STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
Bureau for Medical Services
Office of Pharmacy Services

Bill J. Crouch
Cabinet Secretary

Cynthia E. Beane
Commissioner

Pharmaceutical and Therapeutics Committee

August 28, 2019

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

MINUTES

Committee Members Present:
Bradley Henry, MD, Chair
Tom Kines, RPh, Vice-Chair
Philip Galapon, MD FAAFP
David Gloss, MD
Kelli Lynn Jennings, PharmD
Heather Jones, PA-C
Karrie Murphy, PharmD
Steve Neal, RPh
Chris Terpening, PharmD, PhD

Absent:
John Bernabei, RPh
Toni DiChiacchio, DNP
Hani Nahza, MD
James Rising, MD
Charles Rohrbaugh, RPh

Division of Medicaid Staff Present:
Brian Thompson, PharmD, MS
William Hopkins
Lori Moles, RPh
Doug Sorvig
Gail Goodnight, RPh

BMS Staff Absent

Contract Staff/CHC Staff Present:
Brent Breeding, RPh
Jeffry Barkin, MD, DFAPA
Bettina Lewis, MS, Operational Account Coordinator (by phone)

Other Contract / State Staff Present:
Angie Wowczuk, PharmD (Rational Drug Therapy Program)
Aleshia Heil, PharmD (RDTP, Safe Effective Management of Pain)
Eric Sears, RPh, DXC Technology

I. Call to Order

Dr. Bradley Henry called the meeting to order at 2:08pm

II. Welcome and Introductions

P&T committee members introduced themselves.

III. Administrative Items / Updates

There were no administrative items / updates.

A. Approval of the Previous Meeting Minutes

Chris Terpening made a motion to approve the minutes from the April 24, 2019. The motion was seconded by Philip Galapon. All were in favor and the minutes were approved.

B. PDL Compliance/Generic Percent Report Updates

Dr. Jeffrey Barkin provided an explanation of the PDL Compliance and Generic Percent reports.

A. Dr. Barkin reviewed the PDL Compliance Report; overall compliance for Q2 2019 was 91.7%.

B. Dr. Barkin reviewed the Generic Percent Report; overall generic utilization for Q2 2019 was 86.3%.

IV. Public Comments

There were no speakers for public comment in favor of new drugs.

V. Executive Session

A motion was made to move to executive session by Chris Terpening and seconded by Philip Galapon and all were in favor.

The Committee adjourned for executive session at 2:15pm.

The Committee reconvened at 2:42pm.

VI. New Business

A. Adjustments to Existing Classes

i. Silodosin (Alpha Blockers)

BPH TREATMENTS		
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of at least two (2) chemically distinct 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.		
ALPHA BLOCKERS		
alfuzosin doxazosin tamsulosin terazosin	CARDURA (doxazosin) CARDURA XL (doxazosin) FLOMAX (tamsulosin) HYTRIN (terazosin) RAPAFLO (silodosin) Silodosin[NR] UROXATRAL (alfuzosin)	

Chris Terpening made a motion to approve the changes to the BPH Treatments category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

B. New Therapeutic Class

N/A

C. New Therapeutic Sub-Class

N/A

D. New Drug Reviews

i. Tolsura (Antifungals, Oral)

ANTIFUNGALS, ORAL		
CLASS PA CRITERIA: Non-preferred agents will only be authorized if one (1) of the exceptions on the PA form is present.		
clotrimazole fluconazole* nystatin terbinafine[CL]	ANCOBON (flucytosine) CRESEMBA (isovuconazonium)[CL]** DIFLUCAN (fluconazole) flucytosine griseofulvin*** GRIS-PEG (griseofulvin) itraconazole ketoconazole**** LAMISIL (terbinafine) MYCELEX (clotrimazole) NIZORAL (ketoconazole) NOXAFIL (posaconazole) ONMEL (itraconazole) ORAVIG (miconazole) SPORANOX (itraconazole) TOLSURA (itraconazole)[NR] VFEND (voriconazole)	*PA is required when limits are exceeded. **Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. ***PA is not required for griseofulvin suspension for children up to eighteen (18) 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

ANTIFUNGALS, ORAL		
CLASS PA CRITERIA: Non-preferred agents will only be authorized if one (1) of the exceptions on the PA form is present.		
	voriconazole suspension voriconazole tablets	international normalized ratio (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.**

David Gloss made a motion to approve the changes to the Antifungals,Oral category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

ii. Lexette (Steroids, Topical)

