STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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Cabinet Secretary

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Cynthia E. Beane
Commissioner

Pharmaceutical and Therapeutics Committee

April 28, 2021

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:
Chris Terpening, PharmD, PhD, Vice-Chair
Philip Galapon, MD FAAFP, Chair
David Gloss, MD
Toni DiChiacchio, DNP
John Bernabei, RPh
Charles Rohrbaugh, RPh
Kelli Lynn Jennings, PharmD

Absent:
Tom Kines, RPH
Heather Jones, PA-C
Hani Nahza, MD

Division of Medicaid Staff Present:
Bill Hopkins, Operations Manager
Priya Shah, DUR Coordinator
Doug Sorvig, Data Analyst
Brian Thompson, PharmD, MS, Director
Gail Goodnight, Rebate Pharmacist
Lori Moles, Pharmacist

Contract Staff Present:
Change Healthcare
Ryan Fell, PharmD
Laureen Biczak, MD
Steve Liles, PharmD

Other Contract / State Staff Present:

I. Call to Order

Phillip Galapon, Chairman (presiding in absence of Tom Kines), called the meeting to order at 3:32 PM

II. Welcome and Introductions

Phillip 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 January 27th Meeting Minutes

The Committee moved to approve the January 27, 2020 Meeting minutes. All were in favor with no objections or revisions.

B. PDL Compliance / Generic Percent Report Updates

Ryan Fell provided an explanation of the PDL Compliance and Generic Percent reports.

- Ryan Fell reviewed the Generic Percent Report; overall generic utilization for Q1 2021 was 84.3%

- Ryan Fell reviewed the PDL Compliance Report; overall compliance for Q1 2021 was 92.7%

IV. Public Comments

Public comments for this meeting were only accepted in writing. 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.Antiparkinson's Agents, COMT Inhibitors

ANTIPARKINSON'S AGENTS		
CLASS PA CRITERIA: Patients starting therapy on drugs in this class must show a documented allergy to all preferred agents in the corresponding sub-class, before a non-preferred agent will be authorized.		
	COMT INHIBITORS	
entacapone	COMTAN (entacapone) ONGENTYS (opicapone) TASMAR (tolcapone) tolcapone	COMT Inhibitor agents will only be approved as add-on therapy to a levodopa-containing regimen for treatment of documented motor complications.

David Gloss made a motion to approve the changes to the Antiparkinson's Agents, COMT Inhibitors as recommended; the motion was seconded by Chris Terpening. All members were in favor and the motion was approved.

ii.Glucocorticoids, Inhaled

GLUCOCORTICOIDS, INHALED[AP]		
THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each chemically unique preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present.		
	GLUCOCORTICOIDS	
ASMANEX TWISTHALER (mometasone) budesonide nebulizer 0.5 mg/2 ml & 0.25 mg/2 ml solution* FLOVENT DISKUS (fluticasone) FLOVENT HFA (fluticasone) PULMICORT FLEXHALER (budesonide)	ARMONAIR DIGIHALER (fluticasone) ALVESCO (ciclesonide) ARNUITY ELLIPTA (fluticasone) ASMANEX HFA (mometasone) budesonide nebulizer 1 mg/2ml solution PULMICORT NEBULIZER SOLUTION (budesonide) QVAR REDIHALER (beclomethasone)	*Budesonide Respules are only preferred for children up to nine (9) years of age. For patients nine (9) and older, prior authorization is required and will be approved only for a diagnosis of severe nasal polyps.
	GLUCOCORTICOID/BRONCHODILATOR COMBINATIONS	
ADVAIR DISKUS (fluticasone/salmeterol) ADVAIR HFA (fluticasone/salmeterol) DULERA (mometasone/formoterol) SYMBICORT(budesonide/formoterol)	AIRDUO DIGIHALER (fluticasone/salmeterol) AIRDUO RESPICLICK (fluticasone/salmeterol) budesonide/formoterol BREO ELLIPTA (fluticasone/vilanterol) fluticasone/salmeterol WIXELA (fluticasone/salmeterol)	

Chris Terpening made a motion to approve the changes to the Glucocorticoids, Inhaled as recommended; the motion was seconded by Charlie Rohrbaugh. Philip Galapon recommended DUR board look into criteria for use based on the increased data points and potential clinical benefit to providers that can be obtained by these inhalers. All members were in favor and the motion was approved.

