



STATE MEDICAID DUR BOARD MEETING  
THURSDAY, June 9, 2005  
7:00 a.m. to 8:30 a.m.  
Cannon Health Building  
Room 125



## MINUTES

**Board Members Present:**

**Charles M. Arena, M.D.**  
**Lowry Bushnell, M.D.**  
**Derek G. Christensen, R.Ph.**  
**Dominic DeRose, R.Ph.**  
**Karen Gunning, Pharm D.**

**Bradford D. Hare, M.D.**  
**Jeff Jones, R.Ph.**  
**Wilhelm T. Lehmann, M.D.**  
**Colin B. VanOrman, M.D.**

**Board Members Excused:**

**Bradley Pace, PA-C**  
**Joseph K. Miner, M.D.**

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

**Rae Dell Ashley**  
**Tim Morley**  
**Richard Sorenson**  
**Duane Parke**

**Suzanne Allgaier**  
**Nanette Waters**  
**Brenda Strain**

**Other Individuals Present:**

**Jeff A. Buel, J&J**  
**Craig Boody, Lilly**  
**Alan Bailey, Pfizer**  
**Jim Goddard, Shire**  
**Gary Oderda, Uof U**  
**Loren Greenway, IHC**  
**Carmen Dickson**

**Joseph Yau, VMH**  
**Troy Benavidez, Astra Zeneca**  
**Laura Hill, Takeda**  
**Shawn Kem, GSK**  
**Shane B., Pfizer**  
**Candi Arce- Larreta, Pfizer**  
**Tim Smith, Pfizer**  
**Audrey T. Ozols, Wyeth**

Meeting conducted by: Duane Parke

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1. Minutes for May 2005 were reviewed, corrected and approved.
2. Business carried forward from May 2005:
  - a. Fentanyl/ Duragesic price comparison carried forward again awaiting CMS 1<sup>st</sup> qtr price

tape.

b. Muscle Relaxants Policy- Duane presented and explained the information provided for consideration for the restriction for this class of drugs: no restrictions proposed for the three relaxants used predominantly for spinal cord injured patients- baclofen, dantrolene, and tizanidine. Cumulative of 90 tabs in 90 days recommended for all other members of this class (Chlorzoxazone, Cyclobenzaprine, Metaxalone, Methocarbamol, Orphenadrine, Orphenadrine Compound). Transaction times for claim adjudication were presented by Duane, showing there is time available to impose the suggested restrictions. Raedell recommended 30 in 30 days because of delays in programming. Motion presented for 30 tabs in 30 days to be changed to 90 tabs in 90 days when programming becomes available. Discussion followed regarding withdrawal considerations of current users. Brad notes that tolerance develops and usefulness disappears after about 1 week, and that withdrawal is not a concern. Motion passed to impose 30 tabs in 30 day limit.

c. Butalbital Policy- Duane explained the origin for this action comes from practitioners in the field who have expressed concern over a limitation for APAP containing opiate pain medications, yet there are none for APAP containing Butalbital products. Discussion followed whether or not to treat aspirin containing combinations equally as well. Determination was made to place any restrictions based on the butalbital component which would then limit satisfactorily any APAP or aspirin combinations. The issue of withdrawal for these patients was discussed as well, trying to determine a reasonable quantity for a restriction. Duane noted that any restrictions will require due notice and this issue can be treated in whatever notice is circulated. Motion was made to adopt a cumulative of 30 tabs in 30 days after 90 days of notification. Motion passed.

d. Spiriva Policy- Duane presented the recommendation that Spiriva be restricted to a hard edit of 30 in 30 days with hard edit of no duplicate therapy with other inhaled anticholinergics ( Atrovent and generics, Combivent). Motion made and passed.

e. Ventavis Policy- Duane explained the issues surrounding this product used for pulmonary hypertension: dosed 6 to 9 times daily from single use ampules; not to be used in conjunction with Tracleer, Flolan, or Remodulin; using an expensive, specialized delivery system requiring a backup system. Discussion followed with regard to hospital discharged patients and access for them based on the specialized delivery system. Loren Greenway from IHC asked for recognition and informed the board that the equipment is rented to patients by IHC or an outside provider (in this case Accredo). There was concern about the authorization process coming out of an institution, and the potential for duplicate therapy based on non-labeled indications but the fact that this would be no different than other currently restricted medications was understood. Tim noted that there is policy in place for non-labeled indications and uses which addresses approval or disapproval for those situations. It was decided to carry this issue forward to next month pending protocol information to be sent from IHC for review.

