



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*
JANUARY 27, 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:

Tom Kines, RPh, Chair
Chris Terpening, PharmD, PhD, Vice-Chair
Philip Galapon, MD FAAFP
David Gloss, MD
Bradley Henry, MD
Heather Robinson, PA-C

Absent:

Toni DiChiacchio, DNP
John Bernabei, RPh
Charles Rohrbaugh, RPh
Kelli Lynn Jennings, PharmD
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

Contract Staff Present:

Change Healthcare
Ryan Fell, PharmD
Robert Dinwiddie, PharmD
Jacquelyn Hedlund, MD
Steve Liles, PharmD

Other Contract / State Staff Present:

I. Call to Order

Tom Kines, Chairman, called the meeting to order at 3:34 PM

II. Welcome and Introductions

Tom Kines 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 October 28, 2020 Minutes

The Committee moved to approve the October 28, 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 Q4 2020 was 84.7%
- Ryan Fell reviewed the PDL Compliance Report; overall compliance for Q4 2020 was 91.6%

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.Acne Agents, Topical (Rosacea)

| THERAPEUTIC DRUG CLASS | | |
|--|---|---|
| PREFERRED AGENTS | NON-PREFERRED AGENTS | PA CRITERIA |
| ACNE AGENTS, TOPICAL^{AP} | | |
| ROSACEA AGENTS | | |
| FINACEA GEL (azelaic acid) MIRVASO GEL (brimonidine) metronidazole cream metronidazole gel 0.75% (NDCs 00115-1474-46, 00168-0275-45, 51672-4116-06, 66993-0962-45 only) | FINACEA FOAM (azelaic acid) METROCREAM (metronidazole) METROGEL GEL (metronidazole) METROLOTION (metronidazole) metronidazole lotion metronidazole gel (all other NDCs) NORITATE CREAM (metronidazole) RHOFADÉ (oxymetazoline) ROSADAN (metronidazole) SOOLANTRA CREAM (ivermectin) ZILXI (minocycline) foam | Subclass criteria: Non-preferred agents are available only on appeal and require evidence of 30-day trials of all chemically-unique preferred agents in the sub-class. |

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

ii. Anticonvulsants

| 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. | | |
| THERAPEUTIC DRUG CLASS | | |
| PREFERRED AGENTS | NON-PREFERRED AGENTS | PA CRITERIA |
| topiramate ER* valproic acid VIMPAT (lacosamide) zonisamide | FINTEPLA (fenfluramine) SOLUTION FYCOMPA (perampanel) KEPPRA (levetiracetam) KEPPRA SOLUTION (levetiracetam) KEPPRA XR (levetiracetam) LAMICTAL (lamotrigine) LAMICTAL CHEWABLE (lamotrigine) LAMICTAL ODT (lamotrigine) LAMICTAL XR (lamotrigine) lamotrigine dose pack lamotrigine ER OXTELLAR XR (oxcarbazepine) POTIGA (ezogabine) QUDEXY XR (topiramate ER)*** rufinamide oral suspension SABRIL (vigabatrin) SPRITAM (levetiracetam) STAVZOR (valproic acid) TEGRETOL TABLETS (carbamazepine) TEGRETOL XR (carbamazepine) tiagabine TOPAMAX (topiramate) TRILEPTAL SUSPENSION and TABLETS (oxcarbazepine) TROKENDI XR (topiramate)*** vigabatrin tablet/powder pack XCOPRI (cenobamate) ZONEGRAN (zonisamide) | |

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

iii. Antiparkinson's Agents

| 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. | | |
| DOPAMINE AGONISTS | | |
| APOKYN (apomorphine) PEN bromocriptine pramipexole ropinirole | KYNMOBI (apomorphine) FILM MIRAPEX (pramipexole) MIRAPEX ER (pramipexole)* NEUPRO (rotigotine) | *Mirapex ER will be authorized for a diagnosis of Parkinsonism without a trial of preferred agents. |