iii.Guanylate Cyclase Stimulators

GUANYLATE CYCLASE STIMULATORS[CL]		
	ADEMPAS (riociguat)* VERQUVO (vericiguat)	*Adempas requires a thirty (30) day trial of a preferred agent from any other PAH Class before it 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 Guanylate Cyclase Stimulators as recommended; the motion was seconded by Toni DiChiacchio. All members were in favor and the motion was approved.

iv.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 gluisine)^AP*	ADMELOG (insulin lispro)	*Apidra will be authorized if the following criteria are met: 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..
FIASP (insulin aspart)	AFREZZA (insulin)^CL	
HUMALOG (insulin lispro)	BASAGLAR (insulin glargine)	
HUMALOG JR KWIKPEN (insulin lispro)	HUMALOG KWIKPEN U-200 (insulin lispro)	
HUMALOG KWIKPEN U-100 (insulin lispro)	HUMULIN PENS (insulin)	
HUMALOG MIX PENS (insulin lispro/lispro protamine)	HUMULIN R VIAL (insulin)	
	HUMULIN 70/30 (insulin)	
HUMALOG MIX VIALS (insulin lispro/lispro protamine)	insulin aspart	** 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.
HUMULIN N VIAL (insulin)	insulin aspart/aspart protamine	
HUMULIN R U-500 VIAL (insulin)	insulin lispro	
HUMULIN R U-500 KWIKPEN (insulin)	LYUMJEV (insulin lispro)	
LANTUS (insulin glargine)	NOVOLIN (insulin)	
LEVEMIR (insulin detemir)	SEMGLEE (insulin glargine)	***Tresiba and Tresiba Flextouch may be approved only for: 1.) 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. **OR** 2.) Patients who currently require over 200 units per day of long-acting insulin.
NOVOLOG (insulin aspart)	SOLIQUA (insulin glargine/lixisenatide)**	
NOVOLOG MIX (insulin aspart/aspart protamine)	TRESIBA (insulin degludec)***	
TOUJEO SOLOSTAR (insulin glargine)	TRESIBA FLEXTOUCH (insulin degludec)***	
TOUJEO MAX SOLOSTAR (insulin glargine)	XULTOPHY (insulin degludec/liraglutide)**	

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

v.Immunosuppressives, Oral

IMMUNOSUPPRESSIVES, ORAL

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.

azathioprine	ASTAGRAF XL (tacrolimus)	
cyclosporine	AZASAN (azathioprine)	
cyclosporine, modified	CELLCEPT (mycophenolate mofetil)	
mycophenolate mofetil	ENVARSUS XR (tacrolimus)	
sirolimus	IMURAN (azathioprine)	
tacrolimus capsule	LUPKYNIS (voclosporin)	
	mycophenolic acid	
	mycophenolic mofetil suspension	

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

vi.Laxatives and Cathartics

LAXATIVES AND CATHARTICS

CLASS PA CRITERIA: Non-preferred agents require thirty (30) day trials of each preferred agent before they will be approved, unless one (1) of the exceptions on the PA form is present

THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	**NON-PREFERRED AGENTS**	**PA CRITERIA**
peg 3350	OSMOPREP	
	SUPREP	
	SUTAB (magnesium sulfate, potassium sulfate, sodium sulfate)	

David Gloss made a motion to approve the changes to the Laxatives and Cathartics as recommended; the motion was seconded by Charlie Rohrbaugh. Philip Galapon discussed Sutab as a possible option for patients with disease states involving gastric volume issues and recommended DUR look into criteria for use in this population. All members were in favor and the motion was approved.

vii.Multiple Sclerosis Agents, Non-Interferons

MULTIPLE SCLEROSIS AGENTS[CL]

CLASS PA CRITERIA: All agents require a prior authorization and documented diagnosis of multiple sclerosis. Preferred oral agents require a ninety (90) day trial of any preferred injectable agent. Non-preferred agents require ninety (90) day trials of each chemically unique preferred agent (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present.

