STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

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Cynthia E. Beane
Commissioner

# *Pharmaceutical and Therapeutics Committee*

**April 26th, 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:**
Scott Brown, RPh, Chair
Chris Terpening, PharmD, PhD, Vice-Chair
Philip Galapon, MD FAAFP
David Gloss, MD
John Bernabei, RPh (JJ)
Charles Rohrbaugh, RPh
Krista Capehart, PharmD
Toni DiChiacchio, DNP
Laura Davisson, MD

**Absent:**
Mary Payne, RPh

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

**Contract Staff Present:**
*Change Healthcare*
Ryan Fell, PharmD
Laureen Biczak, MD
Joseph Bergondo, PharmD
Chris Dolfi, Pharm D

**Other Contract / State Staff Present:**

# I. Call to Order

Philip Galapon, Chairman, called the meeting to order at 3:35 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 January 25th Meeting Minutes

The Committee moved to approve the January 25th, 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 93.0%

# 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. Antibiotics, Vaginal

| ANTIBIOTICS, VAGINAL | | |
|---|---|---|
| **CLASS PA CRITERIA:** Non-preferred agents require trials of each chemically unique preferred agent at the manufacturer's recommended duration, before they will be approved, unless one (1) of the exceptions on the PA form is present. | | |
| CLEOCIN OVULE (clindamycin) | CLEOCIN CREAM (clindamycin) | |
| CLINDESSE (clindamycin) | clindamycin cream | |
| metronidazole gel | METROGEL (metronidazole) | |
| NUVESSA (metronidazole) | VANDAZOLE (metronidazole) | |
| SOLOSEC (secnidazole) | XACIATO (clindamycin) GEL | |

Chris Terpening made a motion to approve the changes to the Antibiotics, Vaginal class as recommended; the motion was seconded by Charlie Rohrbaugh. All members were in favor and the motion was approved.

### ii. Antiretrovirals

| ANTIRETROVIRALS[AP] | | |
|---|---|---|
| **CLASS PA CRITERIA:** Non-preferred drugs require medical reasoning beyond convenience or enhanced compliance as to why the clinical need cannot be met with a preferred agent or combination of preferred agents. NOTE: Regimens consisting of preferred agents will result in no more than one additional unit per day over equivalent regimens composed of non-preferred agents. Patients already on a non-preferred regimen shall be grandfathered. | | |
| **GP 120 DIRECTED ATTACHMENT INHIBITORS** | | |
| RUKOBIA (fostemsavir tromethamine) TABLETS | SUNLENCA (lenacapavir) TABLETS, VIALS | |

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

### iii. Cytokine & CAM Antagonists

| CYTOKINE & CAM ANTAGONISTS[CL] | | |
|---|---|---|
| **CLASS PA CRITERIA:** Non-preferred agents require ninety (90) day trials of all preferred agents which are indicated for the diagnosis, unless one (1) of the exceptions on the PA form is present. *Patients stabilized for at least 6-months on their existing non-preferred regimen shall be grandfathered (provided the current therapy is for a labeled indication AND a more cost-effective biosimilar product is not available). In cases where a biosimilar exists but is also non-preferred, the PA vendor shall advise the provider which product is the most cost-effective agent. All off-label requests require review by the Medical Director.* **Full PA criteria may be found on the PA Criteria page by clicking the hyperlink.** | | |
| **OTHERS** | | |
| ACTEMRA subcutaneous (tocilizumab)<br>KINERET (anakinra)<br>ORENCIA CLICKJET/VIAL (abatacept)<br>OTEZLA (apremilast)<br>TALTZ (ixekizumab)*<br>XELJANZ (tofacitinib) | ACTEMRA ACTPEN (tocilizumab)<br>AMJEVITA (adalimumab-atto)<br>COSENTYX (secukinumab)<br>ENTYVIO (vedolizumab)<br>ILARIS (canakinumab)<br>ILUMYA (tildrakizumab)<br>KEVZARA (sarilumab)<br>OLUMIANT (baricitinib)<br>ORENCIA SYRINGE (abatacept)<br>RINVOQ ER (upadacitinib)<br>SILIQ (brodalumab)<br>SKYRIZI (risankizumab)<br>SOTYKTU (deucravacitinib)<br>STELARA subcutaneous (ustekinumab)<br>TREMFYA (guselkumab)<br>XELJANZ XR (tofacitinib) | *Taltz will be authorized for treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis only after inadequate response to a ninety (90) day trial of one preferred ANTI-TNF agent. |

Chris Terpening made a motion to approve the changes to the Cytokine and CAM Antagonists class as recommended; the motion was seconded by Charlie Rohrbaugh. All members were in favor and the motion was approved.