Dr. Galapon made a motion to approve the changes to the Antiparkinson's Agents category as recommended; the motion was seconded by Dr. Terpening. All members were in favor and the motion was approved.

iv. Antiretrovirals

| ANTIRETROVIRALS ^{AP} | | |
|--|---------------------------------------|--|
| THERAPEUTIC DRUG CLASS | | |
| PREFERRED AGENTS | NON-PREFERRED AGENTS | PA CRITERIA |
| 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. | | |
| INTEGRASE STRAND TRANSFER INHIBITORS | | |
| ISENTRRESS (raltegravir potassium) TIVICAY (dolutegravir sodium) TIVICAY PD (dolutegravir sodium) VITEKTA (elvitegravir) | ISENTRRESS HD (raltegravir potassium) | |
| CD4 DIRECTED ATTACHMENT INHIBITORS | | |
| TROGARZO (ibalizumab) INJECTION ^{CL} | | * Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. Trogarzo is only available as a medical claim submitted via HCPCS codes |
| GP 120 DIRECTED ATTACHMENT INHIBITORS | | |
| RUKOBIA (fostemsavir tromethamine) TABLETS ^{CL} | | * Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. |

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

v.COPD Agents

| 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-BETA AGONIST-GLUCOCORTICOID COMBINATIONS | | |
| | TRELEGY ELLIPTA (fluticasone/umeclidinium/vilanterol)* BREZTRI AEROSPHERE (budesonide/glycopyrrolate/formoterol) | * Trelegy Ellipta may be prior authorized for patients currently established on the individual components for at least 30 days. |

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

vi.Crohn's Disease Agents

| CROHN'S DISEASE ORAL STEROIDS | | |
|---|--|--|
| ORAL | | |
| budesonide ER capsule (generic Entocort EC) | ENTOCORT EC (budesonide) ORTIKOS (budesonide) | *Please see the following PDL classes for PDL status of additional agents used for induction and remission (Cytokine and CAM Antagonists/ Immunosuppressives, Oral/ Ulcerative Colitis Agents) |

Dr. Galapon made a motion to approve the addition of Ortikos to the preferred drug list as recommended; the motion was seconded by Dr. Terpening. All members were in favor and the motion was approved. The addition of the new category was approved later in the agenda.

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. | | |

| THERAPEUTIC DRUG CLASS | | |
|---|---|---|
| PREFERRED AGENTS | NON-PREFERRED AGENTS | PA CRITERIA |
| HUMALOG KWIKPEN U-100 (insulin lispro) HUMALOG MIX PENS (insulin lispro/lispro protamine) HUMALOG MIX VIALS (insulin lispro/lispro protamine) HUMULIN N VIAL (insulin) HUMULIN R U-500 VIAL (insulin) HUMULIN R U-500 KWIKPEN (insulin) LANTUS (insulin glargine) LEVEMIR (insulin detemir) NOVOLIN (insulin aspart) NOVOLIN MIX (insulin aspart/aspart protamine) TRESIBA (insulin degludec) TRESIBA FLEXTOUCH (insulin degludec) | HUMULIN PENS (insulin) HUMULIN R VIAL (insulin) HUMULIN 70/30 (insulin) insulin aspart insulin aspart/aspart protamine insulin lispro LYMUJEV (insulin lispro) NOVOLIN (insulin) SOLIQUA (insulin glargine/lixisenatide)** TOUJEO SOLOSTAR (insulin glargine)*** XULTOPHY (insulin degludec/liraglutide)** | 3. Patient has had a trial of a similar preferred agent, Novolog or Humalog, with documentation that the desired results were not achieved.. ** 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 <u>product and</u> 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. ***Toujeo Solostar and Toujeo Max Solostar 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. |

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

viii. 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 <u>each</u> 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) dimethyl fumarate*** GILENYA (fingolimod) | AMPYRA (dalfampridine)** COPAXONE 40 mg (glatiramer)**** glatiramer GLATOPA (glatiramer) MAYZENT (siponimod)***** MAVENCLAD (cladribine) TECFIDERA (dimethyl fumarate)** VUMERITY (diroximel) ZEPOSIA (ozanimod) ZINBRYTA (daclizumab) | 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 |

