

Nebraska Medicaid DUR Board Meeting
Tuesday, July 13, 2010
DRAFT pending approval at September meeting

The Nebraska Medicaid DUR Board met on Tuesday, July 13, 2010 at the Country Inn and Suites in Lincoln.

DUR Board Members in Attendance:

Kevin Borchert, R.P.
Lynn Carlson, R.P.
Elissa Carney, R.P.
Shana Castillo, R.P.
Matt Egger, PharmD. Candidate UNMC
Michael Foncannon, PharmD. Candidate CU
Eric Gall, R.P.
Norman Kelley, M.D.
Charlie Moore, R.P.
Marcia Muetting, R.P., Nebraska DUR Director
Kirk Muffly, M.D.
Phil Vuchetich, R.P.
Robert Wergin, M.D.

DUR Board Members Not in Attendance

Susan Howard, M.D.
David Hutsell, R.P.
Bruce Houghton, M.D.

Guests in Attendance:

Whitney Breunsbach, PharmD. Candidate, UNMC
Barbara Mart, Nebraska Medicaid
Jenny Minchow, R.P. Nebraska Medicaid
Alex Serocca, PharmD. Candidate, CU

Public Members in Attendance:

Mary Deane, AMAG
Rachel Bevis, AstraZeneca
Carol Curtis, AstraZeneca
Jen Kammerer, AstraZeneca
Dee George, Dendreon
Don Larsen, Forest
Jim Bade, GlaxoSmithKline
Carlos Palasciano, Hawthorn Pharma
Andrea Taylor, Johnson & Johnson
Russ Wilson, Johnson & Johnson
Susan Zalenski, Johnson & Johnson
Lindsey Hack, King Pharmaceuticals
Sajani Mehta, King Pharmaceuticals
Kelley Waara-Wolleat, King Pharmaceuticals
Joe Busby, Lilly
Aron Chuc, Lilly
Michael Jay Schoenfeld, Lilly
Barbara Belcher, Merck
Luciano Kolodny, MD, Merck
Harvey Schuck, MD, Merck
Sarah Sullivan, Merck
Jung Caranfa, Novartis
Dana Meier, Novartis

Vaun Olhausen, Novartis
Randy Troxell, Novartis
James Christenson, Taro Pharmaceuticals
Steve Whiten, Taro Pharmaceuticals

I. Opening and Introductions

The meeting was called to order at 6:30 pm. The director noted that a copy of the Open Meeting Laws was available on the front table along with a copy of all meeting materials.

II. Declaration of any Conflict of Interest or changes

None

III. Review of Agenda

A motion to accept the agenda as presented was made by Phil Vuchetich with a second from Bob Wergin. Vote as follows: Borchner-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-yes. Motion carried.

IV. Review of minutes from May meeting

A motion to accept the minutes as written was made by Kevin Borchner with a second from Norman Kelley. Vote as follows: Borchner-yes, Carlson-abstain, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-yes. Motion carried.

V. Update on recommendations from May meeting

Regarding the recommendation from the board for Saphris to remain on prior authorization available by medical necessity, the feedback from the Department was that a definition of criteria is needed to establish a decision tree appropriate for clinical call center staff to work requests. The director shared email communication from eight prescribers or practices regarding concerns about availability of Saphris. Of the emails, two did not refer to Saphris as a first line option in their decision tree. Three emails requested a prior authorization be lifted. Also, three emails expressed concern that Saphris would no longer be available. The board reviewed the draft criteria. Public comment was offered by Harvey Schuck, MD. He noted a concern for the trial and failure of two medications and the negative impact on the patients' care. In addition, he emphasized the cost of hospitalization or rehospitalization for patients not controlled during the required medication trials. Board discussion about availability of Saphris for patients with swallowing issues concluded that other agents are available in liquid and oral disintegrating tablet formulations. Dr. Howard was contacted prior to the meeting and agreed that fourteen days was an adequate trial. Dr. Howard expressed the need for the criteria to include medical justification as to why a trial would not be appropriate. The DUR board feels an electronic prior authorization, if possible, is the preferred process for Saphris. A motion was made by Kirk Muffly with a second from Bob Wergin to recommend the criteria as follows, Patient must:

- be 18 years of age or older
- have a diagnosis of schizophrenia or bipolar I disorder
- had a failed 14 day trial of both risperidone and one other atypical antipsychotic at an appropriate dose for the diagnosis, or medical justification why a trial is not appropriate

Vote as follows: Borchner-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-yes. Motion carried.

The Department asked the DUR board to take a similar approach for first generation antihistamine combination cough and cold products as when the cough and cold list was developed. A sub-committee will review products that would deny with this change and recommend updates to the cough and cold covered products list where appropriate. Norman Kelley, Bob Wergin, Shane Castillo, and Lynn Carlson volunteered to participate in this sub-committee review.

