



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

April 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, M.D., Chair
Bradley Henry, M.D., Vice Chair
Adam Breinig, D.O.
Chris Terpening, Pharm.D., Ph.D.
Tom Kines, R.Ph.
Heather Jones, PA
Mary Payne, M.D.
Kenneth Hilbos, M.D.
Steve Neal, Pharm.D.

Division of Medicaid Staff Present:

Vicki Cunningham, R.Ph.
Brian Thompson, Pharm.D., MS
Bill Hopkins
Doug Sorvig

Contract Staff/GHS Staff Present:

Brent Breeding, R.Ph.
Laureen Biczak, D.O.
Jennifer Seymour

By Phone:

Elizabeth Baldwin, MSN, PNP, APRN-BC

Absent:

Hazi Nazha, M.D.
Jeffrey V. Ashley, M.D.
Scott Brown, R.Ph.

I. Call to Order

Dr. Robert Stanton, Chairman, called the meeting to order at 2:11 pm.

II. Welcome and Introductions

P&T Committee members introduced themselves, including 1 new member: Mary Payne.

A. Approval of the January 27th, 2016 Minutes

Dr. Stanton made a motion to approve the minutes from the January 27, 2016, meeting. All were in favor and the minutes were approved.

B. PDL Compliance/Generic Percent Report Updates

Dr. Biczak walked the Committee through the Generic Percent and Preferred Drug List (PDL) Compliance reports provided to the Committee. PDL compliance was high overall. Generic percentage was as expected overall with expected lower generic utilization in some categories due to preferred brands.

I. Administrative Items / Updates

Vicki Cunningham provided ground rules for public comment.

II. Public Comments

Joseph Loftis, representing NovoNordisk, spoke on behalf of Tresiba.

Louis Moreno, representing Sandoz, spoke on behalf of Xarxio.

Jay Adams, representing the Ryan White Program, spoke on behalf of Triumeq, Descovy, Odefsey.

Christine Teague, representing the Ryan White Program, Part C, spoke on behalf of Triumeq, Odefsey, Descovy.

Paul Miner, representing Gilead, spoke on behalf of Genvoya.

Deanna Merrill, representing GSK/Viiv Healthcare, spoke on behalf of Triumeq.

III. Executive Session

Dr. Stratton made a motion to move to executive session. The motion was seconded by Steve Neal and Dr. Terpening.

The Committee adjourned for executive session at 2:39 pm.

The Committee reconvened at 3:24pm.

IV. New Business

A. Adjustments to Existing Classes

i. Antimigraine Agents

ANTIMIGRAINE AGENTS, TRIPTANS ^{AP}		
TRIPTANS		
IMITREX INJECTION (sumatriptan) ^{CL} IMITREX NASAL SPRAY (sumatriptan) naratriptan rizatriptan rizatriptan ODT sumatriptan tablets	almotriptan AMERGE (naratriptan) AXERT (almotriptan) FROVA (frovatriptan) IMITREX tablets (sumatriptan) MAXALT (rizatriptan) MAXALT MLT (rizatriptan) RELPAX (eletriptan) sumatriptan nasal spray/injection* SUMAVEL (sumatriptan) ZECURITY PATCH (sumatriptan) zolmitriptan zolmitriptan ODT ZOMIG (zolmitriptan) ZOMIG ZMT (zolmitriptan)	In addition to the Category Criteria: Three (3) day trials of each preferred agent will be required before Imitrex injection is authorized. *AP does not apply to nasal spray or injectable sumatriptan.

Dr. Terpening made a motion to approve the change to Antimigraine Agents, Triptans as recommended; the motion was seconded by Dr. Neal. All members were in favor and the motion was approved.

ii. Hepatitis B Treatments

HEPATITIS B TREATMENTS		
BARACLUDE (entecavir) EPIVIR HBV (lamivudine) TYZEKA (telbivudine)	adefovir entecavir HEPSERA (adefovir) lamivudine HBV	

Tom Kines made a motion to approve the change to Hepatitis B Treatments as recommended; Seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

B. Class Removal

iii. Intermittent Claudication Category

INTERMITTENT CLAUDICATION CATEGORY		
cilostazol pentoxifylline	PLETAL (cilostazol)	