NON-INTERFERONS		
AUBAGIO (teriflunomide)* dalfampridine ER** COPAXONE 20 mg (glatiramer) GILENYA (fingolimod) TECFIDERA (dimethyl fumarate)***	AMPYRA (dalfampridine)** BAFIERTAM CAPSULES (monomethyl fumarate) COPAXONE 40 mg (glatiramer)**** dimethyl fumerate*** glatiramer GLATOPA (glatiramer) KESIMPTA INJECTION (ofatumumab) MAYZENT (siponimod)***** MAVENCLAD (cladribine) VUMERITY (diroximel) ZEPOSIA (ozanimod)	**In addition to class PA criteria, the following conditions and criteria may also apply:** *Aubagio requires the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Measurement of transaminase and bilirubin levels within the (6) months before initiation of therapy and ALT levels at least monthly for six (6) months after initiation of therapy **and** 3. Complete blood cell count (CBC) within six (6) months before initiation of therapy **and** 4. Female patients must have a negative pregnancy test before initiation of therapy and be established on a reliable method of contraception if appropriate **and** 5. Patient is between eighteen (18) up to sixty-five (65) years of age **and** 6. Negative tuberculin skin test before initiation of therapy **Dalfampridine ER and Ampyra require the following additional criteria to be met: 1. Diagnosis of multiple sclerosis **and** 2. No history of seizures **and** 3. No evidence of moderate or severe renal impairment. ***Dimethyl fumerate and Tecfidera require the following additional criteria to be met: 1. Diagnosis of relapsing multiple sclerosis **and** 2. Complete blood count (CBC) within six (6) months of initiation of therapy and six (6) months after initiation **and** 3. Complete blood count (CBC) annually during therapy. ****Copaxone 40mg will only be authorized for documented injection site issues.

Charlie Rohrbaugh made a motion to approve the changes to the Multiple Sclerosis Agents, Non-Interferons as recommended; the motion was seconded by David Gloss. All members were in favor and the motion was approved.

viii.Ophthalmics, Anti-Inflammatories-Immunomodulators

OPHTHALMICS, ANTI-INFLAMMATORIES- IMMUNOMODULATORS[CL]

CLASS PA CRITERIA: All agents require a prior authorization. Non-preferred agents require a 60-day trial of the preferred agent(s).

RESTASIS (cyclosporine)	CEQUA (cyclosporine) EYSUVIS (loteprednol) RESTASIS MULTIDOSE (cyclosporine)* XIIDRA (lifitegrast)	***Restasis Multidose** is approvable only on appeal and requires medical reasoning as to why the clinical need cannot be met with the preferred product (Restasis). **All agents must meet the following prior-authorization criteria:** 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** Patient must not have an active ocular infection

Charlie Rohrbaugh made a motion to approve the changes to the Ophthalmics, Anti-Inflammatories-Immunomodulators as recommended; the motion was seconded by David Gloss. All members were in favor and the motion was approved.

ix.Steroids, Topical, Very High and High Potency

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		
THERAPEUTIC DRUG CLASS		
PREFERRED AGENTS	NON-PREFERRED AGENTS	PA CRITERIA
	fluocinonide cream fluocinonide ointment fluocinonide solution fluocinonide/emollient halcinonide cream halobetasol propionate HALOG (halcinonide) IMPEKLO LOTION (clobetasol propionate) KENALOG (triamcinolone acetonide) LEXETTE FOAM (halobetasol) OLUX (clobetasol propionate) OLUX-E (clobetasol propionate/emollient) PSORCON (diflorasone diacetate) TEMOVATE (clobetasol propionate) TOPICORT CREAM, GEL, OINTMENT (desoximetasone) TOPICORT SPRAY (desoximetasone) TOVET FOAM (clobetasol) ULTRAVATE (halobetasol propionate) ULTRAVATE PAC cream VANOS (fluocinonide)	

David Gloss made a motion to approve the changes to the Steroids, Topical, Very High and High Potency as recommended; the motion was seconded by Toni DiChiacchio. All members were in favor and the motion was approved.

