STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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Governor

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Karen L. Bowling
Cabinet Secretary

Pharmaceutical and Therapeutics Committee

August 24th, 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, Chair
Bradley Henry, MD, Vice Chair
Adam Breinig, DO
Heather Jones, PA-C
Steve Neal, PharmD
Chris Terpening, PharmD, PhD

By Phone:
Kenneth Hilsbos, MD
Elizabeth Baldwin, RN, MSN, PNP, APRN-BC

Absent:
Tom Kines, RPh
Mary Payne, MD
Hazi Nazha, MD

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

Contract Staff/GHS Staff Present:
Brent Breeding, RPh
Jeff Barkin, MD
Jacquelyn Hedlund, MD, MS
Jennifer Seymour

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

I. Call to Order

Robert Stanton, Chairman, called the meeting to order at 2:05pm

II. Welcome and Introductions

P&T committee members introduced themselves.

III. Administrative Items / Updates

Vicki Cunningham provided ground rules for public comment.

IV. PDL Compliance/Generic Percent Report Updates

Dr. Barkin walked the committee through the Generic Percent and PDL Compliance reports. PDL compliance was high overall. In some categories, with less generic use, PDL compliance was appropriately high, owing to the positioning of the preferred brands.

A. Approval of the April 27th, 2016 Minutes

Dr. Breinig made a motion to approve the minutes from the April 27th meeting, Steve Neal seconded. All were in favor and the minutes were approved.

V. Public Comments

Dennis Pontani, representing Gilead, spoke on behalf of Odsefey.
Amber Root, representing Actelion, spoke on behalf of Uptravi.

VI. Executive Session

Robert Stanton made a motion to move to executive session. The motion was seconded by Chris Terpening and Dr. Breinig.

The Committee adjourned for executive session at 2:17pm

The Committee reconvened at 3:00pm

VII. New Business

A. Adjustments to Existing Classes

Robert Stanton reminded the Committee members of the long-standing policy that no vote is required for changing PDL status for brand-generic equivalents when such switches are based on financial reasons. Therefore, agenda items i-ix under Adjustments to Existing Class were switched per Change Healthcare's recommendations. Chris Terpening made a motion to approve item x as

preferred; seconded by Dr. Breinig. All members were in favor and the motion was approved.

B. New Drug Reviews

i. Belbuca

ANALGESICS, NARCOTIC LONG - ACTING		
BUTRANS (buprenorphine) EMBEDA (morphine/naltrexone) fentanyl transdermal 12, 25, 50, 75, 100 mcg/hr morphine ER tablets	BELBUCA (buprenorphine buccal film) CONZIP ER (tramadol) DOLOPHINE (methadone) DURAGESIC (fentanyl) EXALGO ER (hydromorphone) fentanyl transdermal 37.5, 62.5, 87.5 mcg/hr hydromorphone ER HYSINGLA ER (hydrocodone) KADIAN (morphine) methadone* morphine ER capsules (generic for Avinza) morphine ER capsules (generic for Kadian) MS CONTIN (morphine) NUCYNTA ER (tapentadol) OPANA ER (oxymorphone) oxycodone ER* OXYCONTIN (oxycodone) oxymorphone ER* tramadol ER** ULTRAM ER (tramadol) XARTEMIS XR (oxycodone/ acetaminophen) ZOHYDRO ER (hydrocodone)	*Methadone, oxycodone ER, and oxymorphone ER will be authorized without a trial of the preferred agents if a diagnosis of cancer is submitted. **Tramadol ER requires a manual review and may be authorized for ninety (90) days with submission of a detailed treatment plan including anticipated duration of treatment and scheduled follow-ups with the prescriber.