Dr. Terpening made a motion to approve the removal of the Intermittent Claudication category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

C. New Therapeutic Class Review

i. Antiretrovirals

ANTIRETROVIRALS	
INTEGRASE STRAND TRANSFER INHIBITORS	
ISENTRESS (raltegravir potassium) TIVICAY (dolutegravir sodium) VITEKTA (elvitegravir)	
NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTI)	
abacavir sulfate didanosine DR capsule EMTRIVA (emtricitabine) EPIVIR SOLUTION (butransine) lamivudine stavudine VIDEX SOLUTION (didanosine) VIREAD (tenofovir disoproxil fumarate) ZIAGEN SOLUTION (abacavir sulfate) zidovudine	RETROVIR (zidovudine) VIDEX EC (didanosine) EPIVIR TABLET (butransine) ZERIT (stavudine) ZIAGEN TABLET (abacavir sulfate)
NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NNRTI)	
EDURANT (rilpivirine) SUSTIVA (efavirenz)	INTELENCE (etravirine) nevirapine nevirapine ER RESCRIPTOR (delavirdine mesylate) VIRAMUNE ER 24H (nevirapine) VIRAMUNE SUSPENSION (nevirapine)
PHARMACOENHANCER – CYTOCHROME P450 INHIBITOR	
TYBOST (cobicistat)	
PROTEASE INHIBITORS (PEPTIDIC)	
EVOTAZ (atazanavir/cobicistat) NORVIR (ritonavir) REYATAZ (atazanavir)	CRIXIVAN (indinavir) LEXIVA (fosamprenavir) INVIRASE (saquinavir mesylate) VIRACEPT (nelfinavir mesylate)
PROTEASE INHIBITORS (NON-PEPTIDIC)	
PREZISTA (darunavir ethanolate)	APTIVUS (tipranavir) PREZCOBIX (darunavir/cobicistat)
ENTRY INHIBITORS – CCR5 CO-RECEPTOR ANTAGONISTS	
SELZENTRY (maraviroc)	
ENTRY INHIBITORS – FUSION INHIBITORS	
FUZEON (enfuvirtide)	
COMBINATION PRODUCTS - NRTIs	
EPZICOM (abacavir/lamivudine) lamivudine/zidovudine	abacavir/lamivudine/zidovudine COMBIVIR (lamivudine/zidovudine) TRIZIVIR (abacavir/lamivudine/zidovudine)
COMBINATION PRODUCTS – NUCLEOSIDE & NUCLEOTIDE ANALOG RTIs	

TRUVADA (emtricitabine/tenofovir)		
COMBINATION PRODUCTS – NUCLEOSIDE & NUCLEOTIDE ANALOGS & INTEGRASE INHIBITORS		
GENVOYA (elvitegravir/cobicistat/emtricitabine/tenofovir)	STRIBILD (elvitegravir/cobicistat/emtricitabine/tenofovir)	TRIUMEQ (abacavir/lamivudine/ dolutegravir)
COMBINATION PRODUCTS – NUCLEOSIDE & NUCLEOTIDE ANALOGS & NON-NUCLEOSIDE RTIs		
ATRIPLA (efavirenz/emtricitabine/tenofovir)	COMPLERA (emtricitabine/rilpivirine/tenofovir)	
COMBINATION PRODUCTS – PROTEASE INHIBITORS		
KALETRA (lopinavir/ritonavir)		

Dr. Biczak recommended the listed additions be made to this category. GHS recommends grandfathering those patients on Non-Preferred drugs. New drugs Odefsey, Descovy are too new to be considered for the PDL at this meeting. Dr. Stanton asked that Dr. Biczak read the list of drugs in the category that are being recommended for preferred and non-preferred status.

Dr. Breinig made a motion to approve the addition of the category as recommended; seconded by Heather Jones. All members were in favor and the motion was approved.

