



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, July 09, 2009
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Neal Catalano, R.Ph.
 Dominic DeRose, R.Ph.
 Wilhelm Lehmann, M.D.

Kathy Goodfellow, R.Ph.
 Bradford Hare, M.D.
 Cris Cowley, M.D.

Board Members Excused:

Mark Balk, PharmD.
 Peter Knudson, D.D.S.
 Bradley Pace, PA-C

Tony Dalpiaz, PharmD.
 Joseph Miner, M.D.
 Joseph Yau, M.D.

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

Tim Morley, R.Ph.
 Lisa Hulbert, R.Ph.
 Jennifer Zeleny, CphT, MPH
 Amber Kelly, R.N.

Merelynn Berrett, R.N.
 Debbie Harrington, R.N.
 Carol Runia
 Robert Miller, M.D.

Other Individuals Present:

Gary Bailey, Forest
 Judy Christensen, Pfizer
 Tony Molchan, Abbott
 Scott Clegg, Lilly
 Mandy Hosford, AstraZeneca
 Alan Bailey, Pfizer
 Sue Heineman, Pfizer
 Roy Lindfield, Schering
 Trenton Ward, Forest
 Reed Murdoch, Wyeth

Elson Kim, Forest
 Ann Gustafson, GSK
 Pam Sardo, Abbott
 Camille Kerr, Allergan
 Steve Hill, Daiichi Sankyo
 Ben Campbell, U of U
 Derck Butters, NovoNordisk
 Jacques Banchy, Schering
 Bret Brewer, EMD Serono
 Candi Arce-Larreta, Pfizer

Bryan Larson, DRRC
 Dan Heincy, Merck
 John Brokers, Lilly
 Mark Miller, Allergan
 Cary Green, Merck
 Lucinda Bateman, M.D.
 Lori Howarth, Bayer
 Pat Wiseman, Medimmune
 Eliot Brintin, U of U

Meeting conducted by: Wilhelm Lehmann, M.D.

- 1 Minutes for June 2009 were reviewed. Dr. Hare moved to approve the minutes. Neal Catalano seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Cathy Goodfellow, and Dr. Cowley.
- 2 Housekeeping: New Board members Cathy Goodfellow and Dr. Cris Cowley were introduced. All Board members were asked to fill out a conflict disclosure form. Also, public speakers were asked to disclose any potential conflicts of interest when addressing the Board.
- 3 DUR Board Resolution: Tim Morley addressed the Board. A proposed draft for the

DUR Board resolution was included in the July DUR Board packet. The Board had initially wanted to send the resolution directly to the Legislature. However, the Division of Health Care Finance requested that the resolution go to the Division to then be forwarded to the Legislature. Currently, the DUR Board is prohibited from discussing matters of cost when considering Prior Authorization. The resolution requests that the DUR Board be able to use this information at their discretion for their deliberations.

Neal Catalano moved to accept the resolution as drafted on the DUR Board letterhead with the State Seal to be added to the final draft. Dominic DeRose seconded the motion.

The motion passed with unanimous votes by Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Cathy Goodfellow, and Dr. Cowley.

- 4 Statins and Fibrates Class Review: Bryan Larson, PharmD from the University of Utah Drug Regimen Review Center addressed the Board with the DRRC's findings on the concomitant use of both drug classes.

Dr. Miller asked about the mechanism of action of fibrates. He also asked if he had heard of a study stating that fibrates might be helpful for the treatment of small vessel disease. Last, he asked about the reasons for rhabdomyolysis. Dr. Larson stated that in the case of gemfibrozil, rhabdomyolysis is thought to be due to its effect on statin metabolism. As far as the mechanism of action, he was not sure. He had also not heard about any effects that fibrates might have on the treatment of small vessel disease.

Dr. Eliot Brinton, endocrinologist and clinical lipidologist, addressed the Board. He stated that he agreed with the presentation that was given by Dr. Larson, and his answers to Dr. Miller's questions. It is not entirely clear by what mechanism of action the fibrates work. They seem to be associated with a reduction in the production of triglyceride-rich lipoproteins from the liver. Peripherally, they seem to be associated with an increase in the clearance of these lipoproteins. The observation about the reduction of microvascular disease is a fairly new one. Diabetic retinopathy, nephropathy, and amputations seem to be reduced. Since this is a fairly recent finding, the possible mechanism behind that has not yet been studied very much. In individuals with residual dyslipidemia who are at high risk for cardiovascular disease, there are statements that discourage the use of gemfibrozil due to the much higher rate of myopathy and rhabdomyolysis. Even though those rates are low, they are quite a bit higher. The fenofibrate products are at least as useful, if not more useful, than gemfibrozil so there has been a strong tendency to use those products. There is also a difference in the labels which has been highlighted. Fenofibrate does have the caution in its label against the concurrent use with statins. Fenofibric acid has been studied and has a formal FDA approved indication for concurrent use with statins. He agreed with what has been presented and endorsed the notion that the Board is considering, which is to make fenofibric acid available to allow for the use of an indicated product. It is helpful and reassuring to patients, physicians, and pharmacists to have the FDA-approved option.

