STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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Cynthia E. Beane
Commissioner

Pharmaceutical and Therapeutics Committee

August 23rd, 2023

Location: WebEx only
Time: Executive Session 2:30 PM – 3:30 PM
Time: Open Session 3:30 PM – 5:00 PM
Charleston, WV 25301
(304) 558-1700

MINUTES

Committee Members Present:
Philip Galapon, MD FAAFP, Chair
Chris Terpening, PharmD, PhD, Vice-Chair
Scott Brown, RPh
David Gloss, MD
John Bernabei, RPh (JJ)
Charles Rohrbaugh, RPh
Krista Capehart, PharmD
Toni DiChiacchio, DNP
Laura Davisson, MD
Mitzi Payne, MD

Absent:
Gail Goodnight, RPh. Rebate Pharmacist

Division of Medicaid Staff Present:
Bill Hopkins, Operations Manager
Priya Shah, PharmD, DUR Coordinator
Doug Sorvig, Data Analyst
Lori Moles, RPh Appeals Pharmacist
Vicki Cunningham, RPh, Director

Contract Staff Present:
Change Healthcare
Jeffrey Barkin, MD
Joseph Bergondo, PharmD

Other Contract / State Staff Present:

I. Call to Order

Philip Galapon, Chairman, called the meeting to order at 3:32 PM

II. Welcome and Introductions

Philip Galapon welcomed all present to the committee meeting. Committee members, Bureau of Medical Services staff, and Change Healthcare staff introduced themselves.

III. Housekeeping Items / Updates

A. Approval of the April 26th Meeting Minutes

The Committee moved to approve the April 26th, 2023, Meeting Minutes. All were in favor with no objections or revisions.

B. PDL Compliance / Generic Percent Report Updates

Joe Bergondo provided an explanation of the PDL Compliance and Generic Percent reports.

- Joe Bergondo reviewed the Generic Percent Report; overall generic utilization for Q1 2023 was 85.6%

- Joe Bergondo reviewed the PDL Compliance Report; overall compliance for Q1 2023 was 92.6%

IV. Public Comments

Public comments for this meeting were accepted in writing only. Written statements were provided to State and Committee members for review prior to this meeting and are available to the public on the State's website.

V. New Business

A. New Drug Reviews

i. Antibiotics, GI & Related Agents

ANTIBIOTICS, GI & RELATED AGENTS		
CLASS PA CRITERIA: Non-preferred agents require a fourteen (14) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
FIRVANQ (vancomycin) metronidazole tablet neomycin tinidazole XIFAXAN 200 MG (rifaximin)*	AEMCOLO (rifamycin) tablet** DIFICID (fidaxomicin)* FLAGYL (metronidazole) metronidazole capsule paromomycin VANCOCIN (vancomycin) Vancomycin VOWST (fecal microbiota spores) capsules XIFAXAN 550 MG (rifaximin)*	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. **Aemcolo may be authorized after a trial of Xifaxan 200mg tablets.

Scott Brown made a motion to approve the changes to the Antibiotics, GI & Related Agents class as recommended; the motion was seconded by Charlie Rohrbaugh. All members were in favor and the motion was approved.

ii. Anticoagulants

ANTICOAGULANTS		
CLASS PA CRITERIA: Non-preferred agents require a trial of each preferred agent in the same sub-class, unless one (1) of the exceptions on the PA form is present.		
ORAL		
ELIQUIS (apixaban)	Dabigatran	
PRADAXA (dabigatran)	PRADAXA (dabigatran etexilate) oral pellets	
warfarin	SAVAYSA (edoxaban)	
XARELTO TABLETS (rivaroxaban)	XARELTO SUSPENSION (rivaroxaban)	

Chris Terpening made a motion to approve the changes to the Anticoagulants class; the motion was seconded by Scott Brown. All members were in favor and the motion was approved.

iii. Antihemophilia Factor Agents

ANTIHEMOPHILIA FACTOR AGENTS[CL]		
CLASS PA CRITERIA: All agents will require prior-authorization, and non-preferred agents require medical reasoning explaining why the need cannot be met using a preferred product.		
All currently established regimens shall be grandfathered with documentation of adherence to therapy.		
FACTOR VIII		
ADVATE	ADYNOVATE	
AFSTYLA	ALTUVIIIO	
ALPHANATE	ELOCTATE	
HEMOFIL M	ESPEROC (Ctrl)	
HUMATE-P	JIVI	
KOATE	VONVENDI	
KOGENATE FS		
KOVALTRY		
NOVOEIGHT		
NUWIQ		
RECOMBINATE		
WILATE		
XYNTHA		
XYNTHA SOLOFUSE		

