Drug Utilization Review Board Meeting
Minutes
September 18, 2013

The West Virginia Medicaid Drug Utilization Review (DUR) Board meeting was called to order with the following in attendance:

Members Present:
Ernest Miller, DO, Chairman
Scott Brown, RPh, Vice Chairman (via phone)
Pat Regan, PharmD
Chris Terpening, PharmD, PhD
KC Lovin, PA-C
Lester Labus, MD
C.K. Babcock, PharmD
Greenbrier Almond, MD
Mary Nemeth-Pyles, MSN, RN, CS
John Vanin, MD
Myra Chiang, MD
Kerry Stitzinger, RPh

Members Absent:
David Elliott, PharmD

DHHR/BMS Staff Present:
Vicki Cunningham, RPh, Director of Pharmacy Services
Bill Hopkins, Pharmacy Operations Manager
Doug Sorvig, Administrative Assistant

Contract Staff:
Steve Small, M.S., RPh, Rational Drug Therapy Program
Julia Rollins, RPh, Molina Medicaid Solutions
Doug Brink, PharmD, Xerox State Healthcare

I. INTRODUCTIONS - Dr. Ernest Miller, Chairman, welcomed everyone to the DUR Board meeting.

II. APPROVAL OF THE MAY 15, 2013 MINUTES - A motion was made to accept the minutes of the May 15, 2013 DUR Board meeting. The motion was seconded and passed.

III. OLD BUSINESS

A. **Election of Officers**

Pat Regan presented the candidates nominated for office. Dr. Lester Labus was elected as DUR Board Chairman and Scott Brown as Vice Chairman for 2014.

B. **Amitiza Prior Authorization Criteria**

Dr. Ernest Miller presented the revised draft Amitiza criteria, with changes that had been requested by the Board at the May meeting. A motion was made and seconded to approve the criteria and the motion passed.

See Attachment A

IV. NEW BUSINESS

A Prior Authorization Criteria-Draft prior authorization criteria were presented for Invokana, Sirturo, Xyrem, Tecfidera and ketoconazole.

1 **Invokana (canagliflozin):** *Will be prior authorized for (6) six months if the following criteria are met:*

- *a Diagnosis of Type II Diabetes;*
- *b Thirty (30) day trial of metformin or metformin combination within the past (6) six months;*
- *c Patient must have HgBa1C < 9%;*
- *d Patient must have glomerular filtration rate >45ml/min/1.73m;*
- *e Prior authorizations will be issued at six (6) month intervals if HgBA1C levels are < 8% (laboratory work submitted must be current).*

See Attachment B

2 Sirturo (bedaquiline fumarate):

- *a Diagnosis of pulmonary multi-drug resistant tuberculosis and*
- *b Treatment given in combination with at least three (3) other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro or*
- *c If in vitro testing results are unavailable, treatment is given in combination with at least four (4) other drugs which the patient's MDR-TB isolate is likely to be susceptible and*
- *d Patient is > 18 years of age,*
- *e Duration of treatment is twenty-four (24) weeks and companion drugs are given for entire period of time.*
- f *Patient is not concurrently taking drugs causing QT prolongation (amiodarone, chloroquine, azithromycin, clarithromycin, citalopram, disopyramine, etc.) or is closely monitored if concurrent administration is necessary.*

See Attachment C

3 Xyrem (sodium oxybate):

- *a Diagnosis of narcolepsy with extensive daytime sleepiness (EDS) and/or cataplexy as confirmed by a sleep study followed by multiple sleep latency testing (MSLT)*
- *b Prescribed by a sleep specialist enrolled in the Xyrem Success Program,*
- *c Member is enrolled in Xyrem Success Program,*

d *Member does not have a history of succinic semialdehyde dehydrogenase deficiency.*

e *Member is not receiving concurrent treatment with sedative hypnotics or central nervous system depressants.*

f *Member has a recent drug screen negative for benzodiazepines, opiates, and illicit drugs.*

g *Member does not have a documented history of alcohol abuse.*

h *Member does not have an history of substance abuse*

i *Member does not have a condition which would require a restricted intake of sodium such as, but not limited to, hypertension or stage 4-5 renal impairment, In addition;*