STEROIDS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.		
VERY HIGH & HIGH POTENCY		
betamethasone dipropionate cream betamethasone valerate cream betamethasone valerate lotion betamethasone valerate oint clobetasol propionate cream/gel/ointment/solution clobetasol emollient clobetasol propionate shampoo fluocinonide gel triamcinolone acetonide cream, ointment triamcinolone acetonide lotion	amcinonide APEXICON (diflorasone diacetate) APEXICON E (diflorasone diacetate) betamethasone dipropionate gel, lotion, ointment BRYHALI LOTION (halobetasol)^{NR} clobetasol lotion clobetasol propionate foam CLOBEX (clobetasol propionate) CLODAN KIT (clobetasol propionate) CLODAN SHAMPOO (clobetasol propionate) CORMAX (clobetasol propionate) desoximetasone cream/gel/ointment diflorasone diacetate DIPROLENE (betamethasone dipropionate/propylene glycol) DIPROLENE AF (betamethasone dipropionate/propylene glycol) DIPROSONE (betamethasone dipropionate) fluocinonide cream fluocinonide ointment fluocinonide solution fluocinonide/emollient halcinonide HALAC (halobetasol propionate) halobetasol propionate HALOG (halcinonide) HALONATE (halobetasol propionate) KENALOG (triamcinolone acetonide) LEXETTE FOAM (halobetasol)^{NR} LIDEX (fluocinonide) LIDEX-E (fluocinonide) OLUX (clobetasol propionate)	

STEROIDS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.		
VERY HIGH & HIGH POTENCY		
	OLUX-E (clobetasol propionate/emollient) PSORCON (diflorasone diacetate) SERNIVO SPRAY (betamethasone dipropionate) TEMOVATE (clobetasol propionate) TEMOVATE-E (clobetasol propionate/emollient) TOPICORT CREAM, GEL, OINTMENT (desoximetasone) TOPICORT SPRAY (desoximetasone) ULTRAVATE (halobetasol propionate) ULTRAVATE PAC cream ULTRAVATE X (halobetasol propionate / lactic acid) VANOS (fluocinonide)	

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

iii. Yupelri (COPD Agents, Anticholinergic)

COPD AGENTS		
CLASS PA CRITERIA: Non-preferred agents require a sixty (60) day trial of one preferred agent from the corresponding sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present.		
ANTICHOLINERGIC[AP]		
ipratropium nebulizer solution SPIRIVA (tiotropium) TUDORZA (aclidinium)	ATROVENT HFA (ipratropium) INCRUSE ELLIPTA (umeclidinium) LONHALA MAGNAIR (glycopyrrolate) SEEBRI NEOHALER (glycopyrrolate) SPIRIVA RESPIMAT (tiotropium) YUPELRI SOLUTION (revefenacin)[NR]	

Philip Galapon made a motion to approve the changes to the COPD Agents, Anticholinergic category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

iv. Inveltys (Ophthalmics, Anti-Inflammatories)

OPHTHALMICS, ANTI-INFLAMMATORIES		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of at least two (2) preferred agents before they will be approved, unless one (1) of the exceptions on the PA form is present. Trials must include at least one agent with the same mechanism of action as the requested non-preferred agent.		
dexamethasone diclofenac DUREZOL (difluprednate) fluorometholone flurbiprofen ILEVRO (nepafenac) ketorolac prednisolone acetate prednisolone sodium phosphate	ACULAR (ketorolac) ACULAR LS (ketorolac) ACUVAIL (ketorolac tromethamine) BROMDAY (bromfenac) bromfenac BROMSITE (bromfenac) FLAREX (fluorometholone) FML (fluorometholone) FML FORTE (fluorometholone) FML S.O.P. (fluorometholone)	

OPHTHALMICS, ANTI-INFLAMMATORIES		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of at least two (2) preferred agents before they will be approved, unless one (1) of the exceptions on the PA form is present. Trials must include at least one agent with the same mechanism of action as the requested non-preferred agent.		
	INVELTYS (loteprednol)[NR] LOTEMAX DROPS, OINTMENT (loteprednol) LOTEMAX GEL (loteprednol) MAXIDEX (dexamethasone) NEVANAC (nepafenac) OMNIPRED (prednisolone) OZURDEX (dexamethasone) PRED FORTE (prednisolone) PRED MILD (prednisolone) PROLENSA (bromfenac) RETISERT (fluocinolone) TRIESENCE (triamcinolone) VEXOL (rimexolone) XIBROM (bromfenac)	

Philip Galapon made a motion to approve the changes to the Ophthalmics, Anti-Inflammatories category as recommended; the motion was seconded by Karrie Murphy. All members were in favor and the motion was approved.

v. Xyosted (Androgenic Agents)

