



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, July 14, 2011
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 114



MINUTES

Board Members Present:

Neal Catalano, R.Ph.
 Kathy Goodfellow, R.Ph.
 Peter Knudson, D.D.S.
 Joseph Yau, M.D.

Tony Dalpiaz, PharmD.
 George Hamblin, R.Ph.
 Kumar Shah

Board Members Excused

Mark Balk, PharmD.
 Bradford Hare, M.D.

Cris Cowley, M.D.
 Joseph Miner, M.D.

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

Marisha Kissel, R.N.
 Annette Leonard, R.N.
 Lisa Hunt, R.Ph.
 Robyn Seely, PharmD.

Heather Santacruz, R.N.
 Merelynn Berrett, R.N.
 Tim Morley, R.Ph.
 Jennifer Zeleny, CPhT., MPH

Other Individuals Present:

John Stockton, Astellas
 Pat Wiseman, Medimmune
 Daryl Wagner, UPHA
 Gary Oderda, U of U
 Chris Hickson, Harmons

Alan Bailey, Pfizer
 Reid Barker, UPHA
 Lori Howarth, Bayer
 Greg Myers, PharmD.

Meeting conducted by: Neal Catalano, R.Ph.

- 1 Cancelled Item – Pharmacy Audits: Tim Morley addressed the Board. Robyn had scheduled one of the auditors from the Office of Internal Audit Services, since there was a lot of interest in Pharmacy audits. Medicaid auditors are not part of the Department of Health; legislation has created a separate agency. All information that Tim is presenting is unofficial. On Monday, Tim learned that attorneys with the Attorney General’s office held a moot court on some of the auditing issues. Some of the audits are going to be taken back, and policy is being developed to address future audits. Cooperation with Medicaid policy on policy matters is likely to change in the future. It was not felt that having auditors address the DUR Board would be profitable, since policies are likely to change. This is not an official announcement, but it is information that Tim had that he felt was valuable to share.

Neal asked if any official announcements will be posted on any websites. Tim stated he did not know, since the OIAS was a separate agency from Medicaid.

The DUR Board asked if the audits were being suspended while policy is being looked at, or if any audits were ongoing. Tim stated he did not know anything about the OIAS schedule, or OIAS audits, other than things that were addressed to him in phone calls that he received, that he felt were concerning.

Tim was asked if there will be any future input sessions for the public, as should have happened. Tim stated that he imagines that there will be, since the outcome has been difficult for all parties concerned. There will be coordination with policy people, and a higher level of cooperation on interpretation of policy and undertaking audits.

Kathy Goodfellow asked if there is a point person in the OIAS, if Medicaid Policy is not the appropriate point of contact. Tim stated that he does not know the appropriate person to contact in the OIAS, but suggested that John Slade, who is one of the auditors, may be able to assist them with questions or refer them to the appropriate person.

Kumar Shah asked if the legislation did not define the role and need for coordination when OIAS created. Tim stated that he does not know the answer, since he is not involved with the inner workings of OIAS.

- 2 Housekeeping: Neal Catalano was introduced as the new Chair of the DUR Board. .

Robyn Seely announced that she is working on recruiting a new Primary Care Doctor for the DUR Board.

Approval of June minutes was deferred until the end of the meeting.

- 3 P&T Committee Report: This month, the P&T Committee will review topical and oral nonabsorbable antifungals. The University of Utah will provide the review. August's agenda will include platelet aggregation inhibitors, and September will be androgens. Agendas were provided for interested parties. Additionally, three new members will join the P&T Committee in July.

Annualized general fund savings from the PDL were presented to the DUR Board.

- 4 Adult Acne PA Review: Robyn Seely addressed the Board, and presented Adult Acne PA criteria that are currently in effect. Approval and denial statistics for the PA were presented to the Board. It was suggested that the PA criteria are working well, and should not change.

Neal asked if the data presented were for all acne products or just generic Retin-A. Robyn stated that she only provided generic Retin-A statistics.

Kathy Goodfellow asked if the documentation required for 25% improvement required anything beyond a statement from the prescriber. Nothing is required beyond a statement

from the prescriber.

Lisa and Robyn added that many of the other topical acne products are managed by the PDL.

Kathy Goodfellow moved to keep the current criteria. George Hamblin seconded the motion. The motion was approved unanimously by Ms. Goodfellow, Dr. Knudson, Dr. Yau, Mr. Hamblin, Mr. Catalano, Mr. Shah, and Dr. Dalpiaz.

