



STATE MEDICAID P&T COMMITTEE MEETING  
 FRIDAY, September 21, 2007  
 7:00 a.m. to 8:30 a.m.  
 Cannon Health Building  
 Room 132



## MINUTES

**Committee Members Present:**

**Lowry Bushnell, M.D.**  
**Thomas Miller, M.D.**  
**Raymond Ward, M.D.**  
**Koby Taylor, Pharm D.**

**Kort DeLost, R.Ph.**  
**David Harris, M.D.**  
**Duane Parke, R.Ph.**

**Board Members Excused:**

**Kort Delost, R.Ph.**  
**Jerome Wohleb, Pharm D.**

**Karen Gunning, Pharm. D.**

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

**RaeDell Ashley**  
**Jennifer Zeleny**  
**Doug Springmeyer**

**Duane Parke**  
**Lisa Hulbert**  
**Lyle Odendahl**

**Other Individuals Present:**

Jeff Buel, J&J  
 Erica Brumleve, GSK  
 Mark Balk, Pfizer  
 Chris Beckwith  
 Tim Hambach, Abbott

Craig Boody, Lilly  
 Reed Murdoch, Wyeth  
 Chris Davis, Lifescan  
 John Vu

Barbara Boner, Novartis  
 Alan Bailey, Pfizer  
 Lynda Tyler  
 Tom Sanders

Note: Roll did not complete circulation - there were 30+ in attendance.

Meeting conducted by: Raymond Ward, M.D., Co-chairman.

1. Introduction of Senator Christensen: Senator Christensen was introduced to the P&T Committee. He was present to observe the proceedings and progress of the P&T Committee.
2. Minutes for August 2007 were reviewed, corrected, and approved.
3. P&T Committee Bylaws: Duane Parke addressed the Committee. Article 2 in the Bylaws establishes the P&T Committee as an advisory and technical board to the Department of Healthcare Finance in the formulation of a Preferred Drug List. Article 4 in the Bylaws states that the agenda will be set by the Manager of the P&T Committee in consultation with

the Chairperson. Reasonable effort will be made to put any supporting material on the P&T Committee website in a timely manner. Article 5 in the Bylaws states that the agendas for upcoming meetings will be posted on the P&T Committee Website at <http://health.utah.gov/medicaid/pharmacy> and in the lobby of the Cannon Health Building in accordance with the Open and Public Meetings Act. Article 9 in the Bylaws states that these Bylaws may be amended, and provides instruction on how amendments are made.

Duane Parke asked for Committee comment on the proposed future agendas for the P&T Committee. The Committee members had no comments.

Dr. Ward asked for public comment on the bylaws. No public comment was made on the proposed P&T Committee Bylaws.

Dr. Miller made a motion to adopt the P&T Committee Bylaws. The motion passed unanimously.

4. DUR Guidelines per Utah Administrative Rules R414-60B: Lyle Odendahl addressed the Committee. Committee members were given a print-out of Administrative Rule Section R414-60B-7. Because the P&T Committee cannot have access to cost information, the Committee must vote based on the clinical and therapeutic considerations only. The Division will then make final decisions based on cost.

Tim Morley addressed the Committee. The DUR Board has reviewed the requirements set forth in R414-60B. The rule is now adopted. Changes to the rule can be taken before the DUR Board for consideration.

Lyle Odendahl stated that now that the rule is effective, the Committee must re-vote on the Statins.

Senator Christensen commented on the rule. Items 1 and 2 in the rule seem to contradict. Cost and clinical value are disparate standards. Clinical value is the first thing to consider before cost.

Dr. Ward pointed out that the P&T Committee is operating under a handicap by not being able to know cost information due to Utah's Sunshine Laws. Senator Christensen was asked if these laws could be addressed in the future. Senator Christensen stated that he plans to address this in the future.

Barbara Boner with PhRMA addressed the Committee. Under the Government Information Act, pricing in the public sector is considered a trade secret. Most State Medicaid P&T Committees look at clinical information, and allow cost information to be considered in the department only.

