Pharmacy and Therapeutics (P&T) Committee Meeting
March 21, 2017
6:00 PM – 8:00 PM
MINUTES

P&T Committee Members

Voting Members:
Randy Grigg, MD
Jennifer Burch, PharmD
Paul Cunningham, MD
Michael Spiritos, MD
John Engemann, MD
David Konanc, MD
Patti Forest, MD

Non-Voting Members:
Lotta Crabtree, JD
Ira Protas, RPh (Chair)
Jamilah Brunson, PharmD (Secretary)
Carl Antolick III, PharmD
B. Steven Bentsen, MD (Beacon Health Options)
Anuradah Rao-Patel, MD (BCBSNC)
Connie Rominger (BCBSNC)
Renee Jarnigan, RPh (CVS Caremark)

State Health Plan (SHP) Staff

Natasha Davis
Neha Zadoo
Lucy Barreto
Margaret Balogun
Robbie Wallace (CVS Health)

Guests

Mike Laraway (NovoNordisk)
Angela Furniss (NovoNordisk)
Kim Turk (GSK)
Edward Turner (UCB)

I. Welcome

Ira Protas welcomed committee members and guests.

II. Introductions

New committee chair Ira Protas, R.Ph. introduced himself as Director of Pharmacy Benefits for the Plan. Ira also introduced new committee member Carl Antolick III, PharmD Clinical Pharmacist for the Plan.

III. Conflict of Interest

Lotta Crabtree, JD ensured there were no conflicts of interest for members with any of the items for discussion.

IV. Minutes from December, 13th 2016 Meeting

The committee members reviewed and approved the December 13, 2016 minutes.

V. Old Business

Dr. Brunson shared information pertaining to the State Health Plan's ***Formulary Customization Decision*** relative to the nonformulary status of Farydak, Tasigna, Belsomra and Alecensa. Due to limited utilization, grandfathered status, formulary alternative and clinical rationale for the exclusion it was the recommendation of the Plan's clinical team to maintain the nonformulary of these products. Dr. Konanc questioned the cost of Emflaza's sky-rocketing price even though it's available in Europe at a faction of the cost. Chair Protas explained that the Plan nor the PBM vender has much influence in that instance, and that we are required to follow FDA and governmental standards.

Chairman Protas provided updates on the implementation of new PBM vendor CVS Caremark. He noted that the implementation has gone well and issues are readily addressed.

Dr. Brunson reviewed the 2017 formulary management strategy of CVS Caremark. These include the removal of hyperinflation products, embrace of biosimilars & follow-on biologic and indication-based formulary options.

Chair Protas made a motion to move to a **closed** session. The motion was seconded, approved and guests not part of the closed session vacated the conference room.

VI. 2017 Q2 Formulary Updates

A. Formulary Removals

Dr. Antolick reviewed shared the 2017 hyperinflation medications slated for removal. All the products are brand name medications with bioequivalent generics or low-cost generic formulary alternatives. Dr. Antolick shared the Plan's cost inflation data for each product from 2014 to present.

Chair Protas requested a motion to approve the formulary removal of the hyperinflation products: E.E.S. ® suspension, ERYPED® suspension, MACRODANTIN® capsules, BETAPACE® and BETAPACE AF® tablets, LANOXIN® tablets, DYRENIUM® capsules, ZONEGRAN® capsules, CAFERGOT® tablets, MIACALCIN® injection and spray, UROXATRAL® 10 mg tablets and VANOXIDE-HC® lotion.
Dr. Engemann made a motion to approve and it was seconded by Dr. Burch. The motion was unanimously approved by committee members.

B. **Formulary Additions**

Dr. Brunson reviewed oncology products:
Cabometyx ™ (cabozantinib) is an oral kinase inhibitor that provided an additional subsequent treatment option to advanced renal cell carcinoma patients that have progressed on prior antiangiogenic therapy. The medication is proposed as an addition at a Tier 6 with specialty guideline management. The *Cabometyx ™ (cabozantinib) Specialty Guideline Management Criteria* content was also reviewed.

