October 21, 2009 DURB Meeting Summary

Issue	Page; Tab	Action	Notes
Roll Call			Present: Dr. Swee, Dr. Marcus, Mr. Schafer, Ms. Olson, Ms. Martinez-Rodriguez, Dr. Barberio, Dr. Gooen, Dr. Gochfeld, Dr. Condoluci, Dr. Moore, Dr. Zanna, Dr Simone Absent: Dr. Woodward, Dr. Lichtbroun, Dr. Moynihan
Review of Minutes	Pages 5-8; Tab 1	Approved	Minutes from June 25, 2009 meeting were approved and are posted to the DURB website: http://nj.gov/humanservices/dmahs/boards/durb/meeting/index.html
Secretary's Report	Page 9-10; Tab 2		First Data Bank (FDB) maximum daily dose standards were implemented in October 2009. DMAHS will provide the Board with reports during future meetings to evaluate drugs that consistently post the edit. The Sedative-Hypnotic Protocol that was approved during the June 2009 DURB meeting was implemented. Upcoming DURB meeting dates are as follows: Wednesday January 13, 2010 Wednesday April 21, 2010 Wednesday June 23, 2010 Wednesday October 20, 2010 The meetings will be held from 11 am to 12 pm in Building 7, Conference Rooms 200 A, B, and C at Quakerbridge Plaza Mercerville, NJ 08625.
Business			
A. Exemption of Prograf® from the State's Mandatory Generic Policy	Pages 11-18; Tab 3	Approved	The NJDURB was presented with an opportunity to discuss and provide a recommendation as to whether or not Prograf® (tacrolimus), an immunosuppressant should be exempt from the State's Mandatory Generic Policy. The drug is classified as a narrow therapeutic index (NTI) drug that must be monitored carefully by prescribers regardless of whether or not a patient is on a brand or a generic.

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			There is a lack of scientific data comparing the brand to the generic product to determine if switching to the generic causes harm to the patient and results in therapeutic failure. At this time, there is only one FDA approved AB rated generic available on the market. The fear is multiple generics entering the market for Prograf® (tacrolimus) manufactured by different generic companies. Physicians feel because they will be unaware of which generic product a pharmacist dispenses the patients may be adversely affected. However, pharmacists in the State of New Jersey are authorized only to dispense AB rated generics based on the FDA Orange Book. Again, emphasizing that the prescribers must initiate and continue monitoring their patients on any NTI drug. The Board recommended that the State temporarily exempt Prograf® (tacrolimus) from the Mandatory Generic Policy for a period of one year and revisit the issue during the October 2010 meeting. The Board is hopeful that more experience and post-marketing data will be available to make a scientific decision as to whether or not this immunosuppressant needs to be exempt from the policy permanently. See attachments
B. Proposed Adult Protocol for Antipsychotic Drugs	Pages 19-22; Tab 4	Approved	New Jersey and the nation have seen a tremendous increase in the use of the atypical antipsychotics [or second generation antipsychotics (SGAs) compared to the typical antipsychotics or first generation antipsychotics (FGAs)]. This increase has been attributed to their "safety" and effectiveness. In spite of the important role they play in treating serious psychiatric disorders, SGAs have been associated with negative side effects that may worsen a patient's cardiovascular profile, increase risk of weight gain, glucose dysregulation/diabetes, and dyslipidemia. DMAHS is of the opinion that it is necessary to consider and develop guidelines that encourage more appropriate use of the SGAs. A significant number of our population being treated for mental health disorders are being treated by non-psychiatrists. The disease states being treated are

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			complicated and do require a thorough knowledge of these powerful agents. An ad hoc committee of the Board presented a protocol for antipsychotic drugs in adults (18 years of age and older) to help monitor safety and ensure that these drugs are being utilized appropriately. This protocol does not limit which agents a prescriber can choose and does not encourage one agent over another. Some important protocol parameters that the Unisys Medical Exceptions Processing (MEP) unit will be monitoring will include: (1) doses above the First Data Bank (FDB) or Board approved maximum daily doses will be subject to prior authorization (PA); (2) two or more antipsychotics prescribed concurrently except for a short period of time will require a PA; (3) depot antipsychotic agents that are prescribed concurrently with oral antipsychotic formulations will require PA; and (4) concurrent use of five or more behavioral health drugs will require a PA. The State will provide the Board with data pertaining to this protocol at upcoming meetings. The Board would like to revisit this protocol in a year as well.
Informational Highlights			
1. Summary of First Data Bank (FDB) Recommendations	Pages 23-28; Tab 5		DMAHS will provide the Board with a report of the top drugs posting the new edit during future meetings.
2. Unisys Prior Authorization Report	Pages 29-32; Tab 6		Unisys is continuously improving the report presented to the Board. "Directed Intervention" has been combined with other appropriate clinical denial categories in an effort to clarify the report. Unisys provided the Board with additional information pertaining to each step of the pharmacy claim MEP/DUR process.
3. NJ HMO Prior Authorization Reporting 2nd Quarter 2009	Pages 33-40; Tab 7		The Board requested that the HMOs provide the total number of claims per quarter in order to put their denials into perspective. This information will be provided to the Board during future meetings as soon as it becomes available.
4. Top Drug Reports	Pages 41-47; Tab 8		The State provided these reports carving out institutional patients in order to identify top drugs utilized in the community setting.

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Follow-up Items from October 2009 Meeting			
Mandatory Generic Policy			DMAHS will present the exempted list of drugs to the Board for their review & clinical input. DMAHS will request that the Board provide a recommendation as to whether or not the drugs on the current list should be exempted or included from the policy.
Reports on Protocols			DMAHS will provide the Board with reports pertaining to approved protocols.
Notification to Providers Regarding DURB Approved Protocols			DMAHS will notify providers of new DUR edits & protocols that affect pharmacy claims.
DURB SFY 2009 annual report			The annual report was provided to the Board for their review and approval. No other changes were suggested. At this time the annual report is awaiting signature from both DHS and DHSS Commissioners.
Follow-up Items from previous NJDURB meetings			
HMO Denial Reporting			The State requested that the Managed Care Organizations provide a format for quarterly denials that is similar to the Unisys report. DMAHS will request that the HMOs provide the total number of claims process for each quarter in addition to the report they submit. The updated report with requested information will be available during the June or October 2010 DURB meeting.

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Retro-DUR Compliance Notification			The State will be working with Unisys to set up a process by which compliance letters can be sent to patients' prescribers concerning specific disease states. The disease states of interest include Asthma, Diabetes, Hypertension, Warfarin, and HIV-AIDS. DMAHS has also requested a Retro-DUR project related to atypical antipsychotics. The Board has requested this be presented as a formal agenda item to prioritize the projects.
Nicotine Replacement Therapy & Rebate Issue			DMAHS will provide the Board with the number of manufacturers who have rebate agreements in effect with CMS on a quarterly basis to track the extent of rebate status changes/fluctuations. The Division will provide the Board in upcoming meetings with the number of manufacturers who have signed the rebate agreements with Centers for Medicare & Medicaid Services (CMS) and Medicaid.
Medical Diagnosis Data			The Division will provide a report consisting of top diagnosis for the FFS Medicaid population based on medical claims data. This information may be useful in comparing to the top drugs utilized within this population.
Summary of First Data Bank (FDB) Recommendations			DMAHS will provide the Board with a report of the top drugs posting the new edit (edit 2100-Maximum Daily Dose) during future meetings. The report will consist of drugs that are constantly posting the edit & where the edit is overridden by the MEP Unit.

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