ANDROGENIC AGENTS		
CLASS PA CRITERIA: A non-preferred agent will only be authorized if one (1) of the exceptions on the PA form is present.		
ANDRODERM (testosterone) ANDROGEL (testosterone) METHITEST (methyltestosterone) testosterone cypionate vial[CL] testosterone enanthate vial[CL]	ANDROID (methyltestosterone) AVEED VIAL (testosterone undecanoate) AXIRON (testosterone) FORTESTA (testosterone) methyltestosterone capsule NATESTO (testosterone) STRIANT BUCCAL (testosterone) TESTIM (testosterone) TESTRED (methyltestosterone) testosterone gel VOGELXO (testosterone) XYOSTED (testosterone enanthate)[NR]	

Chris Terpening made a motion to approve the changes to the Androgenic Agents category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

vi. Xelpros (Ophthalmics, Prostaglandin Analogs)

OPHTHALMICS, GLAUCOMA AGENTS		
CLASS PA CRITERIA: Non-preferred agents will only be authorized if there is an allergy to all preferred agents in the corresponding sub-class.		
PROSTAGLANDIN ANALOGS		
latanoprost TRAVATAN-Z (travoprost)	bimatoprost LUMIGAN (bimatoprost) travoprost VYZULTA (latanoprostene)* XALATAN (latanoprost) XELPROS (latanoprost)^{NR} ZIOPTAN (tafluprost)	*Vyzulta – prior authorization requires failure on a 3-month trial of at least one preferred prostaglandin eye drop used in combination with an agent from another subclass.

Chris Terpening made a motion to approve the changes to the Ophthalmics, Glaucoma Agents category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

vii. Sympazan (Anticonvulsants, Benzodiazepines)

ANTICONVULSANTS		
CLASS PA CRITERIA: For a diagnosis of seizure disorder, non-preferred agents require a fourteen (14) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present; patients currently on established therapies shall be grandfathered. For all other diagnoses, non-preferred agents require a thirty (30) day trial of a preferred agent in the same sub-class before they will be approved, unless one (1) of the exceptions on the PA form is present. In situations where AB-rated generic equivalent products are available, “Brand Medically Necessary” must be hand-written by the prescriber on the prescription for the brand name product to be reimbursed.		
BENZODIAZEPINES^{AP}		
clonazepam diazepam rectal gel diazepam tablets	clobazam* clonazepam ODT DIASTAT (diazepam rectal) KLONOPIN (clonazepam) ONFI (clobazam)* ONFI SUSPENSION (clobazam)* SYMPAZAN (clobazam film)*^{NR}	*Onfi shall be authorized as adjunctive therapy for treatment of Lennox-Gastaut Syndrome without further restrictions. Off-label use requires an appeal to the Medical Director. NOTE: generic clobazam is preferred over brand ONFI.

David Gloss made a motion to approve the changes to the Anticonvulsants, Benzodiazepines category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

viii. Abilify Mycite (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. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy.

Upon discharge, a hospitalized patient stabilized on a non-preferred agent may receive authorization to continue this drug for labeled indications and at FDA recommended dosages. For off-label indications or dosages, a thirty (30) day prior-authorization shall be granted pending BMS review.

SINGLE INGREDIENT

ABILIFY MAINTENA (aripiprazole)CL aripiprazole tablets ARISTADA (aripiprazole)CL clozapine INVEGA SUSTENNA (paliperidone)CL INVEGA TRINZA (paliperidone)* CL olanzapine olanzapine ODT quetiapine** AP for the 25 mg Tablet Only quetiapine ER RISPERDAL CONSTA (risperidone)CL risperidone ziprasidone	ABILIFY MYCITE (aripiprazole)NR ABILIFY TABLETS (aripiprazole) ADASUVE (loxapine) clozapine ODT CLOZARIL (clozapine) FANAPT (iloperidone) FAZACLO (clozapine) GEODON (ziprasidone) GEODON IM (ziprasidone) INVEGA ER (paliperidone) LATUDA (lurasidone)*** NUPLAZID (pimavanserin) **** olanzapine IMCL paliperidone ER PERSERIS (risperidone)CL REXULTI (brexipiprazole) RISPERDAL (risperidone) SAPHRIS (asenapine) SEROQUEL (quetiapine) SEROQUEL XR (quetiapine) VERSACLOZ (clozapine) VRAYLAR (capriprazine)*** VRAYLAR DOSE PAK (capriprazine)*** ZYPREXA (olanzapine) ZYPREXA IM (olanzapine)CL ZYPREXA RELPREVV (olanzapine)	**In addition to class criteria:** *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.** ***For the indication of bipolar depression only, prior authorization of LATUDA or VRAYLAR requires failure of a 30-day trial of either quetiapine OR a combination of olanzapine + fluoxetine. All trials must be at the maximum recommended dose for the diagnosis provided before they would be considered a failure unless an adverse reaction is documented necessitating a change in therapy. All other indications follow class criteria. Patients already stabilized on Latuda or Vraylar shall be grandfathered. ****Nuplazid will only be authorized for the treatment of Parkinson Disease Induced Psychosis after documented treatment failure with quetiapine.

