Drug Utilization Review Board Meeting Minutes
November 17, 2010

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

Members Present:
Ernest Miller, D.O., Chairman
John R. Vanin, M.D.
Lester Labus, M.D.
Steve Judy, R.Ph.
Kc Lovin, PA-C
David Elliott, PharmD
Karen Reed, R.Ph.
Myra Chiang, M.D.
Pat Regan, PharmD
Mary Nemeth-Pyles, M.S.N., R.N., C.S.
Chris Terpening, PharmD, Ph.D.
Greenbrier Almond, M.D.
Scott Brown, R.Ph, Co-Chairman
Dan Dickman, M.D.

Members Absent:
Kerry Stitzinger, R.Ph.

DHHR/BMS Staff Present:
Vicki Cunningham, R.Ph, DUR Coordinator
Peggy King, R.Ph, Pharmacy Director
Gail Goodnight, R.Ph, Rebate Coordinator
Bill Hopkins, Pharmacy Operations Manager
Lynda Ahmad, Secretary

Contract Staff:
Steve Small, R.Ph, Rational Drug Therapy Program
Joe Paradis, R.Ph, Health Information Designs
Eric Sears, R.Ph, Molina Medicaid Solutions
Chad Bissell, PharmD, Goold Health Systems

I. INTRODUCTIONS

Ernest Miller, Chairman, welcomed everyone to the Board meeting. Members of the Board and interested parties introduced themselves.

II. APPROVAL OF THE SEPTEMBER 22, 2010 MINUTES

Ms. Cunningham made a correction to the minutes regarding the status of line extension drugs. She said that only certain line extensions in selected therapeutic categories became non-

preferred and not all line extensions as was stated in the minutes. A motion was made to accept the minutes of the September 22, 2010 DUR Board meeting with the correction. The motion was seconded and passed unanimously.

III. OLD BUSINESS

A. Lotronex Prior Authorization (PA) Criteria

Dr. Miller read the Lotronex draft prior authorization criteria. A motion was made to accept the criteria as written. The motion was seconded and passed unanimously. **(Attachment A)**

B. Suboxone PA Criteria Revisions

Dr. Miller read the revised Suboxone prior authorization criteria. Ms. Cunningham pointed out that minor changes were made to eliminate building prior authorization segments for less than thirty (30) days. This change reduced the number of calls that were made by prescribers to the Rational Drug Therapy Program (RDTP) without diminishing the effect of the prior authorization program. She also explained the lock-in requirement for all members receiving prescriptions for Suboxone/Subutex would be delayed because it would substantially increase the size of the lock-in program. The lock-in program is part of the RetroDUR Vendor contract and the present agreement will not allow for such an increase in the program. Instead, the lock-in program for these members will begin at the time a new RetroDUR contract is executed. A motion was made to accept the criteria as written. The motion was seconded and passed unanimously. **(Attachment B)**

C. Suboxone Program Savings

Ms. Cunningham directed attention to the Suboxone and Subutex Trend Summary. The trend shows a decrease in the number of patients receiving prescriptions, but an increase in the number of prescriptions and a decrease in the cost of claims since the prior authorization program began on August 1. She also said that Mr. Paradis would present a graph of this summary later in the meeting. **(Attachment C)**

IV. NEW BUSINESS

A. Intuniv – Speaker – request from manufacturer

Dr. Shibu Kuncheriah, representing Shire pharmaceuticals, presented information on Intuniv. He emphasized the importance of having Intuniv available for the treatment of children with ADHD and Tourette's syndrome or tics. Points also discussed were the problems of sedation and blood pressure changes when immediate release guanfacine is prescribed for some of these children and the advantages of a controlled release formulation.

B. Update from P & T Committee Meeting of October 27, 2010 – PA Critieria for Non-preferred Drugs

Dr. Miller listed the drugs that were moved in their categories on the Preferred Drug List (PDL). Additions or changes to the prior authorization criteria for the therapeutic classes

discussed are listed below. Criteria for line extensions of certain agents were also discussed.

1. **Acne Agents (Topical)** – In addition, thirty day trials of combinations of the corresponding preferred single agents available are required before the non-preferred combination agents will be authorized.

2. **Alzheimer's Agents** – Aricept ODT (line extension) will be approved only when the oral dosage form is not appropriate for the patient.

3. **Angiotension Modulators** – A thirty (30) day trial of the corresponding strengths of Tekturna and amlodipine concurrently is required before Tekamlo will be approved.

4. **Antipsychotics, Atypical** – All injectable antipsychotic products require clinical prior authorization.

5. **BPH Agents** – Thirty (30) day trials of dutasteride and tamsulosin concurrently are required before the non-preferred agent will be approved.

6. **Erythropoiesis Stimulating Proteins** –
Prior authorization will be given for the erythropoesis agents if the following criteria are met:

   (1) Hemoglobin or hematocrit levels less than 10/30 respectively. For renewal, hemoglobin or hematocrit levels greater than 12/36 will require dosage reduction or discontinuation. Exceptions will be considered on an individual basis after medical documentation is reviewed. (Laboratory values must be dated within six (6) weeks of request.)

   (2) Transferrin saturation ≥ 20%, ferritin levels ≥100 mg/ml, or on concurrent iron therapy. (Laboratory values must be dated within three (3) weeks of request.)