VI. Retrospective DUR

A. Current Profile Review

1. Lock Ins

In May, 14 profiles were reviewed. One patient was evaluated for lock-in, resulting in 20 letters sent to providers. There were nine responses and six recommended lock-in.

In June, 19 profiles were reviewed. Five patients were evaluated for lock-in, resulting in 93 letters sent. There were 33 responses and 30 recommended lock-in.

2. Strattera Compliance

A profile review identified 39 patients as noncompliant on Strattera therapy. Letters will be sent to the prescribers of the identified patients. The board was presented with information demonstrating noncompliance across the class of medications. A consensus was reached among board members that compliance is greatest in ADHD patients utilizing stimulant therapy. Board members expressed concern about noncompliance or drug holidays and their negative effect on Strattera efficacy.

3. Patients taking multiple combination antihypertensive agents

Twelve patients were identified as taking multiple combination antihypertensive agents. Most of the duplication was hydrochlorothiazide, but no combinations exceeded 50mg. Letters will be sent for three patients because the combinations were consistently from multiple prescribers.

B. Old Business

1. Patients taking multiple long-acting stimulants for ADHD

Thirty-three profiles were reviewed and four letters were sent to providers regarding multiple concomitant long-acting stimulants. One response was received and noted that the patient is being monitored and requires multiple medications in order to perform well at home and school.

2. Underuse of statins for patients with Type 2 Diabetes

Two hundred profiles were reviewed. Eighty-six letters were sent and 28 responses were received. More information will be presented at the September 2010 meeting.

3. Patients with diagnoses of diabetes and hypertension not taking either an ACE inhibitor or ARB.

Letters were sent to 133 providers and 47 responses were received. More information will be presented at the September 2010 meeting.

C. Recommendations for Future Profiles Reviews

Ideas presented to the committee:

- greater than 4g acetaminophen per day
- appropriate monitoring of metabolic effects of atypical antipsychotics
- clonidine abuse
- long term use of sedative hypnotics

The director will work with Barbara Dowd from Magellan to select two of the above options for profile review.

VII. Prospective DUR

A. Old Business

1. Request from the Department to develop criteria for Forteo per P & T Committee discussion

The DUR committee received expert opinion from Dr. Recker from Creighton Medical Center regarding his clinical experience with Forteo through Kirk Muffly. Dr. Recker utilizes Forteo in patients with a bone mineral density of -3 or worse, and in any patient with a normal bone mineral density and history of a non-traumatic fracture. Dr. Gallagher from Creighton University contacted the director and concurred with Dr. Recker's recommendations. Public comment was offered by Michael Jay Schoenfeld who recommended Forteo be used in patients at high risk for fracture. He defined high risk as patients with a bone mineral density of -3 or worse, or patients with low bone density (-2.5) and other risk factors.

A motion was made by Norman Kelley with a second from Phil Vuchetich to recommend the criteria as follows,

Forteo® (teriparatide):

- May approve if the client is unable to use preferred products (i.e. intolerance, contraindication, allergy, and previous trial/failure) **OR** the client is at high risk of fracture as defined below.
 - Patients at high risk of fracture include:
 - Bone mineral density of -3 or worse
 - Postmenopausal women with history of non-traumatic fracture(s)
 - Postmenopausal women with two or more of the following clinical risk factors:
 - Family history of non-traumatic fracture(s)
 - Patient history of non-traumatic fracture(s)
 - DXA BMD T-score ≤ -2.5 at any site
 - Glucocorticoid use* (≥ 6 months of use at 7.5 dose of prednisolone equivalent)
 - Rheumatoid Arthritis
 - Postmenopausal women with BMD T-score ≤ -2.5 at any site with any of the following clinical risk factors:
 - More than 2 units of alcohol per day
 - Current smoker
 - Men w/primary or hypogonadal osteoporosis
 - Osteoporosis associated w/sustained systemic glucocorticoid therapy*
 - Initial approval will be for 1 year with ONE renewal if demonstrated compliance. Maximum duration of therapy is 24 months during a patient's lifetime.
 - Approval does not require trial and failure on Miacalcin®.
 - Quantity limit of 3ml per claim for a 28 day supply.
 - Combination therapy with biphosphonates (Actonel®, Boniva®, Didrone®, Fosamax®, alendronate) is not recommended and will NOT be approved.
 - Not approved for pediatric patients or young adults with open epiphyses.
 - Injection must be administered by patient or caregivers (deny if home health administration).
- Vote as follows: Borchert-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-no, Vuchetich-yes and Wergin-yes. Motion carried.

2. Annual Review of Prior Authorization Criteria for Cox II Inhibitors

A motion was made by Norman Kelley with a second from Charlie Moore to recommend modifying criteria on the form 4.e) to read, "Coronary artery or cerebral vascular disease requiring daily aspirin therapy and patient has failed two of the following: meloxicam, nabumetone, diclofenac, sulindac." Vote as follows: Borchert-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-no. Motion carried.