Dr. Ward asked for motions to ratify P&T Committee Decisions on the Statins that were made in the August meeting. Dr. Harris made a motion to ratify the first motion from the August meeting minutes. The motion passed unanimously. Dr. Harris made a second motion to ratify the second motion from the August meeting minutes. That motion passed unanimously.

5. Proton Pump Inhibitors: Dr. Lynda Tyler addressed the Committee. Zegerid is an immediate

release formulation of Omeprazole with Sodium Bicarbonate. It is similar in efficacy to Omeprazole. Dr. Beckwith stated that certain patients who are sodium restricted may not be able to handle the Sodium Bicarbonate in Zegerid.

Dr. Tyler provided the P&T Committee with two tables. Table 1 maps out which PPI's are approved for pediatric use. Table 2 maps out comparisons of dosage forms and preparations made for patients who cannot swallow. Available data indicate that there are no clinical differences between the PPI's for pediatric patients.

Dr. Harris stated that it is important to include access to dosage forms for children who cannot swallow capsules or tablets. The most commonly used dosage form for pediatric patients is the orally disintegrating tablet. Duane Parke asked at what age can most children swallow capsules. Dr. Harris stated that this is very variable.

Diana Lane of Santarus addressed the Committee. It was pointed out in the University of Utah Drug Information Center's review that Zegerid is the only PPI approved for preventing an upper GI bleed. The Zegerid packet is approved for use with a nasogastric tube. Head-to-head studies for night-time GERD comparing Zegerid with esomeprazole and lansoprazole showed benefit. A study of Zegerid use for refractory GERD at an off-label BID dose showed that Zegerid was beneficial. While the 303mg of sodium in Zegerid may not be appropriate for heart patients, the average American consumes 4,000-6,000mg of sodium per day.

Dr. John Fang from the University of Utah Department of Gastroenterology addressed the Committee. Addressing PPI's as a class, for most patients all PPI's are good. It is important to have access to liquid preparations for patients that are tube-fed or cannot swallow. There are some pharmacological differences as well. Esomeprazole is the most potent PPI for healing GERD. Zegerid is pharmacologically effective for nocturnal acid breakthrough. He would like to see access to these drugs maintained.

Dr. Ward stated that access to these drugs will be maintained, since the prescriber can always designate that a particular drug is medically necessary.

Duane Parke read an email from Dr. Clark Helbig. Dr. Helbig provided a study comparing esomeprazole 20mg with lansoprazole 15mg. Copies of this study were distributed to Committee members. According to this study, esomeprazole was better for managing more severe cases. Dr. Helbig asked the Committee to continue to provide coverage for esomeprazole for Classes C & D of erosive esophagitis, Zollinger-Ellison, peptic constrictions, and food impaction. Duane pointed out that the study considered non-equipotent doses. Dr. Miller stated that he shared this concern.

Dr. Harris asked which doses of lansoprazole and esomeprazole would be considered equipotent. Dr. Tyler stated that esomeprazole 20mg would be comparable to lansoprazole 30mg.

Dr. Harris asked if the studies presented on Zegerid were included in the PPI comparison. Dr. Beckwith stated that these studies were not included in any peer-reviewed databases and not easy for practitioners to find.

Dr. Ward asked for a motion to included one non-pill dosage form on preferred status and

determine that all PPI's are otherwise equal. Dr. Miller made this motion, and Dr. Taylor seconded the motion. The motion passed unanimously.

6. Diabetic Supplies: Dr. Koby Taylor addressed the Committee. The four major meter manufacturers were compared in a comparison chart. These four manufacturers are Lifescan, Roche, Bayer, and Abbott. This chart shows in a spreadsheet the meter names, company names, electrochemical properties, accuracy, sample size, alternate site testing ability, software, memory, hematocrit range, and humidity range. There are differences in ease of use. For patients with dexterity problems, the Acensia meter has strips in a disc. This meter has an Arthritis Foundation Ease of Use endorsement. The Extra Precision meter is different from other meters in that it provides blood ketone testing. The Ultra has a small sample size, and the Abbott Freestyle has the smallest sample size of any meter. Only one meter has voice adaptability for the blind. There are studies available for patient preference. As a convenience factor, some meters do not require coding.

