



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, April 13, 2006
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Lowry Bushnell, M.D.
 Derek G. Christensen, R.Ph.
 Karen Gunning, Pharm D.

Jeff Jones, R.Ph.
 Wilhlem T. Lehmann, M.D.
 Joseph K. Miner, M.D.

Board Members Excused:

Bradford D. Hare, M.D.

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.
 Nanette Waters

Other Individuals Present:

Craig Boody, Lilly
 Oscar Fuller, CMS
 Pierre Thoumsin, Amgen
 Jeff Buel, J & J
 Barbara Boner, Novartis
 Bart Watts, TAP

Marianne Paul , U of U
 Cap Ferry, LEC
 Brendan Hopf, Medimmune
 Bran Mangene, BMS
 Todd Jankowski, BMS
 Paul Pereira, TAP

David Case, Astellas
 Owen Boyer, Pfizer
 Alan Bailey, Pfizer
 Mark Weibell, Pfizer
 Steve Gottfredson, Pfizer
 Alan Colledge, Labor Comm

Meeting conducted by: Lowry Bushnell

1. Minutes for March 9, 2006 were reviewed, corrected and approved.
2. Housekeeping: Tim informed the Board that letters updating Board term status will be forthcoming.
3. Business Carried Forward:
 - a. New products and specialty pharmacies: re-statement of policy passed last month. Board members absent from last months meeting were updated on the issue. Board

questions and comments were solicited. No proposals or action taken.

b. Exubera- New rapid acting inhaled Insulin for use in Type I (with long acting insulins) and Type II (monotherapy or in combination with oral hypoglycemics or longer acting insulins) diabetics. Pricing info not available at the time of the meeting. Tim outlined the main concerns for Medicaid which include: Patient misunderstandings on proper usage (especially with inhaled medications) complicating precise dosing, patients with lung conditions, not approved for patients who smoke. Discussion of Proposed Criteria ensued. An appropriate cumulative quantity should be at least 90 if used 3 times daily. RaeDell mentioned the expense that diabetic patients are consuming and the need to determine if this is a frill or a necessity. Karen expressed concern about safety issues associated with its use. She proposed not putting limits according to steroid or beta blocker use. Lowry asked about the impact that postponing action would have on placing a prior. Tim pointed out that any prior authorization action taken must wait 90 days before it can be implemented. Discussion followed and the proposed criteria were discussed, amended and passed as follows:

- 1- written prior approval obtained by physician
- 2- 18 yrs and older
- 3- not approved for smokers
- 4- description of medical necessity which includes a description of the patients underlying pulmonary condition (does not include patient convenience).
- 5- patient not on short acting insulin

c. Drugs used with dialysis- held to next meeting

4. Nexavar- New oral drug for Advanced Renal Cell Carcinoma. Proposed criteria were discussed, and the following were approved:
 - 1- Written prior obtained by the physician
 - 2- Documentation of the diagnosis
 - 3- Approved for patients age 18 and above
 - 4- Not covered for unlabeled/unapproved uses

Proposed criteria for CBC w platelets was suggested to be an informational item to be used with posting of criteria on a website or other means of criteria communication.

5. Sutent- Another new oral drug for Advance Renal Cell Carcinoma with an additional indication for gastrointestinal stromal tumor after disease progression on or intolerance to imatinib (Gleevec). It was pointed out that in the labeling information there is stated that there are no randomized trials of SUTENT demonstrating clinical benefit such as increased survival or improvement in disease-related symptoms in renal cell carcinoma. The following amended criteria were passed:
 - 1- Written prior obtained by the physician
 - 2- Documentation of diagnosis
 - 3- Documentation and history of previous treatments (not 1st line therapy)
 - 4- Approved for patients age 18 and above
 - 5- Not covered for unlabeled/unapproved uses

6. Orencia- New treatment for Rheumatoid Arthritis: Indicated for reducing signs and symptoms, including major clinical response, slowing the progression of structural damage,

and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs, such as methotrexate or TNF antagonists. May be used as monotherapy or concomitantly with DMARDs other than TNF antagonists. Discussion followed about the similarities and differences between these criteria and those for the other rheumatoid biologics, particularly the difference pertaining to a negative TB test, which was nominated for an informational issue for a website posting rather than for a PA criteria. It was proposed that prior authorization criteria for Orencia be the same as for this class as a whole with differences specific to Orencia amended as needed. This is in accordance with the policy established by the Board with regard to PAs assigned by class of drugs where new drugs belonging to a class be automatically placed under the class PA. Accordingly, the following differences apply to the established class PA effective immediately: For use only in the physicians office billed with the appropriate J-code and NDC. Approved.

7. Protopic and Elidel- The issue as it occurs here involves the fact that these two topicals have recently been given boxed warnings by the FDA for risk of malignancies when used in children 2 years and younger. A study of Medicaid claims reveals that most usage is for children under 2 years. Discussion revolved around the mechanism and quality of a control to be used for these drugs. Jeff noted that this is a second line therapy and Karen added that they are not more efficacious than steroids. It was proposed that a hard edit (denial) be imposed for any patient under 2 years old, and that urgent requests for patients under that age limit be brought to the Board.

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.