



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, September 8, 2011
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Neal Catalano, R.Ph.
 Tony Dalpiaz, PharmD.
 Joseph Miner, M.D.
 Joseph Yau, M.D.
 Cris Cowley, M.D.

Kathy Goodfellow, R.Ph.
 Wilhelm Lehmann, M.D.
 Mark Balk, PharmD.
 George Hamblin, R.Ph.

Board Members Excused

Brad Hare, M.D.
 Kumar Shah

Peter Knudson, D.D.S.

Dept. of Health/Div. of Health Care Financing Staff Present:

Robyn Seely, PharmD.
 Tim Morley, R.Ph.
 Lisa V Hunt, R.Ph.
 Annette Leonard, R.N.

Heather Santacruz, R.N.
 Marisha Kissell, R.N.
 Merelynn Berrett, R.N.

Other Individuals Present:

Lori Howarth, Bayer
 Charissa Anne, J&J
 Don McCathery, Vertex
 Richard Reinert, Merck
 Efrin Alton, Merck
 Vern Stacey, GSK
 Lori Honarth, Bayer

Michael Comeaux, Genetics
 Sabrina Aery, BMS
 Lisa Borland, Vertex
 Rachel Bevs, AstraZeneca
 Frank Znbal, Merck
 Brian Strenb, GSK
 Russell Fransen, LFA

Meeting conducted by: Neal Catalano, R.Ph.

1. At 7:04 a.m. Neal Catalano opened the meeting. He reminded everyone to sign in and turned the meeting over to Robyn. She asked that speakers sign a speaker form and announced that our new pharmacy tech has had her baby last Tuesday. The new addition is named Lilly June.
2. Review and Approval of Minutes: Joe Miner moved to accept the minutes. Mark Balk seconded the motion. The motion passed with a unanimous vote.
3. P&T Committee Report: Lisa V. Hunt addressed the Board. The Division added Digestive

Enzymes and Acne therapy drugs to the PDL. The P&T Committee will be reviewing Platelet Aggregation Inhibitors next Thursday and Medicaid is currently reviewing for addition to the PDL contraceptives, anti-fungals, BPH pharmaceuticals, and estrogen hormone replacement therapy.

4. Review of Brand Name Drug PA Criteria: Robyn Seely addressed the Board and reminded them of the last meeting where they discussed brand name drugs and the criteria that is currently used to determine if Medicaid will pay for them. The Division would like the Board to consider adding the requirement of a MedWatch form. Robyn has surveyed other Medicaid states if they currently require this form to be filled out and has not received any responses yet. Maine does require this form currently but we are trying to find out more about how they do this.

The existing criteria was reviewed for both the regular brand name form and for the Schedule II brand name form. Details of adverse reaction, allergy or inadequate response to the generic equivalent are the requirements for the current brand name form where the Schedule II form required documentation from progress notes detailing patient's allergic skin eruption or adverse reaction to the generic.

Mark Balk wanted to know if we wanted to make the Med Watch form required for just generic to branded or should we do it for all allergies for all medications. He also asked if we wanted to follow Maine or other states? The MedWatch form is a great form and it is probably under used, we could recommend it's use but to require it may create an administrative nightmare.

Robyn pointed out that this form would make a hurdle for those who are not really in need of a brand name medication but just want a pink pill instead of a purple one. This would make it so that medical health personnel would only feel it was necessary to fill out the form if someone was really having an anaphylactic reaction and not just when a patient says that they want the brand name drug.

Joe Miner mentioned that the main reason you would see a problem with a generic medication would be when someone was having too low of absorption or too high of absorption from the generic product. Allergy is not as acceptable as problems with absorption.

Neal Catalano mentioned the inconsistency is seen with a lot of pain medications. Mark Balk mentioned that if we want to mandate adverse reactions to medications then the MedWatch form is the way to go. Joe Miner said that it is not just when a patient has an adverse reaction and so it may be beyond the scope of the form. Lisa Hunt mentioned that the FDA want MedWatch forms for more than just adverse reactions.

Mark Balk mentioned that the scope of the MedWatch form is much broader. In fact if a person fails on an antibiotic then a MedWatch form should be technically filled out. Who should fill out the MedWatch form was asked and it should be filled out by the first hand health care professional who it is reported to.

Joe Miner mentioned that a person could even be allergic to a particular dye or ingredient that is in a generic separate from the active medication.

Neal Catalano asked the Board if they would like to move forward on this issue or wait for more information from other states.

Kathy Goodfellow recommended adopting the use of the MedWatch form and then if it becomes too difficult then we can change it. Neal Catalano mentioned that we may want to start with just the case of brand to generic and then see if we want to expand the use to all reactions in the future. Mark Balk mentioned that we if we are going to use the form for brand to generic then we should use it for brand to brand too. If we are going to use this we should use it fully and correctly for every form where we ask people to try one form of treatment first. We should be consistent.

Neal Catalano asked the nursing staff how the use of the MedWatch form could impact their work load. Merelynn Berrett said that the use of the form would make their life easier. Many times they get too little information. George Hamblin asked if they get more requests for pain medications. Merelynn said that most of the requests are for medications other than ones used for pain. Neal Catalano asked what classes does the agency get requests for most often. Merelynn said that usually antidepressants. Anti-Seizure medications that are used as mood stabilizers are requested a lot too.