Accuracy standards for diabetic meters vary by organization. The American Diabetes Association recommends a margin of error of plus or minus 10%. A study by the American Diabetes Association, which was provided to the Committee, examined five meters. None met this criteria. One Touch Ultra and Freestyle Flash came closest to this level of accuracy in several categories of blood sugar. One Touch Ultra was accurate at levels 2-5 and Freestyle Flash was accurate at levels 1-3. Variability between meter values and lab values increased as blood sugar increase.

The ISO recommends accuracy of plus or minus 15mg for blood sugars < 70mg, or plus or minus 20%.

The American Journal of Health-System Pharmacy (AJHP) used a Clark Error Grid to assess accuracy. This organization published a study comparing Freestyle Flash and One Touch Ultra.

Dr. Harris asked if any one meter was better for detecting low blood sugars. Dr. Taylor stated that Freestyle Flash, Logic, and Plus meters detected low blood sugars 70% of the time. None of these meters met the strictest criteria of being accurate within 10%. The Flash and Ultra meters are the most accurate.

Dr. Harris asked how the meters compare for downloadability. Dr. Taylor stated that this is variable. Most diabetes educators are familiar with the downloadability of the Flash and Ultra meters.

As far as accuracy is concerned, Roche meters are not as accurate as the others. They also use more blood, take longer to test, and use out-of-date technology as compared to the other three companies.

Duane Parke stated that he recalls hearing about problems with strips and recalls. He asked Dr. Taylor how much of a problem this is with various companies. Dr. Taylor stated that this is more typically a problem with house brands. The meters tend to use older technology. They are also slower, require more blood, and have more accuracy problems. They also do not provide free meters for patients.

Strip waste is a cost-driver. Abbott meters have a longer window of time to add blood to the

strip. This can reduce strip waste.

Maria Mandelis with Bayer addressed the Committee. When it comes to meters, one size does not fit all. Bayer has two types of meters to address the needs of children, adults, and people with dexterity problems. A third-party study showed that significant testing errors may result from mis-coding. Up to 50% of patients mis-dose 2 units with other meters, versus 1% of patients with auto-coded meters. There is a 24% probability of a significant mis-dose from a mis-code. This can result in excess costs of \$1600 per episode per patient for an episode of hypoglycemia. 41% of experienced testers forget to code.

The Accensia Contour is the only single strip meter with self coding and control marking. Testers cannot fake testing. The strips have hematocrit correction. Diabetics may have extreme hematocrits due to hypertension, heart disease, kidney disease, or because they are a pediatric patient. The meter show low and high blood glucose levels for the past 7 days. It is approved for neonatal use.

The Breeze 2 meter has auto-coding. It is larger for dexterity challenged patients. The strips come in a disc for people with dexterity problems. It is the first and only meter to have an ease of use endorsement from the Arthritis Foundation. This is important because 55% of diabetics have arthritis.

Bayer has had no recalls. Other manufacturers have had recalls of meters because the meters have switched to the European standard of displaying test results in millimoles when dropped. Bayer provides free meters, education, and free batteries for life.

Jeff Buel from Lifescan addressed the Committee. Various Lifescan meters were handed out to Committee members. Lifescan has proven accuracy for five years with 50,000 tests. Lifescan produces the Ultra Mini, the Ultra Smart, and Ultra II meters. All meters take the same strips. They are the number one recommended meter from professionals. Lifescan provides bilingual meters with bilingual support materials. Each meter comes with a DVD, a Spanish language DVD, Gold Program Website access, and Diabetes 101 included in the box. Four out of ten people use Lifescan meters. Including Lifescan on the Preferred Drug List would ensure that continuity of care is uninterrupted. Lifescan also has partnerships with companies that produce insulin pumps.