3. New drugs in existing drug classes currently having restrictions- Duane presented a motion to be brought to the board regarding new members of drug classes that come to market, for which there are restrictions in place for that class, or for drugs receiving new indications. A motion was made to place new members of these drug classes under the restriction criteria already in place for existing drugs within the category. The Board approved this action.
4. Cumulative Limit for short-acting single ingredient Schedule II analgesics- Duane explained

that information for this item is provided as result of a request from the board to consider a cumulative restriction for these drugs. Discussion focused on the table Duane presented which shows that users of greater than 180 tabs/month number in the 100's. The opinion was expressed that Demerol analogs should be considered separately, but in what way was not specified. Methadone and Levorphanol were mistakenly included on the table and are not to be included in this discussion. The appropriate quantity for restriction was discussed considering acute and chronic pain management, breakthrough pain, and use in combination with long-acting analgesics. Motion made and passed to restrict to 180 in 30 days and review in 6 months.

5. Multiple Sclerosis criteria- David Peterson, Pharm D., University of Utah, presented criteria information for multiple sclerosis and the biological agents used in its treatment. Dosing, use, and pricing information was presented for Glatiramer (Copaxone®), Interferon  $\beta$ -1a (Avonex®, Rebif®), Interferon  $\beta$ -1b (Betaseron®), Mitoxantrone (Novantrone®), and Natalizumab (Tysabri®). Products are divided into **groupings** : Immunomodulators are Glatiramer and Interferon products; Mitoxantrone is considered an immunosuppressor/chemotherapy agent; Natalizumab (**not currently available**) is also considered an immunomodulator. **Administration**: Glatiramer and the Interferon products can be administered by the patient at home; Mitoxantrone and Natalizumab must be given in clinic or doctors office by IV infusion. Avonex Interferon  $\beta$ -1a is an IM injection whereas the others are all subcutaneously dosed. **Costs** for all these products are similar, ranging from \$1,200 to \$1,900 (in the criteria the cost for Glatiramer is listed as \$36,656.00; this figure has been discovered to be erroneous) per month. **Indications**: all are indicated for the relapsing/ remitting form of MS; Mitoxantrone is the only one specifically labeled for progressive forms of MS. **Practice Guidelines**: Interferons and Glatiramer are considered 1<sup>st</sup> line agents; Mitoxantrone is not considered 1<sup>st</sup> line for the relapsing/remitting forms of MS because of cardiac toxicity and is the only agent that is approved and has good evidence for secondary progressive and the progressive/relapsing forms. Natalizumab is not addressed in any of the current guidelines. **Duration of therapy**: When effectiveness ceases or intolerability develops. Mitoxantrone has a lifetime maximum dose of 140mg/m<sup>2</sup> or until cardiac failure develops. **Drug -Drug interactions**: Few exist and little is documented.

Derek Challenged the cost estimate for Glatiramer. His experience shows that it is in the same range as all the others.

The issue of generic vs. brand name use when cost for the generic is questionable was raised in the case of Durgesic and fentanyl patches. Raedell said that a legal opinion has been requested of Department counsel and is being awaited. Duane notes that formal pricing information is still lacking, which information is needed for a complete determination of this issue. This item will be carried forward to the next Board meeting.

Next meeting is set for July 14<sup>th</sup>, 2005.  
Meeting Adjourned.

The DUR Board Prior approval sub-committee convened and considered 12 petitions.