Kathy Goodfellow said that she sees a lot of people who request a certain brand of generic products now too. Joe Miner mentioned that maybe it would be best to suggest the use of the form and use education to encourage its use and not make it a requirement. Mark Balk mentioned that it could go out in the Amber sheet.

Neal Catalano asked that if Robyn can find out more from other states to bring that information back to the Board.

Savings associated with the use of the MedWatch form are not known at this time. Mark Balk suggested that we may just be creating more of an administrative workload for providers but it may not cut down on any requests. Robyn Seely reported that even now some providers will make one request and just say the patient says the generic does not work. But when the provider is asked to describe how it does not work they do not respond and the request is then denied.

On the draft on page three Joe Miner asked that we put for bullet number three “Request submission of MedWatch form.” Kathy Goodfellow asked if it was intentional that for Schedule II’s patients could not just say that they had an inadequate response. Robyn Seely said that it was because that is the number one reason for the requests for brand name schedule II medications.

Mark Balk recommended adopting the language from the schedule II document into one form, not necessarily using allergic skin reaction but just allergic reaction. Add in the

request for completion and submission of the MedWatch form.

Mark Balk made a motion to make the two forms into one for both schedule and non-scheduled medications and to use the criteria “Documentation from progress notes detailing patient’s allergic or adverse reaction to the generic equivalent. Recommend completion of a MedWatch form.” Tony Dalpiaz seconded the motion and it carried by a unanimous vote.

- 5 High Dose Simvastatin: CarrieAnn Madden addressed the Board with her report. In June the FDA recommended that the highest dose simvastatin be avoided due to the risk of myopathy and rhabdomyolysis. Patients should be maintained on this dose only if they have been taking it for 12 months or more without muscle toxicity. No new patients should be started on this dose of simvastatin. Patients who do not meet their LDL goals on the 40 mg dose should be switched to other alternative treatment(s).

George Hamblin recommended that the proposed PA language not include that Vytorin does not require a PA. Kathy Goodfellow asked what statins are currently on the PDL. Lisa V. Hunt reported that high dose statins include: Crestor, Lipitor, and simvastatin. Low dose statins include: fluvastatin, lovastatin and pravastatin.

Joe Miner made a motion that this dose of simvastatin should be placed on PA with the rest of the proposed language and Tony Dalpiaz seconded the motion. The motion passed unanimously.

Joseph Yau recommended that an educational article be placed in the Amber sheet informing providers about what drugs are covered in the therapeutic class of statins.

- 6 New Treatments for Hepatitis C: Incivek & Victrelis: Robyn Seely reported that we would take public comment today but that the remainder of the topic will be covered at our next meeting.

Lisa Borland who is the medical affairs representative from Vertex testified about their company’s product Incivek. This drug’s mechanism of action is that it inhibits the HCV NS3/4A protease. It is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naive or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers. This product should never be used as monotherapy. Detailed information was provided on this product and about the studies completed and used for this drug’s approval. Genotype 1 hepatitis is the most common type and the most difficult to treat.

Richard Reinert, Merck, testified on Victrelis. He is their infectious disease consultant. He gave specifics on his company’s product. He gave the main warnings and the need to avoid pregnancy. Anemia has also been associated with Victrelis as well as neutropenia, a metallic taste, and fatigue were also reported. Studies were designed with a lead in design. Early responders sometimes had a reduced duration of treatment of 28 weeks total.

Ms. Deborah Cobb, MSN, FNP-BC, Mountain West Gastroenterology testified on both Incivek and Victrelis. She has been treating hepatitis since the mid 1990's and these drugs represent an amazing step forward in therapy. Debroah Cobb felt that the Board should address the cost of the drug first. She felt the Board needs to look at not only the cost of the drug but the cost of any other drug that has to be added because of the hepatitis C drug. She also pointed out that lab costs should be included. Efficacy should be looked at second. Both of these drugs work well. The Board also needs to think about how the doctor looks at their client and determines what the needs are to keep that person compliant. She has 25 patients on triple therapy for Hepatitis C. The Board needs to think about what is going to be easiest for the providers and the patients. Drug Interactions should also be looked at. How long can a person be taken off of simvastatin while the patient is treated for Hepatitis C because the drugs interact? She thinks that providers need to have the choice to decide which drug is right for our patients.

The board then discussed the idea of putting these drugs on PA or waiting until Robyn gives her report. The guidelines have been updated as of August 26th, 2011. Kathy Goodfellow asked if Utah Medicaid's system has the capability to look back in a patient's history to determine if they are on monotherapy? The current system does not but the new one that should be operational on January 1, 2012 will have that capability.

Mark Balk made a motion that the Board not currently require a PA on either of the two new Hep C drugs but when the new system is available it will be programmed to prevent monotherapy. This motion was seconded by Joe Miner and passed unanimously.

The meeting adjourned.

The next DUR Board meeting was scheduled for Thursday October 13, 2011.

The DUR Board Prior Approval Subcommittee met to consider one petition this month. Mark Balk made the motion and Joe Miner seconded it. The subcommittee approved 90 alprazolam per month for 6 months and asked that a Neurologist be involved with the case.

Minutes prepared by Lisa V. Hunt.