B. New Therapeutic Class Review

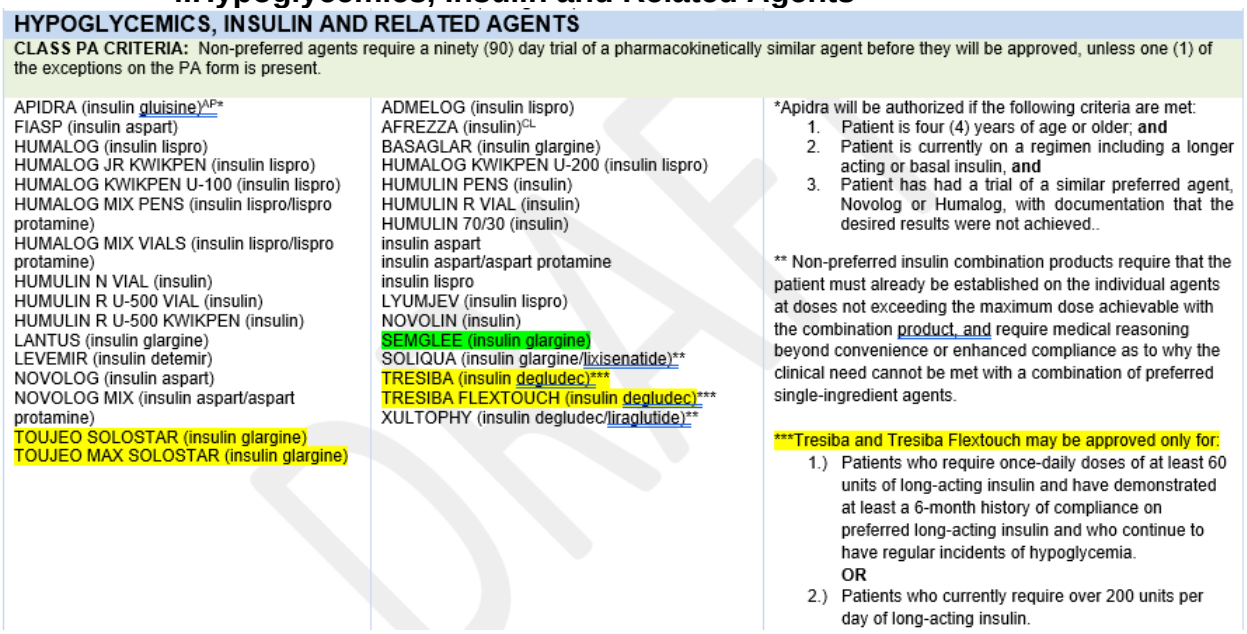
i.Spinal Muscular Atrophy

SPINAL MUSCULAR ATROPHY AGENTS[CL]		
CLASS PA CRITERIA:		
	EVRYSDI (risdiplam)	

David Gloss made a motion to approve the changes to the Spinal Muscular Atrophy as recommended; the motion was seconded by Toni DiChiacchio. All members were in favor and the motion was approved.

C. Drug Class Review

i.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 gluisine)AP*	ADMELOG (insulin lispro)	*Apidra will be authorized if the following criteria are met:
FIASP (insulin aspart)	AFREZZA (insulin)CL	1. Patient is four (4) years of age or older; **and**
HUMALOG (insulin lispro)	BASAGLAR (insulin glargine)	2. Patient is currently on a regimen including a longer acting or basal insulin, **and**
HUMALOG JR KWIKPEN (insulin lispro)	HUMALOG KWIKPEN U-200 (insulin lispro)	3. Patient has had a trial of a similar preferred agent, Novolog or Humalog, with documentation that the desired results were not achieved..
HUMALOG KWIKPEN U-100 (insulin lispro)	HUMULIN PENS (insulin)	
HUMALOG MIX PENS (insulin lispro/lispro protamine)	HUMULIN R VIAL (insulin)	** 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.
HUMALOG MIX VIALS (insulin lispro/lispro protamine)	HUMULIN 70/30 (insulin)	
HUMULIN N VIAL (insulin)	insulin aspart	***Tresiba and Tresiba Flextouch may be approved only for:
HUMULIN R U-500 VIAL (insulin)	insulin aspart/aspart protamine	1.) 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. **OR**
HUMULIN R U-500 KWIKPEN (insulin)	insulin lispro	2.) Patients who currently require over 200 units per day of long-acting insulin.
LANTUS (insulin glargine)	LYUMJEV (insulin lispro)	
LEVEMIR (insulin detemir)	NOVOLIN (insulin)	
NOVOLOG (insulin aspart)	SEMGLEE (insulin glargine)	
NOVOLOG MIX (insulin aspart/aspart protamine)	SOLIQUA (insulin glargine/lixisenatide)**	
TOUJEO SOLOSTAR (insulin glargine)	TRESIBA (insulin degludec)***	
TOUJEO MAX SOLOSTAR (insulin glargine)	TRESIBA FLEXTOUCH (insulin degludec)***	
	XULTOPHY (insulin degludec/liraglutide)**	

Chris Terpening made a motion to approve the changes along with grandfathering for stable patients to the Hypoglycemics, Insulin and Related Agents as recommended; the motion was seconded by Toni DiChiacchio. Philip Galapon noted that move is prudent from a clinical and financial benefit as grandfathering is being utilized and members who are not controlled can move to the preferred long acting alternative. Charlie Rohrbaugh voted nay. All other members were in favor and the motion was approved.

VI. Old Business

There was no old business discussed at this time.

VII. Other Business

There was no other business discussed at this time.

VIII. Next Meeting

The next P&T Committee Meeting is scheduled for August 25th, 2021, from 2:00 PM-5:00 PM, Virtual Meeting.

IX. Adjournment

The committee adjourned the meeting at 4:35 PM.