



STATE MEDICAID DUR BOARD MEETING
 THURSDAY, August 11, 2011
 7:00 a.m. to 8:30 a.m.
 Cannon Health Building
 Room 125



MINUTES

Board Members Present:

Mark Balk, PharmD.
 Neal Catalano, R.Ph.
 Tony Dalpiaz, PharmD.
 George Hamblin, R.Ph.

Bradford Hare, M.D.
 Joseph Miner, M.D.
 Kumar Shah
 Joseph Yau, M.D.

Board Members Excused

Cris Cowley, M.D.
 Kathy Goodfellow, R.Ph.

Peter Knudson, D.D.S.

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

Merelynn Berrett, R.N.
 Rick Sorensen, R.N.
 Annette Leonard, R.N.
 Tim Morley, R.Ph.
 Robyn Seely, PharmD.

Heather Santacruz, R.N.
 Marisha Kissel, R.N.
 Bobbi Hansen, CPhT.
 Jennifer Zeleny, CPhT., MPH

Other Individuals Present:

Sabrina Aery, BMS
 Kim Eggert, Gilead
 John Stockton, Astellas
 Charissa Anne, J & J
 Gary Oderda, U of U

CarrieAnn Madden, U of U
 Lori Howarth, Bayer
 Alan Bailey, Pfizer
 Gary Bailey, Forest

Meeting conducted by: Neal Catalano, R.Ph.

- 1 Housekeeping: Robyn Seely announced that she continues to work on recruiting a new Primary Care Doctor for the DUR Board.

Robyn Seely introduced Bobbi Hansen, a new pharmacy team staff member. Each Board member introduced themselves and their titles.

Review and approval of July minutes: Tony Dalpiaz moved to approve the minutes. Mr. Shah seconded the motion. The motion was approved unanimously by Mark Balk, Dr Hare, Neal Catalano, Dr, Miner, George Hamblin, and Dr. Yau.

- 2 Samsca PA Review: Robyn Seely addressed the Board, and presented Samsca PA criteria with the wording re-worked. She presented both the current wording as printed on PA criteria sheet as well as new clarified wording.

Dr. Yau stated that as he had suggested, the new wording of criteria surrounding hyponatremia and serum sodium being either above or below 125mEq/L is better.

Kumar Shah made a motion to accept the new PA criteria. Dr. Yau seconded the motion. The motion was approved unanimously by Mark Balk, Dr Hare, Neal Catalano, Dr, Miner, George Hamblin, and Tony Dalpiaz.

Kumar Shah asked if old PA criteria is saved and archived. Robyn assured him that all the documents are saved.

- 3 Brand Name Medication PA review: Robyn Seely addressed the Board, and present a proposed change to the prior authorization criteria to obtain brand name medications. Change would require proof of submission of an FDA MedWatch form.

Dr. Hamblin asked if the criteria change would include seizure medications. Robyn Seely stated that the two drugs with narrow therapeutic indexes (Dilantin and Tegretol) are excluded from criteria. Jennifer Zeleny added that anti-epileptic medications already carry their own set of PA criteria, which does not include the FDA MedWatch form.

Dr. Hamblin asked about market place supply issues and how quickly can brand name medications be substituted in these situations. Robyn Seely answered that these situations are resolved with a phone call from the pharmacy and overrides can be issued for 3 months up to one year. Jennifer Zeleny stated additionally that the ASHP website is checked to verify that there is a market place shortage and not just individual wholesalers not having the generic drug available.

Dr. Yau also asked about turn around time to obtain brand name medications. Robyn Seely stated brand name medication PA's can be issued within one business day, however if it is a market place supply issued it can be resolved with few minutes.

Dr. Hamblin asked if the request can be made by either the pharmacist or the physician. Robyn Seely confirmed that the request can be generated by either physician or if the pharmacist feels it is straight forward enough they can make the request too.

Mark Balk suggested that if it is required to submit proof of submitted MedWatch form in this situation it may be pertinent to all situations where a medication is being substituted. Robyn Seely stated that other drug substitution situations already have their own PA criteria in place requiring physicians submit a statement why they are not using the preferred drug, which obtains the same outcome from an authorization point of view.

Tim Morley stated the Utah is not the first state to consider requiring a MedWatch form for brand name substitutions. Information will be gathered and presented to show how other

states use the MedWatch form.

Tony Dalpiaz asked how will patients who are already taking brand name medications be affected by this change, and will they be required to submit proof of a new MedWatch form submission with each PA renewal. Patients currently on brand name medications would be “grandfathered” in and these new requirements would not affect their PA renewals.

Neal Catalano asked if pharmacist would be required to file and keep on hand the MedWatch form for audit purposes. Once the form is submitted for PA it will be on file and stored by Medicaid.

Mark Balk made a motion to hold off for further review of the criteria for a later date. Kumar Shah seconded the motion. The motion was approved unanimously by Dr. Yau, Dr Hare, Neal Catalano, Dr, Miner, George Hamblin, and Tony Dalpiaz.