- 5 Review of Samsca PA criteria: Robyn Seely addressed the DUR Board and presented the current PA criteria and PA approval statistics for Samsca. She suggested that the DUR Board may wish to keep the criteria, since it appears to be working well.

Neal Catalano stated that some of the wording in the criteria is confusing. He suggested better wording for the criteria, based on prescribing information from the package insert.

Dr. Yau asked how to best define hyponatremia if the serum sodium is greater than 125? Is it based on exhibiting symptoms of hyponatremia? Possible wording for new criteria was proposed. Neal suggested, "Documentation that hyponatremia is symptomatic if serum sodium is > 125, and fails to respond to...."

Kumar Shah suggested that changes to the PA be italicized so that it is obvious where the changes are. Mr. Shah also suggested some formatting changes that make the PA criteria easier to interpret. There are other PA criteria with hierarchical bulleting, and this format would make sense for complex criteria such as these.

Robyn summarized the corrections proposed, and stated that she will type and circulate the changes to the DUR Board members for correction prior to the next meeting. The Board will vote to formalize revised criteria at the next meeting.

George Hamblin moved to bring back revised criteria for a formal vote in August. Kathy Goodfellow seconded the motion. The motion was approved unanimously by Ms. Goodfellow, Dr. Knudson, Dr. Yau, Mr. Hamblin, Mr. Catalano, Mr. Shah, and Dr. Dalpiaz.

- 6 Review of Xyrem Criteria: Robyn Seely presented the current Xyrem criteria in use by Utah Medicaid, and provided utilization statistics. She suggested keeping the criteria the same.

Neal Catalano stated that some of the literature stated that the minimum age was 16. Robyn stated that this is not in the FDA labeling, so Medicaid would like to keep the age at 18.

The Board asked if this is metabolized to GHB. Neal stated that it is, but distribution is also very tightly controlled, and the prescriber needs to enroll in a prescriber program and see the patient every 3 months. Neal proposed having more frequent PA updates, since the patient needs to be seen every three months. Since the patient will not get the drug unless they are seen every 3 months, others felt that this was unnecessary and created too great of an

administrative burden.

Dr. Dalpiaz moved to keep the form as is. George Hamblin seconded the motion. The motion was approved unanimously by Ms. Goodfellow, Dr. Knudson, Dr. Yau, Mr. Hamblin, Mr. Catalano, Mr. Shah, and Dr. Dalpiaz.

- 7 Gabapentin extended release formulations and high doses: Dr. Carin Steinvoort from the University of Utah College of Pharmacy addressed the Board on the two new products Gralise and Horizant, and presented her report. Additionally, she addressed the use of high dose gabapentin in the Utah Medicaid population.

Robyn prepared proposed prior authorization criteria based on FDA approved indications for each product. She also suggested limiting high use generic gabapentin.

Tim asked about the potential for off-label use in the extended release products. Dr. Steinvoort stated that they are not substitutable due to different kinetics. The PA criteria would limit the use to FDA approved diagnoses. Medicaid is prevented from managing seizure medications, but this medication is not approved for and has not been studied for seizures.

Dr. Yau added that gabapentin has found its use in psychiatric patients, and sometimes it is used for its calming effect. Robyn asked if psychiatrists often go above 1800mg per day. Dr. Yau stated that the dose is often elevated, because it is fairly safe.

Robyn asked Tim if the two extended-release formulations could be regulated due to mental health use of gabapentin. Tim stated that the extended release formulations are not FDA-approved for mental health or epilepsy, and in the absence of clinical trials to support their use in these areas, they should not be considered mental health or epilepsy drugs.

Dr. Yau felt that the Board should not address high dose generic gabapentin because of use in mental health, but that the Board should approve the criteria for the two extended release formulations.

Kathy Goodfellow moved to accept the criteria as proposed. Dr. Yau seconded the motion. The motion was approved unanimously by Ms. Goodfellow, Dr. Knudson, Dr. Yau, Mr. Hamblin, Mr. Catalano, Mr. Shah, and Dr. Dalpiaz.

- 8 Review and approval of the minutes: Jennifer corrected the date in the minutes to June 9, 2011. Kathy Goodfellow corrected the spelling of her name. Dr. Knudson moved to approve the minutes with the changes. Mr. Shah seconded the motion. The motion was approved unanimously by Ms. Goodfellow, Dr. Knudson, Dr. Yau, Mr. Hamblin, Mr. Catalano, Mr. Shah, and Dr. Dalpiaz.

The next DUR Board meeting was scheduled for Thursday August 11, 2011.

The DUR Board Prior Approval Subcommittee considered 3 petitions this month. One petition was

approved.

Minutes prepared by Jennifer Zeleny