Dr. Breinig made a motion to approve the change to the Analgesics, Narcotic Long-Acting category as recommended; seconded by Chris Terpening. All members were in favor and the motion was approved.

ii. Spritam

ANTICONVULSANTS - ADJUVANTS		
carbamazepine carbamazepine ER carbamazepine XR CARBATROL (carbamazepine) DEPAKOTE SPRINKLE (divalproex) divalproex divalproex ER EPITOL (carbamazepine) felbamate GABITRIL (tiagabine) lamotrigine levetiracetam IR levetiracetam ER oxcarbazepine suspension and tablets	APTIOM (eslicarbazepine) BANZEL(rufinamide) BRIVIACT (brivaracetam)[NR] DEPAKENE (valproic acid) DEPAKOTE (divalproex) DEPAKOTE ER (divalproex) divalproex sprinkle EQUETRO (carbamazepine) FANATREX SUSPENSION (gabapentin) FELBATOL (felbamate)*** FYCOMPA (perampanel) KEPPRA (levetiracetam) KEPPRA XR (levetiracetam) LAMICTAL (lamotrigine)	*Topiramate ER will be authorized after a thirty (30) day trial of topiramate IR. **Vimpat will be approved as monotherapy or adjunctive therapy for members seventeen (17) years of age or older with a diagnosis of partial-onset seizure disorder. ***Patients stabilized on Felbatol will be grandfathered ****Onfi will be authorized if the following criteria are met:

TEGRETOL XR (carbamazepine) topiramate IR topiramate ER* valproic acid VIMPAT(lacosamide)[AP]** zonisamide	LAMICTAL CHEWABLE (lamotrigine) LAMICTAL ODT (lamotrigine) LAMICTAL XR (lamotrigine) lamotrigine dose pack lamotrigine ER ONFI (clobazam) **** ONFI SUSPENSION (clobazam) **** OXTELLAR XR (oxcarbazepine) POTIGA (ezogabine) QUDEXY XR (topiramate ER) SABRIL (vigabatrin) SPRITAM (levetiracetam) STAVZOR (valproic acid) TEGRETOL (carbamazepine) tiagabine TOPAMAX (topiramate) TRILEPTAL SUSPENSION and TABLETS (oxcarbazepine) TROKENDI XR (topiramate) ZONEGRAN (zonisamide)	1. Adjunctive therapy for Lennox-Gastaut **or** 2. Generalized tonic, atonic or myoclonic seizures **and** 3. Previous failure of at least two (2) non-benzodiazepine anticonvulsants and previous failure of clonazepam. (For continuation, prescriber must include information regarding improved response/effectiveness with this medication)

Steve Neal made a motion to approve the change to the Anticonvulsants - Adjuvants category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

iii. ENSTILAR

ANTIPSORIATICS, TOPICAL		
calcipotriene ointment calcipotriene/betamethasone ointment TAZORAC (tazarotene)	calcipotriene cream calcipotriene solution CALCITRENE (calcipotriene) calcitriol DOVONEX (calcipotriene) ENSTILAR (calcipotriene/betamethasone) TACLONEX (calcipotriene/ betamethasone) SORILUX (calcipotriene) VECTICAL (calcitriol)	.

Chris Terpening made a motion to approve the changes to the Antipsoriatics, Topical category as recommended; seconded by Steve Neal. All members were in favor and the motion was approved.

iv. DESCOVY

ANTIRETROVIRALS – NUCLEOSIDE & NUCLEOTIDE ANALOG RTIs		
SINGLE INGREDIENT		
DESCOVY (emtricitabine/tenofovir) TRUVADA (emtricitabine/tenofovir)		

Dr. Breinig made a motion to approve the changes to the Antiretrovirals – Nucleoside & Nucleotide Analog RTIs category as recommended; seconded by Steve Neal. All members were in favor and the motion was approved.

v. ODEFSEY

ANTIRETROVIRALS – NUCLEOSIDE & NUCLEOTIDE ANALOGS AND NON-NUCLEOSIDE RTIs		
ATRIPLA (efavirenz/emtricitabine/tenofovir)	COMPLERA (emtricitabine/rilpivirine/tenofovir)* ODEFSEY (emtricitabine/rilpivirine/tenofovir)	* Complera requires medical reasoning beyond convenience or enhanced compliance as to why the medical need cannot be met with the preferred agents Truvada and Edurant.