Cotellic® (cobimetinib) is a mitogen-activated extracellular signal-regulated kinase inhibitor that, when used in combination with vemurafenib, offers an additional treatment option to patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation. The medication is proposed as an addition at a Tier 6 with specialty guideline management. The *Cotellic® (cobimetinib) Specialty Guideline Management Criteria* content was also reviewed.

Emend® (apripitant) suspension is a substance P/neurokinin 1 receptor antagonist used in combination therapy to treat chemotherapy induced nausea and vomiting in patient greater than or equal to 6 months old. The medication is proposed as an addition at a Tier 3 with quantity limits and prior authorization. The *Emend® - Varubi® Quantity Limit Criteria* and *Emend® - Varubi® Prior Authorization*

Criteria were also reviewed, and Dr. Spiritos agreed that the quantity limits were within normal dosing guidelines.

Lartruvo™ (olaratumab) is a platelet-derived growth factor receptor alpha blocking antibody used in combination with doxorubicin to treat soft tissue carcinoma in patients with a subtype which is not amenable to curative surgery or radiotherapy treatment. The medication is proposed as an addition at a Tier 6 with specialty guideline management. The *Lartruvo™ (olaratumab) Specialty Guideline Management Criteria* content was also reviewed.

Kyprolis® (carfilzomib) is a proteasome inhibitor used in combination therapy to treat relapsed or refractory multiple myeloma in patients who have received one to three lines of therapy. The medication is proposed as an addition at a Tier 6 with specialty guideline management. The *Kyprolis® (carfilzomib) Specialty Guideline Management Criteria* content was also reviewed.

Dr. Brunson asked for any questions or concerns regarding presented oncology medications and criteria specifically soliciting Dr. Spiritos (Oncology). There were no clinical concerns expressed.

Dr. Brunson reviewed infectious disease products:
Impavido® (miltefosine) is an oral alkylphosphocholine agent used to treat leishmaniasis in adults and adolescent patients greater than or equal to twelve years old. The medication is proposed as an addition at a Tier 3 with no utilization management program.

Vemlidy® (tenofovir alafenamide) is a prodrug of tenofovir used to treat chronic hepatitis B virus infection in adult patient with compensated liver disease. The medication is proposed as an addition at a Tier 3 with no utilization management program.

Dr. Brunson asked for any questions or concerns regarding presented oncology medications and criteria specifically soliciting Dr. Engemann (Infectious Disease). There were no clinical concerns expressed.

Dr. Brunson reviewed neurology products:
Adzenys XR- ODT® (amphetamine ext rel) and QuilliChew ER® (methylphenidate ext rel) were presented as additional formulations of stimulant chemical entities already on the formulary. For Attention Deficit Hyperactivity Disorder patients Adzensys XR provides an orally disintegrating tablet option and Quillichew ER provides a chewable tablet option. Both medications are proposed as additions at Tier 3 with quantity limits and prior authorization.
The *Attention Deficit Hyperactivity Disorder Coverage Authorization Criteria* was also reviewed. Dr. Grigg noted outdated diagnosis and symptom presentation language from DSM-IV. Criteria needs updates from DSM-V specifically regarding the presence of symptoms before age 12. Dr. Grigg and Dr. Konanc expressed concerned regarding requiring prior authorization on patients greater than 19 years old. Recommendations were made to change the criteria to apply after age 26. Dr. Konanc expressed clinical concern regarding removal of multiple sclerosis related fatigue as a compendia supported used for this class. Dr. Brunson agreed to take concerns back to clinical team for analysis.

Onzentra Xsail® (sumatriptan nas pow) and Zembrace® SymTouch (sumatriptan injector) were presented as additional formulations of sumatriptan already on the formulary. Both medications are proposed as additions at Tier 3 with generic step therapy, quantity limit and prior authorization programs.
The *Anti-migraine 5-HT$_1$ Agonists Coverage Authorization Criteria* was also reviewed.

Keveyis® (dichlorphenamide) is an oral carbonic anhydrase inhibitor used to treat primary hyperkalemic or hypokalemic periodic paralysis. The medication is proposed as an addition at a Tier 3 with no utilization management program.

