



STATE MEDICAID DUR BOARD MEETING  
 THURSDAY, August 9, 2007  
 7:00 a.m. to 8:30 a.m.  
 Cannon Health Building  
 Room 125



# MINUTES

**Board Members Present:**

Neal Catalano, R.Ph.  
 Mark Balk, PharmD.  
 Don Hawley, D.D.S.  
 Joseph Miner, M.D.

Tony Dalpiaz, Pharm D.  
 Wilhelm Lehmann, M.D.  
 Colin VanOrman, M.D.

**Board Members Excused:**

Derek G. Christensen, R. Ph.  
 Bradley Pace, PA-C

Bradford D. Hare, M.D.  
 Joseph Yau, M.D.

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

Rae Dell Ashley, R.Ph.  
 Tim Morley, R.Ph.  
 Duane Parke, R.Ph.  
 Lisa Hulbert

Suzanne Allgaier, R.N.  
 Merelynn Berrett, R.N.  
 Nanette Waters

**Other Individuals Present:**

Craig Boody, Eli Lilly  
 Tony Molchan, Abbott  
 Shannon Beatty, Medimmune  
 Jeff Buel, J&J  
 Carrie Ann McBeth, DRRC

Matt Johnson, Takeda  
 Erika Brumleve, GSK  
 Jan Johnson, Pfizer  
 Linda Craig, AstraZeneca

Robb Host, Cephalon  
 Alan Baily, Pfizer  
 Elizabeth Stoltz, J&J  
 James Gaustad, Purdue

Meeting conducted by: Dr. Colin VanOrman

1. Minutes for June 2007 were reviewed and approved.
2. Review of Rule R414-60B Amendment: DUR Board members received a handout with the proposed rule amendment. They were asked to look at item #7, Clinical and Cost-related Factors. The P&T Committee shall base their decisions on the following clinical and cost-related factors established by the DUR Board: If clinical and therapeutic factors are substantially equal, then the P&T Committee shall recommend to the Division of Health Care Finance that it consider only cost; if the cost information available to the P&T Committee that the costs are substantially the same, then the P&T Committee makes a

recommendation to the Division of Health Care Finance based on the clinical and therapeutic profiles of the drugs; and in making recommendations to the Division of Health Care Financing, the P&T Committee may also consider whether the clinical therapeutic effects and medical necessity requirements justify the cost differential between drugs in a therapeutic class.

This is a proposed state rule that has already been to public comment and before the Administrative Rules Committee and is ready to be adopted. The current proposed rule includes the portions that have been stricken in the handout. It also does not include the underlined portions. The strike-out and underlined portions are proposed amendments to the rule recommended by the legal department that will go forward once the original rule has been adopted. It is now available to be adopted, but needs to be reviewed by the DUR Board at this time. It is required in statute that the DUR Board approve clinical and cost-related considerations for the Medicaid program.

The DUR Board asked if they will be responsible for establishing the clinical and cost-related factors, or if these are the are going to be factors that the DUR Board agree that these are fair criteria to utilize. Tim Morley stated that these are the skeletal factors that will be used to determine criteria.

The DUR Board asked what part of the rule they would be adopting. They will only be approving the part of the rule that deals with the clinical and cost-related factors.

The DUR Board voted unanimously to approve the rule.

3. P&T Committee Progress Report: Duane Parke addressed the Board. The Division has had a hearing on rules R414-60A and R414-60B and had to appear before the subcommittee on rulemaking. The Division is still moving forwards towards a Preferred Drug List. There will be a P&T Meeting next week, where the Committee will announce the drug classes that will be looked at over the next several months. The Division is still moving towards to October 1, 2007 goal of bringing up a PDL.
4. Business Carried Forward - Xibrom: Tim Morley addressed the Board. Xibrom is a new eye drop indicated for the treatment of post-operative inflammation and post-operative pain in patients who have undergone cataract extraction. This belongs to a class of drugs with many available alternatives for the same indication. Xibrom is substantially more expensive (double, sometimes triple the cost) than many of these alternatives. At this time, the Division is recommending that we put Xibrom on Prior Authorization with the requirement that another drug in this class be utilized prior to trying Xibrom.

The Board wondered what would happen if a patient needed to start the medication pre-operatively, and tried to fill the prescription on a weekend. It was felt that these situations would be few and far between, and that the quick turnaround time of Medicaid PA's would address this. The Division would have an internal discussion of how to handle emergency cases when this prescription needed to be filled over a weekend.

Mark Balk made a motion to accept the criteria as proposed. The Board unanimously voted to accept the PA criteria as proposed by the Division.

