

DRUG UTILIZATION REVIEW BOARD
JULY 21, 2010
205 JEFFERSON STREET JEFFERSON CITY MO 65101

DUR BOARD MEMBERS PRESENT

John Newcomer, MD, Chairman
Susan Abdel-Rahman, PharmD
Randy Beckner, PharmD
Sandra Bollinger, PharmD
Ken Haller, MD
Charlene Heyde, RPh
Kirk Nelson, DO
Ginger Nicol, MD
Jennifer Passanise, FNP
Glenn Talboy, MD

DUR BOARD MEMBERS ABSENT

Joy Gronstedt, DO

MHD STAFF PRESENT

Ian McCaslin, MD, Director
Rhonda Driver, RPh, Director Pharmacy Program
Andrew Haslag, Fiscal Manager
Tisha McGowan, Unit Supervisor
Lisa Clements, Clinical Director Psychology Program
Mary Heet, RN
Jenna Twehus, RN
Allison Lauf, RN
Beth McQuaide, Special Assistant
Angela Wilson, Unit Supervisor
Jackie Hickman, Unit Supervisor
Elizabeth Short, Correspondence and Information Specialist

CONTRACTED STAFF PRESENT

Jennifer Kemp-Cornelius, PharmD, ACS
Mark Roaseau, MD, PharmD, ACS
Rick Pope, PharmD, Magellan Health Services, Inc.
Tom Beetem, RPh, IFOX
Annette Walther, RN, IFOX
Geri Roling, RN, IFOX

OTHERS IN ATTENDANCE

Susan Lewis, Mental Health America	Cindi Keele, NAMI	Donald Carpenter, Harmony Clubhouse	Jen Schwartz, Sanofi Aventis
M. Patty Laster, Genentech	Carol Curtis, Astra Zeneca	Grant Cale, BMS	Eric Blake, Merck
Lee Ding, GNF	Susan Zalenski, Johnson and Johnson	M Kloos, Pfizer	Eric Gardner, Pfizer
Diane Racicot, Strativa	Todd Pails, NNI	?, NNI	Debbie King, Amgen
Todd Houldsworth, OMJ	Jim Graham, COSI	Joe Summers, Takeda	Scott Webb, Amylin
Nick Boyer, Astra Zeneca	Mary Ann Turner, Acorda	Patty Minear, Eli Lilly	Don Larsen, Forest
Arleen Cerbone, Forest	Greg Dougherty, DSI	Mary Deane, AMAG	Chet Steckler, Purdue

*Many names on the sign in sheet were illegible. Sign in sheet on file for review.

DUR Board
July 21, 2010

Welcome, Introductions and Opening Remarks	Chairman, John Newcomer, M.D. called the meeting to order at 10:00 a.m. A quorum was established. Several new members of the Board were welcomed to their first meeting. All attendees introduced themselves. Ian McCaslin, MD, MPA, Division Director took a moment to thank all the members for their service. A folder of correspondence, pertaining to the agenda topics, received and responded to during the quarter was shared with the Board. A copy of this correspondence is available to Board members upon request.
Minutes Approval	Minutes of the April 2010 meeting were reviewed and approved as submitted.
Pharmacy Program/Budget Update	Rhonda Driver, RPh provided a background on the types of statistics that will be provided for the Boards' information each quarter to prepare the new members for the <i>Pharmacy Program Update</i> PowerPoint presentation. Ms. Driver shared slides graphing MO HealthNet eligibles, cost per work day, the average prescription cost, expenditures compared to budget, and fiscal year 2010 savings generated by the Maximum Allowed Cost (MAC) program. The two MAC programs utilized by the Division (traditional and specialty) were explained noting both lists are available on the MO HealthNet Division (MHD) Web page http://dss.mo.gov/mhd/ . Ms Driver pointed out the carve out of all managed care covered members into the fee for service (FFS) pharmacy program beginning October 1, 2009 and shared slides detailing the cost differential (savings) of providing the benefit through FFS versus managed care. Discussion ensued regarding this change indicating it was perceived as a very positive move. Other points of interest, on the pharmacy program timeline, detailed during the presentation were the implementation of Medicare Part D and the beginning of the generics incentive program. Plans to share information regarding the pharmacy tax program at a future meeting were discussed. Ms. Driver continued the presentation with a discussion of antipsychotic medications. She provided background on the previous legislative session and discussion surrounding these medications. John Newcomer, MD, Board Chairman also provided additional background on the "moratorium" on restriction of this drug class in approximately 11 states. Mrs. Driver detailed retrospective efforts in place in Missouri for approximately five years and trends noted. The misinterpretation of the current statute and concurrent under management of the class was discussed. Statistics comparing Missouri to other states in the use of these medications were shared. Data on the use of these medications in the states pediatric patients was detailed. Ms. Driver concluded the presentation with a summary of the impact of implementing a mental health drug monitoring system using the existing clinical management tools. These tools will be discussed in more detail at future meetings. It was noted that these tools allow the use of current published guidelines, input from the provider community and experts through the Division's advisory groups, and a user friendly call center. The mental health drug monitoring system will use these tools. Patients will be grandfathered on current therapies and the group was assured that patient safety is at the for-front of any recommendations made by the Division. Dr. Newcomer mirrored these statements stating the Board has never had a history of making recommendations only for the sake of cost savings and it was his belief the Board has an excellent record of protecting clinical logic. Dr. McCaslin commented on the enormous undertaking facing the new members and the Board as a whole. He also agreed that the focus of the program is on best practices. He noted that meetings are open to the public