Laura Davisson made a motion to approve the changes to the Antihemophilia Factor Agents class as recommended; the motion was seconded by David Gloss. All members were in favor and the motion was approved.

iv. Antimigraine Agents, Acute

ANTIMIGRAINE AGENTS, ACUTE[AP]		
CLASS PA CRITERIA: Non-preferred agents require three (3) day trials of each preferred unique chemical entity as well as a three (3) day trial using the same route of administration as the requested agent (if available), before they will be approved, unless one (1) of the exceptions on the PA form is present.		
OTHER		
NURTEC ODT (rimegepant)*	CAMBIA (diclofenac) D.H.E 45 AMPULE (dihydroergotamine)** dihydroergotamine injection, nasal spray** MIGERGOT RECTAL SUPPOSITORY (ergotamine/caffeine)** MIGRANAL SPRAY (dihydroergotamine)** REYVOW (lasmiditan)** TRUDHESA SPRAY (dihydroergotamine)** UBRELVY (ubrogepant)*** ZAVZPRET (zavegepant) nasal spray	*Nurtec ODT For a diagnosis of **Migraine treatment**: requires three (3) day trials of two (2) preferred chemically distinct triptans before it may be approved, unless one (1) of the exceptions on the PA form is present. Maximum Quantity limit of 8 tablets per 30 days. **All non-preferred Ergot alkaloid agents require three (3) day trials of (2) preferred triptans as well as a three (3) day trial of a preferred triptan using the same route of administration as the requested agent (if available), before they will be approved, unless one (1) of the exceptions on the PA form is present. **Note: Ergot derivatives should not be used with or within 24 hours of triptans.** **Additional Ergot Alkaloid criteria: Nasal spray: dihydroergotamine nasal spray and Trudhesa spray may only be authorized after a trial and failure of Migranal spray. Rectal suppository: Migerot rectal suppository may only be authorized after a trial and failure of a preferred triptan nasal spray. Injection: dihydroergotamine injection and D.H.E 45 ampule may only be approved for cluster headaches. ***Ubrelvy and Reyvow require three (3) day trials of two (2) preferred chemically distinct triptans as well as a three (3) day trial of Nurtec ODT before they may be approved, unless one (1) of the exceptions on the PA form is present.

David Gloss made a motion to approve the changes to the Antimigraine Agents, Acute class as recommended; the motion was seconded by Charlie Rohrbaugh. All members were in favor and the motion was approved.