The Ultra Mini meter comes in various colors, which children prefer. Ultra II allows users to track blood sugar levels before and after meals. The Ultra Smart meter tracks multiple daily tests, and is clinically proven to reduce A1C. It can create graphs and charts based on the multiple daily tests. In studies, the Ultra Smart meter reduced A1C levels in 20 weeks, and sustained those reductions for 46 weeks, while the A1C levels of other patients went up.

The Committee asked if this study on the Ultra Smart meter is published. It is not.

Tim Hambacher with Abbott addressed the Committee. Abbott produces the Freestyle and Precision Xtra line of meters. Freestyle strips have four major differences: coulometry electrochemical measurement techniques, all glucose is measured, smallest sample size on the market with alternate site testing, and a hematocrit range of 15-65%. Other strips use amperometry, measure a small portion of the sample, and extrapolate the results. Freestyle strips have sample detection electrodes. Patients may reapply blood for up to 60 seconds to reduce strip waste. Freestyle strips use glucose dehydrogenase, and other strips use glucose

oxidase. Freestyle strips have a voltage potential near zero. Other chemicals in the blood will not interfere with the test results. The accuracy of Freestyle strips is around plus or minus 5%, whereas other strips are around plus or minus 20%.

The Albany study, which was mentioned by Dr. Taylor, compared the One Touch Ultra and Freestyle Flash to venous blood glucose samples. The Flash meter was more accurate on the Clark Error Grid. The Freestyle Lite is the first non-coding meter from Abbott that just came out. Precision Xtra measures ketones, which Type I diabetics should test when sick. The Sick Day Management Study has shown that ketone blood testing results in 46% fewer Emergency Room visits and 64% fewer hospital admissions for Type I diabetics when they are sick.

Duane Parke read a comment from Dr. Checketts, D.O. that was received by mail. Dr. Checketts is the Co-Director of the Diabetes Care Center at Davis Hospital. 6% of his patients are diabetic. Freestyle meters should be seriously considered. Other meters can have faulty strips and misfire. His office has the capability to download patient information from the Freestyle meters. He has asked the other diabetic meter companies for this capability, and has not received it.

Dr. Ward stated that he would like outcomes data for the specific meter brands, but this does not appear to be available in the literature.

Dr. Ward asked if the Preferred Drug List contracts would be by company, rather than meter. Duane Parke stated that the contracts will be by company, so a contract with one company would place many meters on preferred status. Medicaid does not cover meters - Medicaid covers test strips, and they are the major cost driver. Providers would continue to have access to other companies' strips through the "Dispense As Written - Medically Necessary" override.

Dr. Harris stated that he would prefer to make a decision after listening to a colloquium of diabetologists for an expert opinion. It would be better to have expert opinions based on wider usage than a single expert. Dr. Miller agreed, adding that there are technical issues involved that the Committee does not understand.

Dr. Ward suggested that the Committee could recommend to the Division to proceed as necessary without a Committee recommendation due to the lack of data. Dr. Taylor stated that the Committee should recommend against using Roche products due to lack of accuracy.

Lyle Odendahl advised the Committee to redirect the discussion to clinical matters.

Dr. Taylor recommended that the Division choose among Lifescan, Abbott, and Bayer, but not Roche. There are outcomes data available for diabetic blood glucose testing, but none of those data are specific to any meter or brand.

Dr. Miller pointed out to Senator Christensen that this would be a situation where the Committee should be able to vote based on cost, since there is a lack of clinical data.

Dr. Miller made a motion that the Division should choose from among the four companies based on cost. He felt that Roche should be considered by the Division in the event that Roche strips cost 1/10 the cost of the other companies, for example. Dr. Harris seconded this

motion. Dr. Taylor opposed this motion. The motion passed.

7. Projected Committee Action at Future Meetings: Doug Springmeyer addressed the Committee. There is a proposed schedule for future Committee action on the back of the meeting agenda. Drug manufacturers are invited to submit information to Dr. Linda Tyler of the University of Utah Drug Information Center for consideration.

Next Meeting Set for Friday, October 19, 2007.

Meeting Adjourned.

Minutes prepared by Jennifer Zeleny