   (3) For HIV-infected patients, endogenous serum erythropoietin levels must be≤ 500mU/ml to initiate therapy.

   (4) No evidence of <u>untreated</u> GI bleeding, hemolysis, or Vitamin B-12, iron or folate deficiency.

7. **Lipotropics, Other (Non-statins)** – (Addition to Bile Acid Sequestrant sub-category) In addition, Welchol will be approved for add-on therapy after an insufficient response to the maximum tolerable dose of a statin after 12 weeks of therapy.

8. **NSAIDS** – Requests for Celebrex will be authorized for:

   1) Treatment of patients with a chronic condition and not currently on a proton pump inhibitor **<u>and</u>**

2) are currently on anticoagulant therapy (warfarin, heparin or low molecular weight heparin) **or**

3) treatment of patients with a chronic condition who have a history or risk of serious GI complications, including long-term glucocorticoid therapy.

9. Ophthalmic Antibiotics (Fluoroquinolones) – A prior authorization is required for the fluoroquinolones and the select macrolides agents included in this class for patients under 21 years of age unless there has been a trial of a first line treatment option within the past 10 days.

The American Academy of Ophthalmology guidelines on treating bacterial conjunctivitis recommend as first line treatment options: erythromycin ointment, sulfacetamide drops, or polymyxin/trimethoprim drops. Alternative treatments include bacitracin ointment, sulfacetamide ointment, polymyxin/bacitracin ointment, fluoroquinolone drops, or azithromycin drops. All generic forms of ophthalmic erythromycin, sulfacetamide, and polymyxin/trimethoprim, polymyxin/bacitracin and bacitracin are preferred.

10. Miscellaneous Brand/Generic Agents - A thirty (30) day trial of each preferred unique chemical entity in the corresponding therapeutic category is required before a non-preferred agent will be authorized.

11. Stimulants and Related Agents – **I**ntuniv will be approved for patients with a diagnosis of Tourette's syndrome, tics, autism or disorders included in the autism spectrum after a 14-day trial of guanfacine only.

12. Hypoglycemics, Incretin Mimetics/Enhancers – Ms. Cunningham will do further work on the criteria and e-mail it to the members for approval.

Note: *The following criteria was approved by e-mail on 11/30/2010:*

Januvia/Janumet and Onglyza will be subject to the following edits:

1. *Previous history of a thirty (30) day trial of an oral agent (sulfonylurea, thiazolindinedione (TZD), or metformin.*

2. *Januvia/Janumet will be approved for concurrent use with insulin for three month intervals. For re-authorization, HgBA1C levels must be less than or equal to (≤) 7.*

3. *Current laboratory values must be submitted.*

C. Vivitrol – New Indication - Manufacturer Presentation

Dr. El Khatib made a presentation about Vivitrol and its new indication for the prevention of relapse to opioid dependence after opioid detoxification. He emphasized the advantages of Vivitrol as compared to other agents for the treatment of opioid addiction:

1) Vivitrol is not a controlled substance and presents no danger for diversion,

2) it is not addicting and does not present a danger for an overdose, and

3) because Vivitrol is a sustained release formulation which lasts for thirty (30) days, it prevents the patient from relapsing by providing continuous blockage of the receptors stimulated by opioids to produce euphoria.

D. Vivitrol PA Criteria
Dr. Miller read the draft PA criteria and it will be voted on at the next meeting.
See Attachment D

E. 2011 Meeting Schedule

March 2, 2011
May 25, 2011
September 21, 2011
November 16, 2011

F. Nominating Committee for 2011 Officers
The Nominating Committee will consist of Kc Lovin, Karen Reed and Mary Nemeth-Pyles.

V. REPORTS

A. Rational Drug Therapy Program
Steve Small, Director of the Rational Drug Therapy Program (RDTP), distributed a handout of his slide presentation. He summarized the prior authorization process and top edits and overrides for the months of June, July and August 2010.
See Attachment E

B. Health Information Designs
Joe Paradis, HID, discussed the Suboxone mailings, utilization, and an increase in the number of lock-in profiles reviewed by the RetroDUR program. He also reported on the chronic use of short acting opioids and in concurrence with benzodiazepines.
See Attachment F

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C. Molina Third Quarter Report
Eric Sears gave an overview of the Molina Third Quarter Report.

VI. OTHER BUSINESS/OPEN TO THE FLOOR

A representative from Novartis asked the DUR Board to reconsider the prior authorization criteria for Fanapt.

A representative from Merck stated that for no other state Medicaid program, including the six partner states in the Sovereign States Drug Consortium (SSDC) purchasing pool, has a restriction on the concurrent use of insulin and Januvia.

A pharmacist representing Reckitt Benkiser Pharmaceuticals spoke about the advantages of the Suboxone filmstrip in comparison to Suboxone tablets.

VII. NEXT MEETING AND ADJOURNMENT

A motion was made and seconded that the meeting be adjourned. All were in favor. The meeting was concluded at 6:00 p.m. The next meeting will be held on March 2, 2011, (changed from February 23, 2011), from 4:00 p.m. - 6:00 p.m.

Respectfully submitted,

Lynda L. Ahmad
Secretary