D. New Drug Reviews

ii. Prestalia

ANGIOTENSIN MODULATORS ^{AP}	
benazepril/amlodipine benazepril/HCTZ captopril/HCTZ enalapril/HCTZ fosinopril/HCTZ lisinopril/HCTZ quinapril/HCTZ	ACE INHIBITOR COMBINATION DRUGS ACCURETIC (quinapril/HCTZ) CAPOZIDE (captopril/HCTZ) LOTENSIN HCT (benazepril/HCTZ) LOTREL (benazepril/amlodipine) moexipril/HCTZ PRESTALIA (perindopril/amlodipine) PRINZIDE (lisinopril/HCTZ) TARKA (trandolapril/verapamil) trandolapril/verapamil VASERETIC (enalapril/HCTZ) ZESTORETIC (lisinopril/HCTZ)

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

iii. Varubi

ANTIEMETICS ^{AP}	
SUBSTANCE P ANTAGONISTS	
EMEND (aprepitant)	VARUBI (rolapitant)

Dr. Terpening made a motion to approve the change to the Antiemetics category as recommended; seconded by Dr. Breinig. All members were in favor and the motion was approved.

iv. Zecuity

ANTIMIGRAINE AGENTS, TRIPTANS ^{AP}		
TRIPTANS		
IMITREX INJECTION (sumatriptan) ^{CL} IMITREX NASAL SPRAY (sumatriptan) naratriptan rizatriptan rizatriptan ODT sumatriptan tablets	almotriptan AMERGE (naratriptan) AXERT (almotriptan) FROVA (frovatriptan) IMITREX tablets (sumatriptan) MAXALT (rizatriptan) MAXALT MLT (rizatriptan) RELPAX (eletriptan) sumatriptan nasal spray/injection* SUMAVEL (sumatriptan) ZECUITY PATCH (sumatriptan) zolmitriptan zolmitriptan ODT ZOMIG (zolmitriptan) ZOMIG ZMT (zolmitriptan)	<p>In addition to the Category Criteria: Three (3) day trials of each preferred agent will be required before Imitrex injection is authorized.</p> <p>*AP does not apply to nasal spray or injectable sumatriptan.</p>

Dr. Breinig made a motion to approve the changes to the Antimigraine Agents, Triptans category as recommended; seconded by Steve Neal. All members were in favor and the motion was approved.

v. Aristada

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 ARISTADA (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)	<p>*Abilify will be prior authorized via electronic PA for MDD if the following criteria are met:</p> <ol style="list-style-type: none"> 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 bupropion, an SSRI agent or an SNRI agent and 4. The daily dose does not exceed 15 mg <p>**All injectable antipsychotic products require clinical prior authorization and will be approved on a case-by-case basis.</p> <p>***Invega Trinza will be authorized after four months' treatment with Invega Sustenna</p> <p>****Latuda will be authorized for patients only after a trial of one other preferred drug</p>

		<p>*****Quetiapine 25 mg will be authorized:</p> <ol style="list-style-type: none"> 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. <p>*****Quetiapine 25 mg will not be authorized for use as a sedative hypnotic.</p>
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Dr. Breining made a motion to approve the changes to the Antipsychotics, Atypical category as recommended; seconded by Dr. Neal. All members were in favor and the motion was approved.

vi. Zaxzio

Dr. Breinig made a motion to approve the changes to the Colony Stimulating Factors category as recommended; seconded by Steve Neal. All members were in favor and the motion was approved.

COLONY STIMULATING FACTORS

LEUKINE (sargramostim) NEUPOGEN (filgrastim)	NEULASTA (pegfilgrastim) ZARXIO (filgrastim)	
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vii. Zepatier

HEPATITIS C TREATMENTS^{CL}

HARVONI (ledipasvir/sofosbuvir)* PEGASYS (pegylated interferon) PEG-INTRON (pegylated interferon) ribavirin SOVALDI (sofosbuvir)* TECHNIVIE (ombitasvir/paritaprevir/ritonavir)* VIEKIRA PAK (dasabuvir/ombitasvir/ paritaprevir/ritonavir)* ZEPATIER (elbasvir/grazoprevir)	COPEGUS (ribavirin) DAKLINZA (daclatasvir)* MODERIBA 400 mg, 600 mg MODERIBA DOSE PACK OLYSIO (simeprevir)* REBETOL (ribavirin) RIBASPHERE RIBAPAK (ribavirin) RIBASPHERE 400 mg, 600 mg (ribavirin)	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.
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Steve Neal made a motion to approve the changes to the Hepatitis C Treatments category as recommended; seconded by Dr. Terpening. All members were in favor and the motion was approved.