	and input from any one is welcomed. Copies of the PowerPoint presentation used will be made available on the MHD Web page.
Review of Prior Authorization Meeting:	Copies of the agenda and draft minutes, including public hearing, from the June 17, 2010 <i>Drug Prior Authorization Meeting</i> were included in the members' meeting packet. Ms. Driver took a moment to explain the meeting/recommendation process for new members.
Implementation Schedule	An updated copy of the <i>Proposed Implementation Schedule for Edits</i> , including PDL classes was included in the Members' meeting packet and provided as a handout to all attending. The schedule had been updated with all edits approved at the last quarter's meetings. Ms. Driver thanked the group for their commitment to the program and offered this report as evidence of the hard work that has taken place. This schedule may be found on the MHD web page at http://dss.missouri.gov/mhd/cs/pharmacy/pdf/impsched.pdf
New Drug Review	<ul style="list-style-type: none"> • Discussion - Drug monographs were available for review at http://www.heritage-info.com/mocaidrx for all new products reviewed this quarter (Identified by First Data Bank in January, February, and March 2010). A listing of products recommended for open access, clinical edit, as a PDL product or for continued prior authorization was provided in the Members' meeting packet for discussion and action. This listing was also provided as a handout (see meeting packet) to all attending. Ms. Driver reviewed the new drug review process and MHD recommendations for products whose review was completed this quarter. It was noted that there are very few items on hard prior authorization as most have been moved to some type of clinical or PDL edit. • Decision – In the interest of time the Board agreed to block these and the Preferred Drug List (PDL) recommendations into one inclusive vote, pulling out any issues that might require separate discussion. New Drug recommendations were included in this block vote and approved as submitted. (See Roll Call Vote)
Clinical Edits/Psychotropic Edits Atypical Antipsychotics	<ul style="list-style-type: none"> • Discussion – A copy of the proposed criteria surrounding this drug class was included in the meeting packet and provided to all attendees. Ms. Driver reviewed the format and content of all criteria documents. She also briefly explained the clinical rules system used to edit claims coming into our MMIS system and the goal of transparent approval. A closer look at the tools used will be presented at a future meeting. Dr. Newcomer further explained the process noting that pharmacy claims are submitted real time. The approval and denial criteria for this proposal were stressed. Ms. Driver noted that the approval dosing in the edit was for adults only and was a gentle start in order to avoid an unmanageable number of calls to the call center. Post six months after the implementation data will be reviewed and changes recommended at that point. MHD has not addressed pediatric dosing at this point. Members will be asked to work to identify criteria specific to children as that management piece is planned. Dr. McCaslin expressed concerns with the grandfathering process for children. Ms. Driver responded to questions to why atypical antipsychotics were selected over typical antipsychotics noting utilization and cost. The opportunity is open to include them in future management opportunities. Ms. Driver clarified the compliance model used by MHD (90 of 120 days), the effect of spenddown on the edit process as well as the process should a patient move in and out of eligibility in response to questions from the Board. A letter from the <i>Federation of Missouri Advocates for Mental Health and</i>