For Narcolepsy with Daytime Sleepiness, must have

Documented history of therapeutic failure of the following, as documented by Epworth Sleepiness scale of greater than or equal to (≥)10 or repeated Maintenance of Wakefulness Test (MWT) or MSLT with a mean sleep latency of 8 minutes or less:

a *Modafanil or armodafanil at maximum recommended doses*

b *Methylphenidate, methamphetamine or dextroamphetamine at maximum recommended doses or*

c *Intolerance to or contraindication for the above agents*

For Narcolepsy with cataplexy, must have

1. *Documented history of therapeutic failure, contraindication or intolerance to:*

a *Tricyclic antidepressants*

b *SSRI's and SNRI's*

See Attachment D

4 Prior Authorization Criteria for Tecfidera (dimethyl fumarate) will be approved if the following is met:

a *Diagnosis of relapsing multiple sclerosis*

b *Complete blood count (CBC) within six (6) months of initiation of therapy and six (6) months after initiation*

c *Complete blood count (CBC) annually during therapy.*

See Attachment E

5 Prior Authorization Criteria for Ketoconazole will be approved if the following is met:

a *Diagnosis of one of the following fungal infections: blastomycosis, coccidioidomycosis, histoplasmosis, chromomycosis, or paracoccidiodomycosis*

b *No history of acute or chronic liver disease*

c *Baseline assessment of the liver status including alanine aminotransferase (ALT), aspartate aminotransferase (AST), total bilirubin, alkaline phosphatase, prothrombin time, and international normalized ration (INR) before starting treatment.*

d *Weekly monitoring of serum ALT for the duration of treatment (if the*

ALT values increase to a level above the upper limits 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 lever tests be obtained. (Liver tests should be repeated to ensure normalization of values.)

e *Assessment of all concomitant medication for potential adverse drug interactions with ketoconazole.*

f See Attachment F

Motions were made and seconded to approve the criteria for Invokana, Sirturo, Xyrem and Tecfidera. The Board requested revisions of the ketoconazole criteria. The revised criteria will be reviewed at the November DUR Board meeting.

B CHIP Prior Authorization for Stimulants:

Ms. Cunningham presented an overview of the current prior authorization criteria and requirements for approval of stimulants for children covered by the Children's Health Insurance Program (CHIP):

1 Diagnosis of an Attention Disorder [Attention Deficit Disorder (ADD) or Attention Deficit Hyperactive Disorder (ADHD]

2 Behavior therapy (nondrug therapy) must be tried before pharmacotherapy in patients new to therapy. A detailed, written plan for behavior health therapy management must be initiated by an appropriately licensed and credential professional [physician, psychiatrist, social worker trained and experienced with Attention Disorders, or an AD/HD Coach certified by the Institute for the Advancement of AD/HD Coaching (IAAC). If the member is not new to drug therapy, behavior therapy should be used as an adjunct to therapy.

3 Evaluation in person by a physician initially and on an annual basis.

4 The member's age must be within the FDA approved age range.

Ms. Cunningham explained that the criteria presented was not complete, but contained only those that could be adopted by Medicaid due to contracting for some preferred agents.

Ms. Cunningham also stated that the Medicaid program appoves all agents in the methylphenidate category for children > six (6) years of age for ADHD. All agents in the amphetamine category are approved for children > six (6) years of age, with the exception of dextroamphetamine and mixed amphetamine salts which are approved for children > three (3) years of age. There are currently 823 children in Medicaid under age six (6) taking stimulants. After a lengthy discussion, the Board asked for a report that included the drug and dosage prescribed for children less than six (6) years of age taking stimulants

V. REPORTS

A Rational Drug Therapy Program - Steve Small gave an overview of program activities for the second quarter. The presentation included May, June and July 2013 program summaries, edit overrides and prior authorizations.
See Attachment G

B Xerox State Healthcare – Dr. Brink gave an overview of the Retrospective Drug Utilization Review Program.