v. Antipsychotics, Atypical

ANTIPSYCHOTICS, ATYPICAL		
CLASS PA CRITERIA: All antipsychotic agents require prior authorization for children up to eighteen (18) years of age. All PA requests for antipsychotics for children 6 years of age and younger will be reviewed by Medicaid's consultant psychiatrist. Non-preferred agents require thirty (30) day trials of two (2) preferred agents, including the generic formulation of the requested agent (if available), before they will be approved unless one (1) of the exceptions on the PA form is present. When determining requests for non-preferred products, any trial utilizing a preferred agent whose dose or duration was limited due to adverse effects or clear lack of efficacy will be considered complete only if the agent was being taken within the FDA-approved therapeutic ranged.* Patients shall be grandfathered onto their existing therapy, provided the requested agent is being used according to the manufacturer label. Continuation of therapy for an off-label indication or non-standard dosage may be granted a thirty (30) day prior-authorization while the Medical Director reviews the request. *According to manufacturer dosing recommendations		
SINGLE INGREDIENT		
ABILIFY MAINTENA (aripiprazole)[CL] aripiprazole tablets ARISTADA (aripiprazole)[CL] ARISTADA INITIO (aripiprazole)[CL] asenapine sublingual tablets clozapine	ABILIFY ASIMTUFII (aripiprazole) ABILIFY MYCITE (aripiprazole) ABILIFY TABLETS (aripiprazole) ADASUVE (loxapine) aripiprazole ODT aripiprazole solution	**The following criteria exceptions apply to the specified products:** *Invega Hafyera may only be authorized after four months' treatment with Invega Sustenna or at least a one three-month cycle with Invega Trinza.
INVEGA HAFYERA (paliperidone)*[CL] INVEGA SUSTENNA (paliperidone)[CL] INVEGA TRINZA (paliperidone)**[CL] lurasidone olanzapine olanzapine ODT paliperidone ER PERSERIS (risperidone)[CL] quetiapine** AP for the 25 mg Tablet Only quetiapine ER RISPERDAL CONSTA (risperidone)[CL] risperidone solution, tablet, ODT ziprasidone	CAPLYTA (lumateperone) clozapine ODT CLOZARIL (clozapine) FANAPT (iloperidone) GEODON (ziprasidone) GEODON IM (ziprasidone) INVEGA ER (paliperidone) LATUDA (lurasidone) LYBALVI (olanzapine and samidorphan)*** NUPLAZID (pimavanserin) **** olanzapine IM[CL] REXULTI (brexipiprazole) RISPERDAL (risperidone) SAPHRIS (asenapine) SECUADO (asenapine) SEROQUEL (quetiapine) SEROQUEL XR (quetiapine) UZEDY (risperidone) VERSACLOZ (clozapine) VRAYLAR (cariprazine)**** VRAYLAR DOSE PAK (cariprazine)***** ZYPREXA (olanzapine) ZYPREXA IM (olanzapine)[CL] ZYPREXA RELPREVV (olanzapine)	**Invega Trinza will be authorized after four months' treatment with Invega Sustenna **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.** ***Patient must have had a positive response with olanzapine and experienced clinically significant weight gain (documentation must be provided) which necessitated disruption of treatment. Patient must also have had an intolerance, inadequate treatment response or contraindication to 2 preferred antipsychotics (such as aripiprazole and ziprasidone) which have a lower potential of weight gain prior to Lybalvi approval. ***Prior to initiating Lybalvi, there should be at least a 7-day opioid-free interval from the last use of short-acting opioids, and at least a 14-day opioid-free interval from the last use of long-acting opioids to avoid precipitation of opioid withdrawal.*** ****Nuplazid may only be authorized for the treatment of Parkinson Disease Induced Psychosis after documented treatment failure with quetiapine. ***** Vraylar may be authorized for the indication of Bipolar Depression only after failure of a 30-day trial of Latuda and a 30-day trial of either quetiapine OR a combination of olanzapine + fluoxetine. All other indications require class criteria to be followed.

Scott Brown made a motion to approve the changes to the Antipsychotics, Atypical class (Abilify Asimtufi) as recommended; the motion was seconded by Laura Davisson. All members were in favor and the motion was approved.

Charlie Rohrbaugh made a motion to approve the changes to the Antipsychotics, Atypical class (Uzedy) as recommended; the motion was seconded by Laura Davisson. All members were in favor and the motion was approved.

vi. Growth Hormones and Achondroplasia Agents

GROWTH HORMONES AND ACHONDROPLASIA AGENTS[CL]		
CLASS PA CRITERIA: Non-preferred agents require three (3) month trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
GENOTROPIN (somatropin) NORDITROPIN (somatropin)	INCRELEX (mecasermin) NUTROPIN AQ (somatropin) OMNITROPE (somatropin) SAIZEN (somatropin) SEROSTIM (somatropin) SKYTROFA (lonapegsomatropin) SOGROYA (somapacitan-beco) VOXZOGO (vosoritide)** ZOMACTON (somatropin) ZORBTIVE (somatropin)	Patients already on a non-preferred agent will receive authorization to continue therapy on that agent for the duration of the existing PA. *Full PA criteria for Voxzogo may be found on the PA Criteria page by clicking the hyperlink.

Scott Brown made a motion to approve the changes to the Growth Hormones and Achondroplasia Agents class as recommended; the motion was seconded by David Gloss. All members were in favor and the motion was approved.