viii. Tresiba Insulin

HYPOGLYCEMICS, INSULIN AND RELATED AGENTS

<p>HUMALOG (insulin lispro) HUMALOG MIX VIALS (insulin lispro/lispro protamine) HUMULIN VIALS (insulin) LANTUS (insulin glargine) LEVEMIR (insulin detemir) NOVOLOG (insulin aspart) NOVOLOG MIX (insulin aspart/aspart protamine)</p>	<p>AFREZZA (insulin)^{CL} APIDRA (insulin glulisine)^{AP*} HUMALOG PEN/KWIKPEN (insulin lispro) HUMALOG MIX PENS (insulin lispro/lispro protamine) HUMULIN PENS (insulin) NOVOLIN (insulin) TOUJEO SOLOSTAR (insulin glargine)** TRESIBA (insulin degludec)</p>	<p>*Apidra will be authorized if the following criteria are met:</p> <ol style="list-style-type: none"> 1. Patient is four (4) years of age or older; and 2. Patient is currently on a regimen including a longer acting or basal insulin, and 3. Patient has had a trial of a similar preferred agent, Novolog or Humalog, with documentation that the desired results were not achieved. <p>**Toujeo Solostar will be authorized only after 6 months of compliance on preferred long-acting insulin. Toujeo will only be approved for once daily doses of at least 60 units.</p>
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Dr. Breinig made a motion to approve the addition to Hypoglycemics, Insulin and Related Agents category, seconded by Dr. Terpening. All members were in favor and the motion was approved.

E. New Generics

i. Dutasteride

BPH TREATMENTS	
5-ALPHA-REDUCTASE (5AR) INHIBITORS	
finasteride	<p>AVODART (dutasteride) CIALIS 5 mg (tadalafil) dutasteride PROSCAR (finasteride)</p>

Dr. Kines made a motion to approve the addition to the BPH Treatments category as recommended; seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

ii. Entecavir

HEPATITIS B TREATMENTS	
<p>BARACLUDE (entecavir) EPIVIR HBV (lamivudine) TYZEKA (telbivudine)</p>	<p>adefovir entecavir HEPSERA (adefovir) lamivudine HBV</p>

Steve Neal made a motion to approve the addition to the Hepatitis B Treatments category as recommended; seconded by Dr. Adam Breinig. All members were in favor and the motion was approved.

iii. Fluvastatin ER

LIPOTROPICS, STATINS ^{AP}		
STATINS		
atorvastatin CRESTOR (rosuvastatin) lovastatin pravastatin simvastatin ^{CL*}	ALTOPREV (lovastatin) fluvastatin fluvastatin ER LESCOL (fluvastatin) LESCOL XL (fluvastatin) LIPITOR (atorvastatin) LIVALO (pitavastatin) MEVACOR (lovastatin) PRAVACHOL (pravastatin) ZOCOR (simvastatin)*	Twelve (12) week trials each of two (2) of the preferred statins, including the generic formulation of a requested non-preferred agent, are required before a non-preferred agent will be authorized unless one (1) of the exceptions on the PA form is present. *Zocor/simvastatin 80mg tablets will require a clinical PA

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

iv. Naproxen CR

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) naproxen CR oxaprozin PONSTEL (meclofenamate) SPRIX (ketorolac) TIVORBEX (indomethacin) tolmetin VOLTAREN (diclofenac) ZIPSOR (diclofenac potassium)	

	ZORVOLEX (diclofenac)	
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Dr. Breinig made a motion to approve the changes in the NSAIDs category as recommended; seconded by Dr. Terpening. All members were in favor and the motion was approved.

v. Dipyridamole/aspirin

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

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

V. Old Business

No old business was identified for discussion.

VI. Next Meeting – August 24, 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.

VII. Other Business

No other business was identified for discussion.

VIII. Adjournment

Dr. Robert Stanton adjourned the meeting at 3:47pm.