Chris Terpening made a motion to approve the changes to the Antipsychotics, Atypical category as recommended; the motion was seconded by Philip Galapon. All members were in favor and the motion was approved.

ix. Cequa (Ophthalmics, Anti-inflammatories-Immunomodulators)

OPHTHALMICS, ANTI-INFLAMMATORIES- IMMUNOMODULATORS		
CLASS PA CRITERIA: See below for individual sub-class criteria.		
	CEQUA (cyclosporine)[NR] RESTASIS (cyclosporine) XIIDRA (lifitegrast)	The following prior authorization criteria apply to both Restasis and Xiidra: 1.) Patient must be sixteen (16) years of age or greater; **AND** 2.) Prior Authorization must be requested by an ophthalmologist or optometrist; **AND** 3.) Clinically diagnosed tear deficiency due to ocular inflammation in patients with keratoconjunctivitis sicca or dry eye syndrome (also known as dry eye); **AND** 4.) Patient must have a functioning lacrimal gland; **AND** 5.) Patient using artificial tears at least four (4) times a day over the last thirty (30) days; **AND** 6.) Patient must not have an active ocular infection

Philip Galapon made a motion to approve the changes to the Ophthalmics, Anti-Inflammatories-Immunomodulators category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

x. Bryhali Lotion (Steroids, Topical)

STEROIDS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.		
VERY HIGH & HIGH POTENCY		
betamethasone dipropionate cream betamethasone valerate cream betamethasone valerate lotion betamethasone valerate oint clobetasol propionate cream/gel/ointment/solution clobetasol emollient clobetasol propionate shampoo fluocinonide gel triamcinolone acetonide cream, ointment triamcinolone acetonide lotion	amcinonide APEXICON (diflorasone diacetate) APEXICON E (diflorasone diacetate) betamethasone dipropionate gel, lotion, ointment BRYHALI LOTION (halobetasol)[NR] clobetasol lotion clobetasol propionate foam CLOBEX (clobetasol propionate) CLODAN KIT (clobetasol propionate) CLODAN SHAMPOO (clobetasol propionate) CORMAX (clobetasol propionate) desoximetasone cream/gel/ointment diflorasone diacetate DIPROLENE (betamethasone dipropionate/propylene glycol) DIPROLENE AF (betamethasone dipropionate/propylene glycol) DIPROSONE (betamethasone dipropionate) fluocinonide cream fluocinonide ointment fluocinonide solution fluocinonide/emollient halcinonide HALAC (halobetasol propionate) halobetasol propionate HALOG (halcinonide) HALONATE (halobetasol propionate) KENALOG (triamcinolone acetonide) LEXETTE FOAM (halobetasol)[NR] LIDEX (fluocinonide)	

STEROIDS, TOPICAL		
CLASS PA CRITERIA: Non-preferred agents require five (5) day trials of one (1) form of **EACH** preferred unique active ingredient in the corresponding potency group before they will be approved, unless one (1) of the exceptions on the PA form is present.		
VERY HIGH & HIGH POTENCY		
	LIDEX-E (fluocinonide) OLUX (clobetasol propionate) OLUX-E (clobetasol propionate/emollient) PSORCON (diflorasone diacetate) SERNIVO SPRAY (betamethasone dipropionate) TEMOVATE (clobetasol propionate) TEMOVATE-E (clobetasol propionate/emollient) TOPICORT CREAM, GEL, OINTMENT (desoximetasone) TOPICORT SPRAY (desoximetasone) ULTRAVATE (halobetasol propionate) ULTRAVATE PAC cream ULTRAVATE X (halobetasol propionate / lactic acid) VANOS (fluocinonide)	

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

xi. Symjepi (Epinephrine, Self-injected)

EPINEPHRINE, SELF-INJECTED		
CLASS PA CRITERIA: A non-preferred agent may be authorized with documentation showing the patient's inability to follow the instructions, or the patient's failure to understand the training for the preferred agent(s).		
epinephrine (labeler 49502 only)	ADRENACLICK (epinephrine) epinephrine (all labelers except 49502) EPIPEN (epinephrine) EPIPEN JR (epinephrine) SYMJEPI (epinephrine)^{NR}	

Tom Kines made a motion to approve the changes to the Epinephrine, Self-Injected category as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

VII. Old Business

There was no old business discussed at this time.

VIII. Other Business

There was no other business discussed at this time.

IX. Next Meeting

The next meeting will be held on October 30, 2019, 9am-5pm, Charleston Civic Center.

X. Adjournment

Dr. Henry adjourned the meeting at 3:04pm.