vii. Hypoglycemics, Insulin and Related Agents

HYPOGLYCEMICS, INSULIN AND RELATED AGENTS		
CLASS PA CRITERIA: Non-preferred agents require a ninety (90) day trial of a pharmacokinetically similar agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
APIDRA (insulin glulisine) HUMALOG (insulin lispro) HUMALOG JR KWIKPEN (insulin lispro) HUMALOG KWIKPEN U-100 (insulin lispro) HUMALOG MIX PENS (insulin lispro/lispro protamine) HUMALOG MIX VIALS (insulin lispro/lispro protamine) HUMULIN 70/30 (insulin) HUMULIN R U-500 VIAL (insulin) HUMULIN R U-500 KWIKPEN (insulin)	ADMELOG (insulin lispro) AFREZZA (insulin)[CL] BASAGLAR (insulin glargine) FIASP (insulin aspart) HUMALOG KWIKPEN U-200 (insulin lispro) HUMULIN PENS (insulin) HUMULIN R VIAL (insulin) HUMULIN N VIAL (insulin) insulin glargine insulin lispro junior kwikpen insulin lispro protamine mix	* Non-preferred insulin combination products require that the patient must already be established on the individual agents at doses not exceeding the maximum dose achievable with the combination product, and require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a combination of preferred single-ingredient agents. **Patients stabilized on Tresiba may be grandfathered at the request of the prescriber, if the prescriber considers the preferred products to be clinically inappropriate.
insulin aspart flexpen, penfill, vial insulin aspart/aspart protamine pens, vials insulin glargine (labeler 00955 only) insulin lispro kwikpen U-100, vial LANTUS (insulin glargine) LEVEMIR (insulin detemir) NOVOLOG (insulin aspart) NOVOLOG MIX (insulin aspart/aspart protamine) NOVOLIN N (insulin) TOUJEO SOLOSTAR (insulin glargine) TOUJEO MAX SOLOSTAR (insulin glargine)	LYUMJEV (insulin lispro) NOVOLIN (insulin) REZVOGLAR (insulin glargine-aglr) SEMGLEE (insulin glargine) SOLIQUA (insulin glargine/lixisenatide)* TRESIBA (insulin degludec)** TRESIBA FLEXTOUCH (insulin degludec)** XULTOPHY (insulin degludec/liraglutide)*	**Tresiba U-100 may be approved only for: Patients who have demonstrated at least a 6-month history of compliance on a preferred long-acting insulin and who continue to have regular incidents of hypoglycemia. **Tresiba U-200 may be approved only for: Patients who require once-daily doses of at least 60 units of long-acting insulin and have demonstrated at least a 6-month history of compliance on preferred long-acting insulin and who continue to have regular incidents of hypoglycemia.

Scott Brown made a motion to approve the changes to the Hypoglycemics, Insulin and Related Agents class as recommended; the motion was seconded by Charlie Rohrbaugh. All members were in favor and the motion was approved.

viii. Lipotropics, Statins

LIPOTROPICS, STATINS[AP]		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
STATINS		
atorvastatin lovastatin pravastatin rosuvastatin simvastatin**	ALTOPREV (lovastatin) ATORVALIQ (atorvastatin) CRESTOR (rosuvastatin) EZALLOR SPRINKLE (rosuvastatin)* fluvastatin fluvastatin ER LESCOL XL (fluvastatin) LIPITOR (atorvastatin) LIVALO (pitavastatin) PRAVACHOL (pravastatin) ZOCOR (simvastatin)** ZYPITAMAG (pitavastatin)	Non-preferred agents require twelve (12) week trials of two (2) preferred agents, including the generic formulation of the requested non-preferred agent, before they will be approved, unless one (1) of the exceptions on the PA form is present. *Ezallor SPRINKLE will only be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia. **Zocor/simvastatin 80mg tablets will require a clinical PA.

Scott Brown made a motion to approve the changes to the Lipotropics, Statins class as recommended; the motion was seconded by Laura Davisson. All members were in favor and the motion was approved.

ix. PAH Agents – PDE5s

PAH AGENTS – PDE5s[CL]		
CLASS PA CRITERIA: Non-preferred agents require a thirty (30) day trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present. - Patients stabilized on non-preferred agents will be grandfathered.		
sildenafil tablets	ADCIRCA (tadalafil) LIQREV (sildenafil) REVATIO IV (sildenafil) REVATIO SUSPENSION (sildenafil) REVATIO TABLETS (sildenafil) sildenafil suspension (generic Revatio)* TADLIQ SUSPENSION (tadalafil)**	*sildenafil suspension may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia AND documentation is provided as to why the clinical need cannot be met with Revatio. **Tadliq may be authorized for those who are unable to ingest solid dosage forms due to documented oral-motor difficulties or dysphagia AND after a thirty (30) day trial of Revatio resulting in an inadequate treatment response.