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

ix. NSAIDS, Topical

| NSAIDS ^{AP} | | |
|--|--|--|
| CLASS PA CRITERIA: See below for sub-class PA criteria. | | |
| TOPICAL | | |
| FLECTOR PATCH (diclofenac)* VOLTAREN GEL (diclofenac)** | diclofenac gel diclofenac solution LICART PATCH (diclofenac) PENNSAID (diclofenac) | *Flector patches are limited to two per day. **Voltaren Gel will be limited to 100 grams per month. Non-preferred agents require a thirty (30) day trial of the preferred Topical agent and thirty (30) day trials of each preferred oral NSAID before they will be approved, unless one(1) of the exceptions on the PA form is present. |

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

x. Pituitary Suppressive Agents, LHRH

| PITUITARY SUPPRESSIVE AGENTS, LHRH ^{CL} | | |
|--|---|--|
| CLASS PA CRITERIA: Unless otherwise noted, non-preferred agents are available only on appeal. | | |
| LUPANETA (leuprolide) LUPRON DEPOT KIT (leuprolide) LUPRON DEPOT-PED KIT (leuprolide) SYNAREL (nafarelin) TRELSTAR (triptorelin) TRIPTODUR (triptorelin) VANTAS (histrelin) ZOLADEX (goserelin) | leuprolide ORLISSA (elagolix)* DRIAHNN (elagolix-estradiol-norethindrone) SUPPRELIN LA KIT (histrelin) | * Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. |

Dr. Galapon made a motion to approve the changes to the Pituitary Suppressive Agents, LHRH category as recommended; the motion was seconded by Dr. Terpening. All members were in favor and the motion was approved.

B. New Therapeutic Class Review

i. Crohn's Disease Oral Steroids

| CROHN'S DISEASE ORAL STEROIDS | | |
|---|--|---|
| ORAL | | |
| budesonide ER capsule (generic Entocort EC) | ENTOCORT EC (budesonide) ORTIKOS (budesonide) | Please see the following PDL classes for PDL status of additional agents used for induction and remission (Cytokine and CAM Antagonists/ Immunosuppressives, Oral/ Ulcerative Colitis Agents) |

Dr. Galapon made a motion to approve the new additions of budesonide ER capsule and Entocort EC as well as the new drug category to the preferred drug list as recommended; the motion was seconded by Dr. Terpening. All members were in favor and the motion was approved.

C. Drug Class Review

i. Hepatitis C Treatments

| HEPATITIS C TREATMENTS ^{CL} | | |
|--|---|---|
| CLASS PA CRITERIA: For patients starting therapy in this class, preferred regimens may be found on the PA Criteria page. Requests for non-preferred regimens require medical reasoning why a preferred regimen cannot be used. | | |
| MAVYRET (pibrentasvir/glecaprevir)* ribavirin sofosbuvir/velpatasvir (labeler 72626)* ZEPATIER (elbasvir/grazoprevir)† | COPEGUS (ribavirin) DAKLINZA (daclatasvir)* EPCLUSA (sofosbuvir/velpatasvir)* HARVONI (ledipasvir/sofosbuvir)* ledipasvir/sofosbuvir* MODERIBA 400 mg, 600 mg MODERIBA DOSE PACK PEGASYS (pegylated interferon) PEG-INTRON (pegylated interferon) OLYSIO (simeprevir)* RIFRETOL (ribavirin) | *Full PA criteria may be found on the PA Criteria page by clicking the hyperlink. |

Dr. Galapon made a motion to approve the changes to the Hepatitis C Treatments category as recommended; the motion was seconded by Dr. Terpening. All 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 April 28th, 2021, from 2:00 PM-5:00 PM, Virtual Meeting.

IX. Adjournment

The Committee adjourned the meeting at 4:15 PM.