



**STATE MEDICAID DUR BOARD MEETING**  
**THURSDAY, June 08, 2006**  
**7:00 a.m. to 8:30 a.m.**  
**Cannon Health Building**  
**Room 114**



# MINUTES

**Board Members Present:**

**Charles Arena, M.D.**  
**Lowry Bushnell, M.D.**  
**Bradford D. Hare, M.D.**  
**Colin VanOrman, M.D.**

**Dominic DeRose, R.Ph.**  
**Joseph K. Miner, M.D.**  
**Don Hawley, D.D.S.**

**Board Members Excused:**

**Karen Gunning, Pharm D.**  
**Wilhlem T. Lehmann, M.D.**  
**Bradley Pace, PA-C**

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

**Rae Dell Ashley, R.Ph.**  
**Tim Morley, R.Ph.**  
**Richard Sorenson, R.N.**

**Suzanne Allgaier, R.N.**  
**Merelynn Berrett, R.N.**

**Other Individuals Present:**

**Craig Boody, Lilly**  
**Oscar Fuller, CMS**  
**Alan Bailey, Pfizer**  
**Cap Ferry, LEC**  
**Shawn Prince, Elan**  
**Jeff Hatch, BMS**  
**Doug Ethel, GSK**

**Nash Haleem, Takeda**  
**Keith Strother, Takeda**  
**Alan Sloan, Purdue**  
**Dan Manning, Schering**  
**Nancy Fairchild, Sepracor**  
**Troy Sampson, BMS**  
**Erica Brumleve, GSK**

**Matt Johnson, Takeda**  
**Michael Stevens, Davis MH**  
**Roy Lindfield, Schering**  
**Tom Holt, Schering**  
**Tanner Taylor, UCB**  
**Doug Poulsen, BMS**

Meeting conducted by: Lowry Bushnell

1. Minutes for May 11, 2006 were reviewed, corrected and approved.
2. Housekeeping: Board members were asked their thoughts about a special meeting with the physicians from the CNS project around October. Board consensus was to keep it to a regularly scheduled meeting; .
3. Business Carried Forward: None

4. Increlex- Synthetic Human Insulin like growth factor for treating growth failure in children suffering from severe primary Insulin like growth factor deficiency, or who have developed neutralizing antibodies for Growth Hormone. This drug is targeted towards close to the same demographic group for whom growth hormone is prior authorized. Suggested criteria are:
  - a. Physician documentation supporting primary IGFD diagnosis
  - b. Age <18 years and >2yrs
  - c. No cancer diagnosis
  - d. GH and IGF-1 levels at or below defined limits
  - e. Not on chronic steroid therapy
  - f. No uncorrected thyroid deficiencies
  - g. Written prior
  - h. 1year auth
  - i. Reauth: same as original

Criteria was approved.

5. Long Acting Beta Agonists- Dan Manning, PharmD Schering Plough respiratory Medical Scientist Specialist and Doug Ethel, PharmD., Glaxo Smith Kline Regional Medical Scientist addressed the Board. Both referred to the new FDA boxed warning issued for the LABAs. LABAs should not be initiating nor monotherapy. They should be used as add-on therapy after starting with an inhaled corticosteroid. The FDA warning is the result of reports of increased complications and death associated with the use of the LABAs. Charlie offered input from his understanding surrounding the controversy referencing the SMART study done by Glaxo which became the basis for the warning. SMART looked at long-term outcomes that focused on a sub-group of African Americans where most of the deaths occurred. These patients were given an LABA without proper monitoring. NIH did some studies one called the SOCS trial which compared two groups, one taking salmeterol alone and the other oral corticosteroids. The Salmeterol only group had more exacerbations than the corticosteroid group because they did not have the control. This would support the SMART conclusions, but they were not controlled well. Lowry suggested that since the conclusions of these studies are controversial that while putting controls on these medications would be done to protect the public, it will interfere with the patients and the physicians access to the products, especially if these differences are subtle. Joe agreed. He stated that this is a large group of clients and these are extremely useful medications; perhaps education of some sort would be good but restricting them would do more harm than good. Discussion turned to the results of a meta-analysis study that was reported in the Annals of Internal Medicine, which it was felt did not add much to the issue. Board consensus was to take no action or request further information.
6. Amitiza- Dr. Nash Haleem, DVM Takeda Senior Clinical Outcomes Manager addressed the Board. Amitiza is a new entry into the constipation market. It works by drawing fluids into the lumen of the gut and increasing the water content of the stool. It is indicated for Chronic Idiopathic Constipation in the adult population. It was noted that this agent is a new entry into the existing category that includes Zelnorm and historically we place new entries under

the same restrictions as previous members. Some discussion ensued regarding the criteria surrounding ruling out drug induced constipation. It was suggested that since the intent of the requirement is to rule out opiate induced constipation, then the wording be changed to say that. The criteria were amended to be:

- a. documented diagnosis of chronic constipation
- b. documented failure within the last 12 months using:
  1. one fiber laxative and
  2. two stimulant laxatives
- c. opiate induced constipation be ruled out.

The criteria were accepted and passed.