Charlie Rohrbaugh made a motion to approve the changes to the PAH Agents – PDE5s class as recommended; the motion was seconded by Scott Brown. All members were in favor and the motion was approved.

x. Proton Pump Inhibitors

PROTON PUMP INHIBITORS[AP]		
CLASS PA CRITERIA: Non-preferred agents require sixty (60) day trials of both omeprazole (Rx) and pantoprazole at the maximum recommended dose*, inclusive of a concurrent thirty (30) day trial at the maximum dose of an H_2 antagonist before they will be approved, unless one (1) of the exceptions on the PA form is present.		
NEXIUM PACKETS (esomeprazole)** omeprazole (Rx) pantoprazole tablets PROTONIX GRANULES (pantoprazole)**	ACIPHEX (rabeprazole) ACIPHEX SPRINKLE (rabeprazole) DEXILANT (dexlansoprazole) dexlansoprazole DR capsule esomeprazole magnesium KONVOMEP (omeprazole/sodium bicarbonate) lansoprazole Rx NEXIUM (esomeprazole) omeprazole/sodium bicarbonate (Rx) pantoprazole granules packet PREVACID CAPSULES (lansoprazole) PREVACID SOLUTABS (lansoprazole)** PRILOSEC Rx (omeprazole) PROTONIX DR TABLETS (pantoprazole) rabeprazole ZEGERID Rx (omeprazole/sodium bicarbonate)	*Maximum recommended doses of the PPIs and H2-receptor antagonists may be located at the BMS Pharmacy PA criteria page titled "Max PPI and H2RA" by clicking on the hyperlink. **Prior authorization is required for members nine (9) years of age or older for these agents.

Chris Terpening made a motion to approve the changes to the Proton Pump Inhibitors class (Konvomep) as recommended; the motion was seconded by Laura Davisson. All members were in favor and the motion was approved.

Charlie Rohrbaugh made a motion to approve the changes to the Proton Pump Inhibitors class (pantoprazole granules) as recommended; the motion was seconded by Krista Capehart. All members were in favor and the motion was approved.

xi. VMAT Inhibitors

VMAT INHIBITORS		
CLASS PA CRITERIA: All agents require a prior authorization. Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.		
AUSTEDO TABLET (deutetrabenazine) AUSTEDO XR (deutetrabenazine) INGREZZA CAPSULE (valbenazine) tetrabenazine tablet	xenazine tablet	

Chris Terpening made a motion to approve the changes to the VMAT Inhibitors class as recommended; the motion was seconded by Krista Capehart. All members were in favor and the motion was approved.

B. Class Review

i. Lipotropics, Other (Non-statins)

LIPOTROPICS, OTHER (Non-statins)		
CLASS PA CRITERIA: Non-preferred agents require a twelve (12) week trial of a preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
PCSK-9 INHIBITORS		
PRALUENT (alirocumab)* REPATHA (evolocumab)*	LEQVIO (inclisiran)	*Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.

Chris Terpening made a motion to approve the changes to the Lipotropics, Other (Non-statins) class as recommended; the motion was seconded by Laura Davisson. All members were in favor and the motion was approved.

ii. Stimulants and Related Agents

STIMULANTS AND RELATED AGENTS		
CLASS PA CRITERIA: A PA is required for adults eighteen (18) years of age or older. Non-preferred agents require a thirty (30) day trial of at least one preferred agent in the same subclass and with a similar duration of effect and mechanism of action, unless one (1) of the exceptions on the PA form is present. **NOTE**: Children under the age of 18 may continue their existing therapy at the discretion of the prescriber.		
NARCOLEPTIC AGENTS		
armodafinil^ modafinil^ NUVIGIL (armodafinil)^ PROVIGIL (modafinil)^ SUNOSI (solriamfetol)^^	sodium oxybate WAKIX (pitolisant)*** XYREM (sodium oxybate) XYWAV (calcium, magnesium, potassium, and sodium oxybate)	* Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. ** Sunosi is approvable only with documentation of treatment failure after 30-day trials of both armodafinil and modafinil. ***Wakix is approvable only with documentation of treatment failure after 30-day trials of armodafinil, modafinil and Sunosi.

Charlie Rohrbaugh made a motion to approve the changes to the Stimulants and Related Agents class as recommended; the motion was seconded by Scott Brown. All members were in favor and the motion was approved.

VI. Old Business

VII. Other Business

There was no other business discussed at this time.

VIII. Next Meeting

The next P&T Committee Meeting is scheduled for October 25th, 2023, from 9:00 AM-5:00 PM, In Person Meeting.

IX. Adjournment

The committee adjourned the meeting at 4:16 PM.