### iv. 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. | | |
| **AMPHETAMINES** | | |
| ADDERALL XR (amphetamine salt combination)<br>amphetamine salt combination ER<br>amphetamine salt combination IR<br>dextroamphetamine ER<br>dextroamphetamine IR | ADDERALL (amphetamine salt combination)<br>ADZENYS XR ODT (amphetamine)<br>ADZENYS ER SUSP (amphetamine)<br>amphetamine tablets<br>DESOXYN (methamphetamine)<br>DEXEDRINE ER (dextroamphetamine)<br>dextroamphetamine solution<br>DYANAVEL XR SUSP, TABLETS (amphetamine)<br>EVEKEO (amphetamine)<br>EVEKEO ODT (amphetamine)<br>methamphetamine<br>MYDAYIS (dextroamphetamine/amphetamine salt)*<br>PROCENTRA solution (dextroamphetamine)<br>VYVANSE CHEWABLE (lisdexamfetamine)<br>VYVANSE CAPSULE (lisdexamfetamine)<br>XELSTRYM (dextroamphetamine) patches<br>ZENZEDI (dextroamphetamine) | **In addition to the Class Criteria**: Thirty (30) day trials of at least three (3) antidepressants are required before amphetamines will be authorized for depression.<br><br>*Mydayis requires a 30-day trial of at least one long-acting preferred agent in this subclass and a trial of Adderall XR. |

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.

## B. Class Review

### i. 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<br>aripiprazole tablets<br>ARISTADA (aripiprazole)CL<br>ARISTADA INITIO (aripiprazole)CL | ABILIFY MYCITE (aripiprazole)<br>ABILIFY TABLETS (aripiprazole)<br>ADASUVE (loxapine)<br>aripiprazole ODT | **The following criteria exceptions apply to the specified products:** |
| asenapine sublingual tablets<br>clozapine<br>INVEGA HAFYERA (paliperidone)*CL<br>INVEGA SUSTENNA (paliperidone)CL<br>INVEGA TRINZA (paliperidone)** CL<br>lurasidone<br>olanzapine<br>olanzapine ODT<br>paliperidone ER<br>PERSERIS (risperidone)CL<br>quetiapine** AP for the 25 mg Tablet Only<br>quetiapine ER<br>RISPERDAL CONSTA (risperidone)CL<br>risperidone solution, tablet, ODT<br>ziprasidone | aripiprazole solution<br>CAPLYTA (lumateperone)<br>clozapine ODT<br>CLOZARIL (clozapine)<br>FANAPT (iloperidone)<br>GEODON (ziprasidone)<br>GEODON IM (ziprasidone)<br>INVEGA ER (paliperidone)<br>LATUDA (lurasidone)<br>LYBALVI (olanzapine and samidorphan)***<br>NUPLAZID (pimavanserin) ****<br>olanzapine IMCL<br>REXULTI (brexipiprazole)<br>RISPERDAL (risperidone)<br>SAPHRIS (asenapine)<br>SECUADO (asenapine)<br>SEROQUEL (quetiapine)<br>SEROQUEL XR (quetiapine)<br>VERSACLOZ (clozapine)<br>VRAYLAR (cariprazine)****<br>VRAYLAR DOSE PAK (cariprazine)*****<br>ZYPREXA (olanzapine)<br>ZYPREXA IM (olanzapine)CL<br>ZYPREXA RELPREVV (olanzapine) | *Invega Hafyera may only be authorized after four months' treatment with Invega Sustenna or at least a one three-month cycle with Invega Trinza.<br><br>**Invega Trinza will be authorized after four months' treatment with Invega Sustenna<br><br>**Quetiapine 25 mg will be authorized:<br>1. For a diagnosis of schizophrenia **or**<br>2. For a diagnosis of bipolar disorder **or**<br>3. When prescribed concurrently with other strengths of Seroquel in order to achieve therapeutic treatment levels.<br>**Quetiapine 25 mg will not be authorized for use as a sedative hypnotic.**<br><br>***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.***<br><br>****Nuplazid may only be authorized for the treatment of Parkinson Disease Induced Psychosis after documented treatment failure with quetiapine.<br><br>***** 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. |