B. New Business

1. DUR Board review of New Drug Products to determine if Prior Authorization is appropriate

a. Embeda

The director noted that this drug is classified as nonpreferred on the preferred drug list. In one year, there were 5 patients for which the drug was requested. There were four approvals, four changes in therapy, and two denials. Several requests were made for one patient. Public comment was offered by Kelley Waara-Wolleat discussing the unique delivery system incorporating naltrexone. She also gave detailed descriptions of a likeability study and an IV simulated abuse study. A motion was made by Norman Kelley with a second by Eric Gall to recommend the following criteria, Embeda be used in patients:

- with a history of drug abuse, or with a family member with a history of drug abuse
- no concomitant use of other long-acting narcotics (oral and transdermal)
- with a pain contract on file with the prescriber

Vote as follows: Borchert-yes, Carlson-yes, Carney-no, Castillo-no, Gall-yes, Kelley-yes, Moore-yes, Muffly-no, Vuchetich-yes and Wergin-no. Motion carried.

b. Fanapt

The director noted that three patients had received treatment with Fanapt. There were five approvals with one denial for an off-label indication. Public comment was offered by Dana Meier. She noted that the drug is only indicated for the acute treatment of schizophrenia. In drug trials, akathisia and EPS were similar to placebo. Some patients have experienced small QT changes. Also, the average weight gain in 12 week trials was 2.1 kg. A motion was made by Bob Wergin with a second by Shana Castillo to recommend the criteria as follows,

Patient must:

- be 18 years of age or older
- have a diagnosis of schizophrenia
- had a failed 14 day trial of both risperidone and one other atypical antipsychotic at an appropriate dose for the diagnosis, or medical justification why a trial is not appropriate

Vote as follows: Borchert-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-yes. Motion carried.

2. Annual Review of Prior Authorization Criteria of Lower Sedating Antihistamines

The director noted changes to the following criteria based upon product prescribing materials:

- Allegra 30 mg tablets; 2 years old and up
- Xyzal 5 mg tablets; 12 years old and up
- Xyzal oral solution; 6 months and up

No public comment was offered. A motion was made to approve the criteria as amended by Kirk Muffly with a second by Norman Kelley. Vote as follows: Borchert-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-yes. Motion carried.

3. Annual Review of Prior Authorization for Seroquel XR 50 mg and 150 mg

Thirty-two requests were approved, 1 change in therapy, and 13 denied for Seroquel XR 50 mg. Thirty-seven requests were approved and 7 denied for Seroquel XR 150 mg. Jen Kammerer offered public comment. She noted the new indication of Seroquel XR 150 mg as an adjunct treatment for major depressive disorder. Also, she read the black box warnings to the committee members. A motion was made by Norman Kelley with a second by Kirk Muffly to recommend an electronic prior authorization with criteria as follows,

Patient must:

- Have a diagnosis of schizophrenia, bipolar or major depressive disorder (only for use as adjunct treatment with the following medications: paroxetine, fluoxetine, sertraline, escitalopram, citalopram, duloxetine, venlafaxine, amitriptyline, or bupropion)
- 18 years of age or older
- Need documentation why immediate release is not appropriate for client
- Dose is being titrated approve one month
- Dose was higher and is being lowered documented on claims history review approve one year
- Drug was started at inpatient facility and patient is stable approve one year
- Quantity limit:
 - Seroquel XR 150 mg: 1 tablet/day
 - Seroquel XR 50 mg: 2 tablets/day

Vote as follows: Borchert-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Kelley-yes, Moore-yes, Muffly-yes, Vuchetich-yes and Wergin-yes. Motion carried.

VIII. Special Requests from the Department

None

VIII. Future Meeting Dates

September 14

November 9

January 11, 2011

March 8, 2011

IX. Concerns and Comments from:

Board

A board member expressed concern as they had become aware of a Medicaid patient who had been readmitted into the hospital after failure to obtain a nonpreferred medication upon discharge. Barb Mart stated that First Health Services Corporation trained pharmacists in the emergency procedures for prior authorization. It was unknown as to if this was an isolated incident. Jenny Minchow noted that there have been no reports to the Department of hospital readmission being the direct result of failure to obtain non-preferred medications.

Director

None

State Representatives

None

X. Adjournment

A motion to adjourn at 9:10 pm was made by Kirk Muffly with a second from Bob Wergin. Vote as follows: Borchert-yes, Carlson-yes, Carney-yes, Castillo-yes, Gall-yes, Houghton-yes, Howard-yes, Hutsell-yes, Kelley-yes, Moore-yes, Muffly-no, Vuchetich-no and Wergin-yes. Motion carried.