Minutes

Drug Utilization Review Board Meeting

September 10, 2008

Meeting Purpose: Quarterly Open Board Meeting 6:00-8:00 P.M.
Meeting opened at 6:10 P.M. by Chairman, Brian O'Neil.

Agenda Items:

I.	**Welcome and Introductory Remarks**
II.	**Acceptance of June 2008 DUR Board Minutes**
III.	**Incretin-Based Therapies Update**
IV.	**Revlimid Initiative**
V.	**Regranex Initiative**
VI.	**Azole Antifungal Initiative**
VII.	**MassHealth Drug List**
VIII.	**DUR Operational Update**
IX.	**MassHealth Update**

Agenda Item	Discussion	Conclusions/Follow Up
Review of Minutes	The Board reviewed and accepted the minutes to the June 11, 2008, DUR Board meeting with no changes noted.	**Conclusion**
Action		**Follow Up** Minutes accepted as written.

Agenda Item	Discussion	Conclusions/Follow Up
Incretin-Based Therapies Update	Incretin-based therapies in the treatment of type 2 diabetes mellitus were reviewed and discussed. Clinical trials and guidelines for Byetta and Januvia were reviewed. It was noted that the current high denial rate of Byetta PA's are most likely due to the requirement of an Insulin trial. Instead it is suggested to change the requirements for Byetta to 2 oral antihyperglycemic agents from different classes at adequate doses. HbA1c modified to >7% for both medications A brief discussion about lifestyle changes regarding diabetes management followed. Diet and exercise are a natural first step in disease management but are outside of the realm of this discussion.	**Conclusion** Guidelines for Byetta and Januvia reviewed and slight modifications will be implemented

Action	Remove insulin trial as a requirement to receive Byetta and modify HbA1c to >7% for both medications.	**Follow Up** A follow-up QA analysis will be conducted to assess the impact of the revised guidelines.

Agenda Item	Discussion	Conclusions/Follow Up
Revlimid QA	The current MassHealth guidelines for Revlimid approvals were reviewed and discussed. Recent utilization data, expenditure data, and PA requests and decisions were presented and evaluated.	**Conclusion** All prior authorizations evaluated were consistent and followed the current MassHealth guideline. Based on the review, PA should be removed.
Action	Remove Revlimid from PA	**Follow Up** Utilization numbers will be reviewed in the future to evaluate the decision in changing the PA status.

Agenda Item	Discussion	Conclusions/Follow Up
Regranex	A recent (May 2008) black box warning on Regranex regarding the increased risk of cancer-related mortality in patients using more than three tubes of the medication lead to this retrospective analysis to identify utilization within the MassHealth population. This analysis examined the possibility of developing quantity limits and prior authorization requirements.	**Conclusion**
Action	Due to the increased risk of cancer-related mortality in patients using more than three tubes, it was recommended that quantity limits be placed on this medication. The allowable amount will be one tube/month for a maximum of three months. All other subsequent requests will require prior authorization. It was asked what form(s) of cancer surfaced, causing the FDA to take this action, but this information was unclear due to the type of retroactive analysis that was performed. It was also asked if this review of a black box warning would set a standard for MassHealth to place all medications with “Black Box Warnings” on PA, and Dr. Jeffrey replied that it would not; however he noted that this would be worth looking into with legal council.	**Follow Up** Prescribers whose patients meet the following two criteria will be contacted by phone: 1. have had a lifetime exposure of > three tubes; and 2. have active prescriptions with more than three refills. The safety of the medication will be further discussed as will the rationale about why MassHealth will be placing the product on PA.

Agenda Item	Discussion	Conclusions/Follow Up
Azole Antifungal Initiative	A quality assurance analysis (QA) was performed for posaconazole and voriconazole to examine their place in therapy due to the recent publication of updated consensus guidelines.	**Conclusion** It was recommended that voriconazole should require prior authorization and posaconazole should continue to require prior authorization. The rationale on these decisions is based on a review of the consensus guidelines and the recently performed QA analysis.
Action	The QA analysis pointed out several areas for program improvement and change. A guideline will be developed which will incorporate both agents. Smart PA and POS rules will be created to help relieve prescriber PA processing. MassHealth is also pushing the Smart PA software technology to better identify members who may have started therapy in a hospital or are seen by specialists and should be relieved of the PA process. This technology is in its infancy and not ready to be used as sole PA decision processor at this time.	**Follow Up** A follow-up QA in six months will be completed to assess the outcome of the new guideline.

Agenda Item	Discussion	Conclusions/Follow Up
MassHealth Drug List	There are 23 new additions to the drug list effective October 15, 2008, and changes in prior authorization for five drugs, effective November 3, 2008. Drugs no longer requiring prior authorization are Emend Tri-fold (aprepitant) and Revlimid (lenalidomide). Select therapeutic class tables were modified to include evaluation criteria September 2, 2008, and several new therapeutic class tables were added to the drug list with evaluation criteria effective that same date.	**Conclusion** **Follow Up**
Agenda Item	**Discussion**	
DUR Operational Update	Looking at July 2007 to July 2008 the number of PA's is consistent. Call volume, number of abandoned calls and the number of appeals for the same timeframe are also fairly consistent.	**Conclusion** **Follow Up**

Agenda Item	Discussion	
MassHealth Update Dr. Paul Jeffrey	Dr. Jeffrey reported that the MassHealth pharmacy program has remained stable this year as far costs are concerned. CMS looked at nine states for generic utilization during the months of April, May, June and July. During that time frame, Massachusetts had a generic drug utilization rate of over 80%. When questioned by a member of the Board if this topped all Medicaid programs, Dr. Jeffrey stated that NHP is also close to the 80% mark. This high rate of generic utilization is probably the major reason for stability in the pharmacy program. The top three drugs are still atypical antipsychotics, and the top fourth and fifth drugs are Lamictal and Depakote. Expect to see the rankings drop for Lamictal and Depakote as soon as the generics become available for these medications. At that time, it's expected that the number four drug will probably be Suboxone. Four of the top 10 drugs are controlled substances. Risperidal is number 10 due to a recent market introduction of the generic risperidone, and is only available as a single source costly generic. However, as more generic manufacturers bring the product to the market, the cost and ranking for risperidone should continue to fall. October 1, 2008, sees the final changes to tamper evident prescriptions going into effect. CMS auditing appears to be focused on whether MassHealth is getting the word out about tamper-proof prescription pads and their requirements. This may change as we move further into the year and CMS issues further advice for the audit process. Pharmacy regulation changes will go into effect September 15, 2008. Some changes have to do with pricing around "Usual and Customary," and others have to do with granting the MassHealth Drug list refill limitation authority. Quantity limits will be changed back to 90 days for family planning medications or when MassHealth is the secondary payer and the primary allows for 90 day fills for the medication	**Conclusion** The new fiscal year is off to a good start. Revenue is being closely monitored for the next couple of months.
Action	A bulletin regarding tamper-proof prescription pads will be going out October 1, 2008. Prescriptions must contain all three tamper proof elements at that time.	**Follow Up** Dr. Jeffrey will keep bringing updates back to this group.

Meeting adjourned at 7:35 P.M.

Respectfully Submitted,

Amy Levy, R.Ph, MHP
DUR Program Director