and use of naloxone, citing pharmacokinetic studies. Dr. Stanton commented on the importance of having preferred drugs in the opiate dependence treatments category, in the context of the State's opiate dependence issues.

Dr. Adam Breinig made a motion to approve the addition to the Opiate Dependence Treatments category as recommended and the motion was seconded by Dr. Bradley Henry. All members were in favor and the motion was approved.

VII. Old Business

No old business was identified for discussion.

VIII. Next Meeting – April 27, 2016, 2 PM - 5 PM, Diamond, Rooms B10 and B11

Dr. Stanton provided a confirmation of the planned date and time for the next meeting.

IX. Other Business

No other business was identified for discussion.

X. Adjournment

Dr. Robert Stanton adjourned the meeting at 3:50pm.