Exondys 51 ™ (eteplirsen) is a new molecular entity FDA approved with accelerated orphan drug designation for Duchenne muscular dystrophy. The medication is proposed as an addition at a Tier 6 with specialty guideline management. The *Exondys 51 ™ (eteplirsen) Specialty Guideline Management Criteria* content was also reviewed.

Belsomra® (suvorexant) is an orexin B receptor antagonist used to treat insomnia. The medication is proposed as an addition at a Tier 3 with prior authorization and step therapy programs. The *Belsomra® (suvorexant) Coverage Authorization Criteria* content was also reviewed.

Dr. Brunson asked for any questions or concerns regarding presented neurology medications and criteria specifically soliciting Dr. Grigg (Psychiatry) and Dr. Konanc (Neurology). There were further no clinical concerns expressed.

Dr. Brunson also reviewed these additional proposed formulary additions:
Rayaldee® (calcifediol ext rel) was presented as an additional formulation of vitamin D_3 analogs. This product provides an extended release option and is proposed for addition at Tier 3 with no utilization management.

Veltassa® (patiromer) is a non-absorbed cation polymer used as adjunctive therapy in treatment of chronic unstable hyperkalemia refractory to other treatment options. This product is proposed for addition at Tier 2 with no utilization management.

Corlanor® (ivabradine) is a selective hyperpolarization-activated cyclic nucleotide-gated channel inhibitor agent. It is used to reduce the risk of hospitalization for worsening heart failure in patients on maximum tolerate doses or a contraindication to beta blockers. The medication is proposed as an addition at a Tier 2 with prior authorization criteria. The *Corlanor Coverage Authorization Criteria* content was also reviewed.

Linzess® (linaclotide) 72mcg capsule was presented as an additional strength of the Linzess capsules already on formulary. This product is proposed for addition at Tier 3 with no utilization management.

Obredon® (hydrocodone/ guaifenesin) was presented as an additional formulation of opioid antitussive combinations already on formulary. This product is proposed for addition at Tier 3 with no utilization management.

Dr. Brunson asked for any questions or concerns and no further clinical concerns were expressed.

C. Formulary Omissions
Chairman Protas reviewed medications that were previously omitted from the formulary secondary to coding issues during the PBM vendor transition. Corrections were made and applied to more than 1,500 products and all products with applicable tiering were reviewed with the committee.

Chairman Protas asked for a motion to approve the formulary additions as presented with exception of clinical concerns expressed regarding the *Attention Deficit Hyperactivity Disorder Coverage Authorization Criteria*. Dr. Engemann made a motion to approve and it was seconded by Dr. Burch. The motion was unanimously approved by committee members.

D. Tier Changes

Dr. Antolick reviewed medications proposed to change tier placement. For the products moving to a non-preferred tier all have a bioequivalent generic or low-cost formulary options. Six medications are proposed to move to preferred tiers to provide additional options on the formulary. Dr. Burch made a motion to approve and it was seconded by Dr. Engemann. The motion was unanimously approved by committee members.

VII. Utilization Management Criteria

Dr. Brunson reviewed the content of the *Narcolepsy Agent Coverage Authorization Criteria*. Dr. Konanc expressed clinical concern regarding removal of multiple sclerosis related fatigue and idiopathic hyper somnolence as a compendia supported uses for this class. Dr. Brunson agreed to take concerns back to clinical team for analysis.

Dr. Forest reviewed the content of the *Short Acting Beta$_2$-Adrenergic Agonist Coverage Authorization Criteria* and *Long-Acting Beta$_2$-Adrenergic Agonist Coverage Authorization Criteria*. The programs include only quantity limits. There were no clinical concerns expressed.

Chairman Protas asked for a motion to approve the formulary tier changes and utilization programs as presented with exception of clinical concerns expressed regarding the *Narcolepsy Agent Coverage Authorization Criteria*. Dr. Engemann made a motion to approve and it was seconded by Dr. Burch. The motion was unanimously approved by committee members.

IX. Next Meeting Date

Chairman Protas announced that the next P&T committee meeting will be held on Tuesday May 23rd 2017 and that a new charter for the P&T Committee will be presented for vote.