Steve Neal made a motion to approve the changes to the Antiretrovirals – Nucleoside & Nucleotide Analogs and Non-Nucleoside RTIs category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

vi. TOLAK

IMMUNOMODULATOR, GENITAL WARTS & ACTINIC KERATOSIS		
CONDYLOX GEL (podofilox) EFUDEX (fluorouracil) imiquimod	ALDARA (imiquimod) CARAC (fluorouracil) CONDYLOX SOLUTION (podofilox) diclofenac 3% gel fluorouracil 0.5% cream fluorouracil 5% cream podofilox SOLARAZE (diclofenac) TOLAK (fluorouracil 4% cream) VEREGEN (sinecatechins) ZYCLARA (imiquimod)*	*Zyclara will be authorized for a diagnosis of actinic keratosis.

Dr. Henry made a motion to approve the changes to the Immunomodulator, Genital Warts & Actinic Keratosis category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

vii. ENVARSUS XR

IMMUMOSUPPRESSIVES, ORAL		
azathioprine cyclosporine cyclosporine, modified mycophenolate mofetil RAPAMUNE (sirolimus) sirolimus tacrolimus capsule	ASTAGRAF XL (tacrolimus) AZASAN (azathioprine) CELLCEPT (mycophenolate mofetil) ENVARSUS XR (tacrolimus) IMURAN (azathioprine) MYFORTIC (mycophenolic acid) mycophenolic acid mycophenolic mofetil suspension PROGRAF (tacrolimus) NEORAL (cyclosporine, modified) SANDIMMUNE (cyclosporine) ZORTRESS (everolimus)	

Dr. Henry made a motion to approve the changes to the Immunosuppressives, Oral category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

viii. VIBERZI

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS		
AMITIZA (lubiprostone)[CL]* LINZESS (linaclotide) [CL]*	alosetron FULYZAQ (crofelemer)* LOTRONEX (alosetron) MOVANTIK (naloxegol)* RELISTOR (methylnaltrexone)* VIBERZI (eluxadoline)	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

Dr. Henry made a motion to approve the changes to the Irritable Bowel Syndrome/Short Bowel Syndrome/Selected GI Agents category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

ix. VIVLODEX

NSAIDs – COX II SELECTIVE		
meloxicam tablet MOBIC SUSPENSION (meloxicam)	CELEBREX (celecoxib) celecoxib meloxicam suspension MOBIC TABLET (meloxicam) VIVLODEX (meloxicam)	COX-II Inhibitor agents will be authorized if the following criteria are met: Patient has a history or risk of a serious GI complication **or** Agent is requested for treatment of a chronic condition **and** 1. Patient is seventy (70) years of age or older, **or** Patient is currently on anticoagulation therapy**.**

Dr. Henry made a motion to approve the changes to the NSAIDs – COX II Selective category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

x. UPTRAVI

PAH AGENTS – SELECTIVE PROSTACYCLIN RECEPTOR AGONISTS		
epoprostenol VENTAVIS (iloprost)*	FLOLAN (epoprostenol) ORENITRAM ER (treprostinil) REMODULIN (treprostinil sodium) TYVASO (treprostinil) UPTRAVI (selexipag) VELETRI (epoprostenol)	*Ventavis will only be authorized for the treatment of pulmonary artery hypertension (WHO Group 1) in patients with NYHA Class III or IV symptoms.

Dr. Henry made a motion to approve the changes to the PAH Agents – Selective Prostacyclin Receptor Agonists category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

xi. DURLAZA ER

PLATELET AGGREGATION INHIBITORS		
AGGRENOX (dipyridamole/ASA) BRILINTA (ticagrelor) clopidogrel EFFIENT (prasugrel)	dipyridamole dipyridamole/aspirin DURLAZA ER (aspirin) PERSANTINE (dipyridamole) PLAVIX (clopidogrel) TICLID (ticlopidine) ticlopidine ZONTIVITY (vorapaxar)	

Dr. Breinig made a motion to approve the changes to the Platelet Aggregation Inhibitors category as recommended; seconded by Dr. Henry. All members were in favor and the motion was approved.