7. Emsam- Dr. Michael Stevens, Medical Director at Davis behavioral health, addressed the board. Emsam is an older MAOI repackaged in a new delivery system. He did not think that open access to the drug is warranted, but that there are some advantages that should be considered. Principally that the delivery systems allows higher dosing to advantageous levels while postponing the dietary adverse and pressor effects that normally accompany MAOIs. Lowry expressed concern that this might become a first choice (MAOIs are some of the best anti-depressants) for patients wanting to avoid the dietary problems and also the fact that many physicians trained in the last 15 years have not had the training to properly prescribe and manage them. He also stated the biggest concern for doctors prescribing is the serotonin syndrome that can be very serious, but for patients the biggest concern will be a lifestyle issue. Dr. Stevens noted nevertheless that even diligent patients trying to avoid problems can make mistakes unknowingly and have problems, and this product may stem some of that. The use of combination therapy was mentioned and Lowry stated that there would be problems with SSRIs and SNRIs used in conjunction with MAOIs by anyone other than a tertiary patient of a skilled physician. TCAs must also be carefully used together with MAOIs, and Lowry suggested that any of these combinations would only be seen by the time you get to the doctors that should use MAOIs. Lowry stated that one of the biggest benefits of this product is that the pharmaceutical sales force would go out and re-educate doctors about MAOIs. Discussion surrounding the proposed criteria followed and changes were made to be:

- a. Physician documentation of failure with three other antidepressants including one MOAI.
- b. Previous failure on an oral MAOI
- c. No concurrent antidepressant therapy
- d. Authorization period for one year

Criteria was approved and passed.

Next meeting set for May 11, 2006

Meeting adjourned.

The DUR Board Prior approval sub-committee convened and considered 5 petitions. Drug Histories were for 12 months unless otherwise noted.

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June 8, 2006

Petitions to the DUR Board

#### Patient #1

This request is a re-authorization request for Enbrel 50mg twice weekly for a 63 year old female patient of Gerald Krueger, MD University of Utah Dermatology Department suffering with pustular psoriasis. Dr. Kruegers petition states, "I saw this patient on March 16, 2006. Her psoriasis was completely in remission. [She] has also experienced no side effects from the Enbrel therapy. Since this patient's psoriasis is so well controlled under her current regimen, I am requesting that she be allowed to continue her Enbrel therapy at a dose of 50mg biweekly."

**The board denied this petition pending information from the doctor supporting the need for twice weekly dosing to continue contrary to approved dosing recommendations.**

#### Patient #2

Sam Coates, MD is requesting Provigil 100mg daily for a 13 year old male diagnosed with a high functioning form of Apergers disorder, Depression and Anxiety. He is currently taking Abilify 5mg a day. Dr Coates states that he has "recently started him back on Provigil 100mg, which he took consistently between 2002 and 2005, originally prescribed by a neurologist. After starting the medication, the patient showed significant improvement in mood, attention span, energy level and motivation and cooperation at school. He stopped the medication in 2005, but behavior has deteriorated and necessitating restarting the medication. That is my rational for putting him back on the Provigil and he is reportedly functioning better again. **The Board denied this petition.**

#### Patient #3

The third petition to the Board comes from Michael Stevens, MD from Davis Behavioral Health, requesting Straterra 40mg for a 13 year old female patient currently using Concerta 54mg for ADHD, Bipolar disorder, and Mood disorder NOS. She has been given samples of Straterra and he feels she has responded well to the combination. He states, "It is my hope that Straterra 40mg in combinations with Concerta 54 mg daily will sufficiently treat [her] ADHD and Depressive symptoms." **The Board approved this petition.**

#### Patient #4

The fourth petition to the Board comes from Kristine Hindert, MD from the Children's Center requesting Focalin 5mg twice daily for a 4 year 10 month old male who has been "very aggressive leading to expulsions from 5 daycare centers. He has ADHD and a mood disorder. He has been in a therapeutic preschool since 9/24/04. Despite intensive day treatment services in this program, his latest daycare threatened to expel him." Dr Hindert has tried him on Trazodone which help his aggression but not his disruptive behavior, and Adderall XR which helped his disruptive behavior but caused severe moodiness. Aggression worsened and since Adderall

could not be increased due to side effects, Risperdal was added with questionable response.

Dr Hindert then explains that Concerta was tried with excellent response but poor sleep. She then tried regular Methylphenidate but he did poorly due to “rapid metabolizing.” Wellbutrin was also ineffective. He is now being tried on Strattera. Dr Hindert states that she recently has tried him on Focalin, and he has done extremely well with no side effects. **The Board denied this petition as a result of no history in the Medicaid profile for any of the stimulants mentioned, no results given for the Strattera trial, no mention of mood stabilizer usage, and no use of any treatment from December to April.**

#### Patient #5

For the 5<sup>th</sup> petition, Deborah Thorpe, APRN with the Huntsman Institute is requesting Oxycontin 40mg q 8h, Oxycodone 15mg i-ii q 3h prn breakthrough, and Actiq 800mcg q2h prn severe pain for a 23 year old female with sickle cell anemia, “a chronic, devastating, and often progressive painful illness that results in highly variable opioid dosing requirements depending on the location, frequency, and extent of the sickling process. She has both chronic and intermittent acute episodes of pain that will most likely continue for the rest of her lifetime.” In the past year, she has been hospitalized 8 times, each visit preceded by multiple ER visits. At present the Oxycontin dose has provided adequate relief, however when she has episodic severe pain it usually requires much higher doses over shorter periods of time to get the pain controlled. Deborah has advised her to go to the ER to seek relief because she runs out of the available medications and experiences significant nausea and vomiting, becomes dehydrated and febrile. **The Board denied this request due to the episodic and highly variable opioid dosing requirements which differ in many ways from cancer pain regimens. The Board feels that current coverage is rational and affirms its coverage policy for the opiate analgesics.**