Kumar Shah expressed that by placing generic MedWatch expectations on all PA’s they may become lost. Neal Catalano stated that the process is fairly quick online and it could become an issue for busy pharmacies.

- 4 Cholinergic Agonists for the treatment of dry mouth: Dr. CarrieAnn Madden addressed the Board; she presented evidence for the off-label use of Pilocarpine ophthalmic solution and purposed PA requirements for Pilocarpine and Cevimeline tablets.

Robyn Seely states that she did not prepare a PA criteria sheet for this because she considered if it is something that could be managed by the preferred drug list. Could possibly be managed by the PDL but P&T has not considered this.

Mark Balk questioned the policy surrounding government reimbursement for off-label use stating a PA is required. Off label use can be reimbursed if it is the preferable drug and by placing a PA on the tablets it would be accomplished.

Mark Balk stated that if off label use is to be approved then it would require two relatively large, peer reviewed studies to support it he also does not feel the evidence presented fits that criteria. Dr. Madden mentioned that the criteria she was recommending did not require failure on the ophthalmic drops, just a diagnosis of the FDA approved medications. If the recommendation is that you have to try and fail the ophthalmic drops then she agrees, the multiple study criteria would be appropriate. Neal Catalano added that for Federal government reimbursement of off label use the two studies would be required.

Dr. Madden stated that the coverage issue can stand alone, without any mention of the ophthalmic drops, due to inappropriate prescribing of cholinergic agonists along with anti-cholinergic medications. Mark Balk stated that when treating with anti-cholinergic medications it would make sense to remove the medication before prescribing a cholinergic agonist to counter-act it, however it does not appear this is happening per Dr Madden.

Dr. Miner stated that when treating with an anti-cholinergic medication if a patient comes in

complaining of dry mouth instinct is to automatically prescribe the cholinergic agonist (Pilocarpine) without realizing that they will cancel each other out, until the patient complains that the initial medication does not appear to be working.

The Board asked Dr. Yau if he experiences the same effect on his patients when taking anti-psychotics if the cholinergic agonist cancel out any effects of the initial medication. Dr. Yau stated that it does not appear to be happening and that dual prescribing of the two medications is not common practice that he sees.

Neal Catalano asked for clarification of the off label use policy. Tim Morley quoted policy regarding how many and by whom the studies must take place in order to authorize. Neal Catalano turned questioning back to Dr. Madden to make clear if there were any large studies done and stated that the board is in a tuff situation without the backing of said studies.

Dr. Yau stated that the overlapping of anti-cholinergic medication with cholinergic agonist is easy to happen when the patient is seeing multiple prescribers.

Dr. Madden stated that the use of cholinergic agonist is not highly common among Medicaid clients based off of statistics showing only 55 patients, however among these patients the prescribing of 20+ medications seems to be common.

Neal Catalano asked if there is a way to eliminate the recommend use of the ophthalmic solution and place PA criteria on the tablets to address the dual prescribing issue. He also asked if there were any visitors from the public that would like to comment or address this topic, none present.

The Board asked if there problems with the brand name prescribing of the tablets. Robyn Seely stated that if the generic drops cost less than the brand name tablets than they can be considered for a preferred status.

Mark Balk made a motion to delay the discussion and have the P&T committee review for consideration to be added to the PDL. Dr. Hare seconded the motion. The motion was approved unanimously by Dr. Yau, Kumar Shah, Neal Catalano, Dr, Miner, George Hamblin, and Tony Dalpiaz.

- 5 Sprycel PA Criteria: Robyn Seely addressed the Board, and presented evidence for coverage of and proposed prior authorization criteria for Sprycel. She also presented current PA criteria for Tassigna, and recommended that the criteria for Sprycel be the same.

Dr. Miner asked about the requirement that therapy include the use of Gleevec. Robyn Seely stated that some patients start with other medications in addition to the Gleevec, and this requirement is only asking that the Gleevec be among the previous treatments.

Neal Catalano asked if the ‘documented intolerance...to Gleevec’ requirement can be done away with. Mark Balk suggested that the PA requirement is not necessary for either drug if they are first line agents. Robyn Seely stated that she recommended keeping the drugs on PA

due to cost.

Robyn Seely recognized Sabrina Aery (appearing in place of Mr. Joseph Broughman). Sabrina re-iterated and confirmed the points that Robyn had presented. She added that the mandated rebates on Sprycel make it cheaper than Gleevec.

Tony Dalpiaz asked if the PA requirements are to follow the labeled indications then should there be the same PA criteria for Gleevec. Mark Balk added that if the criteria is all the same then there should either be a PA on all three medications or none of them.

Mark Balk made a motion to not require PA on Tassigna and to cover Sprycel without PA. George Hamblin seconded the motion. The motion was approved unanimously by Dr. Yau, Kumar Shah, Neal Catalano, Dr. Miner, Dr. Hare, and Tony Dalpiaz.

- 6 The next DUR Board meeting was scheduled for Thursday September 7, 2011.

Minutes prepared by Bobbi Hansen