5. Tykerb: Dr. Jalpa Patel, Pharm. D., GSK Oncology Regional Medical Scientist addressed the

Board. Tykerb was approved in March of this year to be used in conjunction with Xeloda for the treatment of patients with advanced metastatic breast cancers tumors that over-express the HER-2 gene, and have received prior therapy including an anthracycline, a taxane, and trastuzumab. In the breast cancer environment, about 20-25% of patients will over-express this target HER-2 receptor. The majority of these women will get numerous months with treatment. In the pivotal trials, the women who received an anthracycline, a taxane, or trastuzumab and progressed, and were then treated with a combination of Tykerb and Xeloda rather than Xeloda alone, did have a significant improvement in time to progression. The trial ended early and allowed all patients to switch to the Tykerb plus Xeloda arm due to these results. Tykerb is an oral dual tyrosine kinase inhibitor that specifically targets the EGFR and HER-2 molecule. What is commonly seen in breast cancer and other solid tumors, the tumors over-express a variety of proteins on their cell surface receptors all called EGFR's. There are four components of EGFR family - EGFR-1 and EGFR-2 (also called HER-2), and EGFR-3 & 4, which have not been as well established in the pathogenesis of tumors. EGFR-1 and HER-2 have a known pathogenesis in breast cancer tumors, and women who over-express these receptors often have more resistant cancers with a worse prognosis. Tykerb works intercellularly. It is a small molecule that comes into the cell and inhibits the intercellular binding site of HER-2 molecule, which is the signal that tells breast cancer cells to continually recuperate and survive. The recommended dose of Tykerb is 1250mg orally days 1-21 in combination with Xeloda 2000mg/m<sup>2</sup> divided into two doses throughout the day on days 1-14. Side effects include diarrhea. There are specific management guidelines in the package insert to help physicians manage the diarrhea that may occur. Left ventricular function was also monitored closely during clinical trials. In various clinical trials of over 3,500 patients, only about 1.6% experienced a decrease in ejection fraction. There are guidelines for dose decrease and disease management in the package insert for this as well. QT prolongation has also been seen in advanced cancer patients receiving Tykerb. Use caution when administering Tykerb to any patient with a history of QT prolongation. Close monitoring of echocardiograms, and other things that can prolong the QT interval, such as magnesium and potassium. Tykerb is extensively metabolized in the liver. Use caution in patients with severe hepatic impairments.

RaeDell Ashley asked how many times the 21 day cycle needed to be repeated. The cycle is repeated until disease progression.

Tim Morley asked what was the mean time to progression. It was 27.1 weeks in the combination arm versus 18.6 weeks in the Xeloda only arm.

Mark Balk asked if there was a break from the Tykerb in the cycle. There is not a break in the Tykerb. It is taken continuously, whereas Xeloda is not. The wording in the package insert has caused some confusion about this, so it is likely that the wording in the package insert will be changed.

Tim Morley asked if there is blood level monitoring that is done to monitor Tykerb levels. If Tykerb is given with a CYP-3A4 inhibitor, one could take less Tykerb and potentially decrease expense. There have been no studies done on this to date. There are some recommendations in the package insert Tykerb doses be decreased as low as 500mg if co-administered with a CYP-3A4 inhibitor, based on studies done in healthy volunteers. There are no standard blood levels, however, so it would not be considered safe to advocate this.

Tim Morley addressed the Board. The reason that this has been brought to the DUR Board

is that Tykerb is not a first-line treatment. When that is the case, the Division generally brings it to the Board for Prior Authorization consideration. The other parameters that the Division is proposing for Prior Authorization are: minimum age of 18 years, a diagnosis of metastatic breast cancer with an over-expression of HER-2, prior therapy with one of the medications listed, and to be given with Xeloda.

Dr. Miner made a motion to approve the propose criteria. The Board unanimously approved the proposed Prior Authorization criteria.

6. Elestrin: Tim Morley addressed the Board. This is a topical gel that is a new formulation of estradiol. It is indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause. It does not offer a great advantage to currently available treatments of those things, it just presents a new formulation. In the studies reviewed, the topical gel formulation didn't offer to appear anything of an advantage. Costs of other formulations of estradiol are available on the information provided to the DUR Board. The estradiol containing products cost the Division approximately \$500,000 per year. The Division has presented Prior Approval criteria, but there is not really a compelling argument for a Prior Approval on this product. No other drugs in this class have Prior Authorization criteria, unless they are brand name products with available generics. Most of the current utilization in the Medicaid program is for generic tablets.

Board members felt that if Elestrin has a Prior Authorization put on it, so should Estrasorb. The Board felt that if Prior Authorization was warranted due to cost, the entire class of estradiol products should be scheduled for discussion.

Don Hawley made a motion to schedule a discussion of the entire estradiol class of products. The Board unanimously passed the motion.

7. Xolegel: Tim Morley addressed the Board. Xolegel is ketoconazole topical gel. There are other topical ketoconazole products available as generics. This gel is FDA indicated for, among other things, seborrheic dermatitis. The studies reviewed did not seem to show an advantage of this product over other ketoconazole preparations. However, there is the problem of FDA indication, because the creams are indicated as antifungal.

The DUR Board stated that the current accepted treatment of seborrheic dermatitis is antifungal. They also felt that putting gel in the scalp was easier than cream. Shampoo is also a good alternative.

The recommended PA criteria would be failure on another ketoconazole formulation within the last 12 months, and age 12 or over.

Mark Balk made a motion to accept the above PA criteria. The motion passed unanimously.

Next meeting set for September 13, 2007  
Meeting adjourned.

The DUR Board Prior Approval Subcommittee convened and considered 2 petitions.