1 Recent Retrospective Drug Utilization Activities

a **March 2013** - An educational newsletter was mailed out on neuropathic pain. The newsletter also contained information about the change in status of Lyrica to non-preferred on the Preferred Drug List and prior authorization criteria. Letters were sent to 4,487 providers to inform them of the change for their patients.

b **May 2013-**Biologic Agents newsletter mailed to 4,427 Provider

c **June 2013-**Chronic Anxiety Intervention-Letters were mailed to 757 prescribers targeting 7478 members.

d **August 2013-**Coordination of Care Intervention focusing on Atypcial Antipsychotics-Letters were mailed to 406 prescribers focusing 1,317 patients.

2 Program Assessment - Dr. Brink also presented the results of the Program Assessments for July 2012-December 2012 and January 2013-June 2013. He highlighted the top five classes for drug expenditures and the top five areas for future clinical interventions.

3 Intervention Outcomes:

a. Outcome Assessment for the Hyperlipidemia Management Intervention delivered in June, 2012 - The intervention was successful in reducing the total number of clinical indicators for target patients by 64.9% compared to a 57.4% decrease in the targeted control group. There was an estimated increase in cost of $8.33 per patient due to increased prescribing and compliance with the hypolipemic agents.

b Outcome Assessment for the Depression Management Intervention delivered in September, 2012 - The intervention was successful in reducing the total number of clinical indicators for target patients by 46% compared to a 39.4% decrease in the targeted control group. There was a (6) six month savings of $121,358.88.

c Outcome Assessment for the Antibiotic Overutilization Intervention delivered in September, 2012 - The intervention was successful in reducing the total number of clinical indicators for target patients by 46%, compared to a 39.4% decrease in the targeted control group. There was a (6) six months savings of $121,358.88

Dr. Brink presented an updated intervention on Antibiotic Overutilization for consideration by the Board. He stated that West Virginia led the nation in use of antibiotics in 2007 and was second in the number of antibiotic prescriptions per patient in 2010. The Board approved the proposal.
See Attachment H

C. **Molina Second Quarter Report -** Julia Rollins gave an overview of the Molina 2013 Second Quarter Report. The presentation included a review of the Quarterly Overall Summary Report.
See Attachment I

VI. OTHER BUSINESS- OPEN TO THE FLOOR –

A Board member asked where to direct complaints about Managed Care Organization (MCO) coverage problems that could not be resolved with the MCO

help desks. Ms. Cunningham responded said they could be directed to her e-mail address Vicki.M.Cunningham@wv.gov.

Another member inquired as to why Medicaid did not cover vaccines administered at the pharmacy until members were twenty one years of age, when state law allowed pharmacists to vaccinate patients over the age of nineteen (19). Ms. Cunningham explained that Medicaid members were covered by the Vaccines for Children program until age twenty one (21).

Ms. Cunningham responded to a question regarding Medicaid Expansion, saying that the program would be called the West Virginia Health Bridge and enrollment would begin on October 1, 2013, and coverage on January 1, 2014.

Ms. Cunningham presented Ernest Miller with a thank you gift for his service as Chairman of the DUR Board for the past four years.. CK Babcock was acknowledged for receiving the Excellence in Innovation Award from the West Virginia Pharmacy Association.

VII. **NEXT MEETING AND ADJOURNMENT -** A motion was made and seconded to adjourn the meeting. All were in favor. The meeting was concluded at 5:50 p.m. The next meeting will be held on Wednesday, November 20, 2013, from 4:00 PM-6:00 PM.