Dr. Pamela Sardo from Abbott addressed the Board. The effects of LDL-lowering are well known. Despite the LDL lowering with statins, there is a residual coronary artery disease risk that can remain and may be modifiable. The guidelines address other factors besides LDL-lowering, which are non-HDL. Trilipix is the only fibric acid derivative extensively studied and FDA approved for combination use with statins in high-risk patients with mixed dyslipidemia. It is indicated as an adjunct to diet in combination

with a statin to reduce triglycerides and to increase HDL in patients who have mixed dyslipidemia with a coronary heart disease risk or risk equivalent who are on an optimal dose of statins to achieve their LDL goals. It is also approved as monotherapy. In studies, Trilipix was statistically significantly better than comparator groups when co-administered with low-dose and moderate dose statins. No cases of rhabdomyolysis or safety signals were reported in the studies. Trilipix is contraindicated in patients with severe renal impairment, gall bladder disease, and liver disease.

The DUR Board asked if step therapy is currently required for fibrates. Medicaid does not currently have a step therapy requirement.

The DUR Board asked if Medicaid could pay for combination therapy that is off-label. Lisa Hulbert stated that this is for the DUR Board to decide.

Tim Morley asked if there is any claims data that indicates the level of concomitant use of statins and fibrates. Dr. Larson summarized claims data from calendar year 2008 that was examined for the DRRC study.

Dr. Brinton commented about the possibility of step therapy. Fibrates are indicated as first-line therapy in patients whose primary problem is either high triglyceride or low HDL. In those cases, the statin may not be indicated, so a fibrate may be given as monotherapy. A statin might be added to that at a later time, if needed. He did not think that it was a good idea to have a step therapy requirement, since, in practice, the therapy could be added in either direction.

Cathy Goodfellow asked Dr. Brinton whether he has seen cases of rhabdomyolysis in his practice. He has not personally been involved in cases, but has been aware of cases either in institutions where he has worked or in speaking with the treating physicians of these cases. It is quite unusual to have a full case of rhabdomyolysis. Statin myopathy is quite a bit more common, and that can occur in up to 40% of patients that are put on a statin. It seems to be more common with gemfibrozil than with the other fibrates.

Dr. Lehmann asked Dr. Larson if he felt that gemfibrozil should be restricted in some way. Dr. Larson stated that his opinion, after preparing the review, is that the selection of these agents should be left at the discretion of the prescribing physician.

Dr. Lehmann stated that his impression had been that fibrates are overprescribed in primary care. He felt that sometimes people would get put on these drugs because of an "H" flag in their blood tests, without regard to what their lipid goals should be. However, after reviewing the usage data provided by DRRC, it doesn't necessarily suggest that patients are being treated this way.

Neal Catalano moved to keep the fibrate coverage unchanged. Cathy Goodfellow seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Cathy Goodfellow, and Dr. Cowley.

- 5 Topical Acne Criteria for Coverage: Lisa Hulbert addressed the Board. This topic was reviewed 3 months ago, and Medicaid was asked to bring back criteria recommendations. Proposed recommendations for expanding coverage for non-cosmetic reasons that came out of that meeting were presented to the Board.

Cathy Goodfellow moved to adopt the proposed criteria for enhanced coverage. Neal Catalano seconded the motion. The motion passed with unanimous votes by Neal Catalano, Dr. Hare, Dominic DeRose, Dr. Lehmann, Cathy Goodfellow, and Dr. Cowley.

6 Fibromyalgia: Ben Campbell, PharmD., with the University of Utah DRRC addressed the Board and presented information on the Fibromyalgia disease state and drugs used to treat it. The DRRC also presented recommendations for drugs that should be available to treat the condition.