xii. DYANAVEL XR

STIMULANTS & RELATED AGENTS - AMPHETAMINES		
amphetamine salt combination IR dextroamphetamine ER dextroamphetamine IR PROCENTRA solution (dextroamphetamine) VYVANSE (lisdexamfetamine)	ADDERALL XR* (amphetamine salt combination) ADZENYS XR ODT (dextroamphetamine/amphetamine) NR amphetamine salt combination ER DESOXYN (methamphetamine) DEXEDRINE ER (dextroamphetamine) DEXEDRINE IR (dextroamphetamine) dextroamphetamine solution DYANAVEL XR (dextroamphetamine/amphetamine) EVEKEO (amphetamine) methamphetamine ZENZEDI (dextroamphetamine)	**In addition to the Category Criteria**: Thirty (30) day trials of at least three (3) antidepressants are required before amphetamines will be authorized for depression. *Adderall XR is preferred over its generic equivalents.

Dr. Henry made a motion to approve the changes to the Stimulants & Related Agents – Amphetamines category as recommended; seconded by Chris Terpening. All members were in favor and the motion was approved.

xiii. QUILLICHEW ER

STIMULANTS & RELATED AGENTS – NON-AMPHETAMINE		
clonidine IR DAYTRANA (methylphenidate) dexmethylphenidate IR FOCALIN XR (dexmethylphenidate) guanfacine ER** guanfacine IR	APTENSIO XR (methylphenidate) armodafinil NR clonidine ER CONCERTA (methylphenidate) dexmethylphenidate XR	Strattera does not required a PA for adults eighteen (18) years of age or older. Strattera will not be authorized for concurrent administration with amphetamines or

METADATE CD (methylphenidate) METHYLIN SOLUTION (methylphenidate) methylphenidate IR methylphenidate ER (generic CONCERTA) QUILLIVANT XR (methylphenidate) STRATTERA (atomoxetine)*	FOCALIN IR (dexmethylphenidate) INTUNIV (guanfacine extended-release) KAPVAY (clonidine extended-release)** METHYLIN CHEWABLE TABLETS (methylphenidate) methylphenidate chewable tablets, solution methylphenidate CD methylphenidate ER methylphenidate LA modafinil*** NUVIGIL (armodafinil) *** PROVIGIL (modafinil) *** QUILLICHEW ER (methylphenidate) RITALIN (methylphenidate) RITALIN LA (methylphenidate)	methylphenidates, except for thirty (30) days or less for tapering purposes. Strattera is limited to a maximum of 100 mg per day. **Guanfacine ER and Kapvay/clonidine ER will be authorized if the following criteria are met: 1. Fourteen (14) day trials of at least one (1) preferred product from the amphetamine and non-amphetamine class **and** 2. A fourteen (14) day trial of clonidine IR (for Kapvay) and guanfacine IR (for guanfacine ER) unless one (1) of the exceptions on the PA form is present**.** In cases of a diagnosis of Tourette's syndrome, tics, autism or disorders included in the autism spectrum, only a fourteen (14) day trial of clonidine (for Kapvay) will be required for approval. ***Provigil is preferred over its generic equivalent and Nuvigil. These drugs will only be authorized for patients sixteen (16) years of age or older with a diagnosis of narcolepsy.

Dr. Henry made a motion to approve the changes to the Stimulants & Related Agents – Non-Amphetamine category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

C. New Generics

i. alosetron

IRRITABLE BOWEL SYNDROME/SHORT BOWEL SYNDROME/SELECTED GI AGENTS		
AMITIZA (lubiprostone)[CL]* LINZESS (linaclotide) [CL]*	alosetron FULYZAQ (crofelemer)* LOTRONEX (alosetron) MOVANTIK (naloxegol)* RELISTOR (methylnaltrexone)* VIBERZI (eluxadoline)	

Informational only. No vote.

VIII. Old Business

No old business was identified for discussion.

IX. Next Meeting – October 24, 2016, 2 PM - 5 PM, Civic Center, 2nd Floor

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

X. Other Business

No other business was identified for discussion.

XI. Adjournment

Robert Stanton adjourned the meeting at 3:33pm