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

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

### ii. Multiple Sclerosis Agents

| 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 two (2) chemically unique preferred agents (in the same sub-class) before they will be approved, unless one (1) of the exceptions on the PA form is present. | | |
| **INTERFERONS[AP]** | | |
| AVONEX (interferon beta-1a)<br>AVONEX PEN (interferon beta-1a)<br>BETASERON (interferon beta-1b)<br>REBIF (interferon beta-1a)<br>REBIF REBIDOSE (interferon beta-1a) | EXTAVIA KIT (interferon beta-1b)<br>EXTAVIA VIAL (interferon beta-1b)<br>PLEGRIDY (peginterferon beta-1a) | |
| **NON-INTERFERONS** | | |
| COPAXONE 20 mg (glatiramer)<br>dalfampridine ER**<br>dimethyl fumerate***<br>GILENYA (fingolimod)<br>KESIMPTA INJECTION (ofatumumab)****<br>leriflunomide | AMPYRA (dalfampridine)**<br>AUBAGIO (teriflunomide)*<br>BAFIERTAM CAPSULES (monomethyl fumarate)<br>COPAXONE 40 mg (glatiramer)*****<br>glatiramer<br>GLATOPA (glatiramer)<br>MAVENCLAD (cladribine)<br>MAYZENT (siponimod)******<br>PONVORY (ponesimod)<br>TASCENSO ODT TABLETS (fingolimod lauryl sulfate)<br>TECFIDERA (dimethyl fumarate)***<br>VUMERITY (diroximel)<br>ZEPOSIA (ozanimod) | **In addition to class PA criteria, the following conditions and criteria may also apply:**<br><br>*Aubagio requires the following additional criteria to be met:<br>7. Diagnosis of relapsing multiple sclerosis **and**<br>8. 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**<br>9. Complete blood cell count (CBC) within six (6) months before initiation of therapy **and**<br>10. Female patients must have a negative pregnancy test before initiation of therapy and be established on a reliable method of contraception if appropriate **and**<br>11. Patient is between eighteen (18) up to sixty-five (65) years of age **and**<br>12. Negative tuberculin skin test before initiation of therapy<br><br>**Dalfampridine ER and Ampyra require the following additional criteria to be met:<br>4. Diagnosis of multiple sclerosis **and**<br>5. No history of seizures **and**<br>6. No evidence of moderate or severe renal impairment.<br><br>***Dimethyl fumerate and Tecfidera require the following additional criteria to be met:<br>4. Diagnosis of relapsing multiple sclerosis **and** |

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

# VI. Old Business

## A. Antipsoriatics, Topical

| ANTIPSORIATICS, TOPICAL | | |
|---|---|---|
| **CLASS PA CRITERIA:** Non-preferred agents require a thirty (30) day trial of a preferred agent. Documentation describing the reason for failure of the preferred agent must be provided. The required trial may be overridden when documented evidence is provided that the use of these preferred agent(s) would be medically contraindicated. | | |
| calcipotriene solution<br>DOVONEX (calcipotriene)<br>ENSTILAR (calcipotriene/betamethasone)<br>TACLONEX (calcipotriene/ betamethasone) | calcipotriene cream<br>calcipotriene ointment<br>calcipotriene/betamethasone ointment, suspension<br>calcitriol<br>SORILUX (calcipotriene)<br>tazarotene cream<br>VTAMA (tapinarof)<br>ZORYVE (roflumilast) cream | |

Notification was made to the committee that both Dovonex (calcipotriene) and Enstilar (calcipotriene/betamethasone) were move to Preferred status on the PDL.

# 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 23rd, 2023, from 3:30-5:00 PM, Virtual Meeting.

## IX. Adjournment

The committee adjourned the meeting at 4:20 PM.