Dr. Hare stated that he did not believe that Fibromyalgia is a neuropathic pain problem, as stated in the presentation. The cause of Fibromyalgia and Fibromyalgia pain is really not known. Although the condition is treated with drugs used for neuropathic pain, it does not necessarily mean that Fibromyalgia pain is neuropathic. Ben Campbell stated that he agreed with this assessment.

Tim Morley asked if there is an objective test for diagnosing Fibromyalgia. Dr. Hare stated that there are established criteria for making the diagnosis, but unfortunately many of the criteria overlap with other areas of chronic pain. There are no objective blood tests or x-rays that can be used to make the diagnosis. Sorting it out from other problems is often very difficult. Dr. Hare stated that it is a real condition, but it is poorly understood. Much research is still being done in this area. He stated that these drugs in the setting of a multi-modal treatment may be beneficial in helping patients participate in other areas of treatment recommended by the review. However, by themselves, they are not very beneficial for the treatment of Fibromyalgia.

The Board asked about the incidence of side-effects at gabapentin doses as high as 2400mg/day. Dr. Campbell stated that the side-effects with gabapentin were actually less severe than with the recommended doses of pregabalin, which are even higher.

Sue Heineman, PharmD., from Pfizer addressed the Board. Looking at the gabapentin trial versus the pregabalin trials, there was only one study done with gabapentin. Gabapentin does not have an indication for Fibromyalgia. The response rate in the gabapentin trial was also 30% versus a 50% response rate with pregabalin. In March, there was a letter sent by the Attorney Generals of 16 states, including Utah, to CMS regarding the use of off-label medications, and requiring that patients fail off-label medications before they can receive a medication that has the indication. This was not something that was driven by Pfizer, but was something that the Attorney General of Utah helped support. The Attorney Generals have been very proactive in keeping the pharmaceutical industry honest with regard to off-label promotions. She urged that the Board use caution, because the Attorney Generals are looking at it. They are even requesting the CMS not require that failure on an off-label drug not be required before a drug with a labeled indication be prescribed. Pregabalin was the first medication to be given an FDA labeled indication for Fibromyalgia, and there is good evidence to support its use. In response to the question about an increase in side-effects with gabapentin doses, the answer is that increased side effects are not seen because it is not a dose-dependent absorption. With pregabalin, there is dose dependant absorption, so there is no dose-creep that is seen with gabapentin. The Board was requested to allow the treating physician to decide whether or not to initiate treatment with gabapentin or pregabalin.

Dr. Lucinda Bateman addressed the Board. She came as a clinician and to offer her expertise, if it is helpful. She is a general internist who trained at the University of Utah.

She is now in her tenth year of operating a clinic that specializes in the treatment of unexplained chronic fatigue and Fibromyalgia. Her clinic has been a site for clinical trials for five different drugs for Fibromyalgia, and has been a speaker for Pfizer, Lilly, and Forrest, which represent the three companies that have FDA-approved drugs for Fibromyalgia. Her career as an internist started in 1991 – a year after the American College of Rheumatology published guidelines for the diagnosis and treatment of Fibromyalgia – so her career has bridged the time that Fibromyalgia has been officially recognized as a disease. Fibromyalgia is an important health concern. The literature has defined and established criteria for the diagnosis of Fibromyalgia. There have been thousands of studies about Fibromyalgia. Although the FDA-approved drugs are not the only drugs available to treat Fibromyalgia, they are probably the most effective drugs to treat especially the pain aspects of the condition. For many years, she managed patients only with off-label medications. Now, there are drugs with these indications that have been studied specifically to manage the pain aspect of Fibromyalgia. She believes that they are probably the most effective agents, and she would be happy to discuss her clinical experience. Ongoing research on Fibromyalgia, particularly the non-pain aspects, is needed. One of the problems with Fibromyalgia is that it does not have a medical home. There is really no Fibromyalgia specialist, and usually falls into the laps of primary care physicians. Primary care physicians need to be more educated about the condition, but they also need access to medications that are effective for the treatment of Fibromyalgia. Too many hoops to jump through for primary care physicians hinder treatment for patients. Prior to the FDA approval of medications for Fibromyalgia, there was a very long delay in the diagnosis of the condition. Patients were marginalized and utilization was high. Improved treatment of this illness will lead to reduced medical costs.

John Brokars from Lilly Outcomes Division addressed the Board regarding the indications, safety, and efficacy of Cymbalta.

Board discussion was postponed until August due to lack of time.

Next meeting set for August 13, 2009

Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 1 petition.

Minutes prepared by Jennifer Zeleny