	<p><i>Substance Abuse Services</i> was circulated to the group. The letter expressed overall support for utilization management and patient safety editing and expressed support for the criteria under recommendation, however expressed practical concerns for the Board's consideration including: what happens if a prescribing physician cannot be reached immediately when an alert is triggered, spendown, total number of prescriptions and co-morbidity of illnesses, and a request to add the diagnosis of "bipolar" to the SSRI and SNRI edits as it seems to have been an oversight. Cindi Keele Co-Chair of the Federation, detailed these concerns and requested grandfathering criteria be presented in writing. Ms. Driver will add details to the criteria documents. Ms. Keele stated that the Federation is pleased with the details the Division is taking into consideration as these edits are developed and generally pleased with the recommendations. Donald Carpenter, Harmony Clubhouse also addressed the Board expressing concerns on the limitation on number of prescription and asked if a process to provide an advance warning to providers might be added to the editing process. Susan Crane-Lewis, Co-Chair of the Federation echoed the support of the process to embrace patient safety however wanted to draw attention to the treatment of co morbidity of illness and concern concerning a limit of 5 psychotropic medications.(see poly-pharmacy edit) She suggested that the five medication limit be started with the pediatric population. She also commended the Division for immediately addressing concerns with the inclusion of anticonvulsant medications in the poly-pharmacy edit. A letter from the National Alliance on Mental Health (NAMI) supported the efforts of the state to establish edits for patient safety however suggested that it was more appropriate to start the process with children under 18 years of age to address the concerns for parents, providers, advocates and the public. The letter went on to detail concerns with editing adult populations at this time including the closure of two state run acute care facilities in July 2010, and difficulty in finding a psychiatrist who accepts MO HealthNet. Dr. McCaslin requested the Board expedite the review process for children using the pediatric expertise available in the membership. Comments from the Board indicated that the edits would likely support better provider involvement and felt this was long overdue.</p> <ul style="list-style-type: none"> ● Decision – Following this discussion the Board approved the Atypical Antipsychotic recommendation as presented. (See Roll Call Vote)
<p>Psychotropic Medication Polypharmacy</p>	<ul style="list-style-type: none"> ● Discussion — A copy of the proposed criteria surrounding this product was included in the meeting packet and provided to all attendees. Ms. Driver reviewed the document detailing the criteria surrounding anticonvulsants as mentioned in the atypical antipsychotic discussions above. Members suggested that anticonvulsant agents used as mood stabilizers be listed under both categories on the edit document. Discussion ensued surrounding limits for pediatric patients. General consensus was that five prescriptions for children was not uncommon. Members discussed the need for additional editing for children five and under and recommended that a limit of three be added without an annual confirmation of diagnosis for this age group. Ms. Crane-Lewis stated she felt the Federation would be supportive of this addition. Education to the providers should be provided via MO HealthNet News e-mails. ● Decision – Following this discussion the Board approved the Psychotropic Medication Polypharmacy recommendation with the suggested changes. (See Roll Call Vote)

SSRI and SNRI	<ul style="list-style-type: none"> ● Discussion – A copy of the proposed criteria documents was included in the meeting packet. Ms. Driver reviewed each document. She noted that an existing edit for SSRI's (generic products as reference products) was incorporated into the new proposal. Approval Diagnoses and recommended dosing was reviewed. Ms. Driver noted a change recommended by Dr. Parks and the Drug Prior Authorization Committee to allow one SSRI and one SNRI concurrently for 30 days. A brief discussion of serotonin syndrome ensued. A representative of Pfizer Pharmaceuticals asked for clarification of the Board's view of use of serotonic agents. He stated the published criteria document did not reflect the historic discussion of the Board. Ms. Driver clarified that the published criteria is what is in place and the discussion was to provide information in the form of a news letter. Dr. Newcomer stated the Board had actually backed away from that discussion. ● Decision – Following this discussion the Board approved the SSRI and SNRI recommendation as presented. (See Roll Call Vote)
Preferred Drug List (PDL)	<p>Products and classes under review this quarter have existing contracts through September 30, 2010. Recommended changes to the edits were bolded for easy identification. Ms. Driver explained the process used to develop the PDL including the clinical review and the financial solicitation which is completed by Magellan Health Services (formerly First Health Services, Inc.) Rick Pope, PharmD, Magellan Account Manager was introduced.</p>
Beta Adrenergic Blockers and Diuretic Combinations	<ul style="list-style-type: none"> ● Discussion – Ms. Driver reviewed the criteria document included in the meeting packet. Preferred and non preferred products were reviewed as well as approval and denial criteria. No change was recommended. ● Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Calcium Channel Blockers/Dihydropyridines	<ul style="list-style-type: none"> ● Discussion – Ms. Driver reviewed the criteria document including preferred and non-preferred products and approval/denial criteria. No change was recommended. This edit is a generally a generics first edit. ● Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Calcium Channel Blockers/Nondihydropyridines	<ul style="list-style-type: none"> ● Discussion – Ms. Driver reviewed the criteria document pointing out no changes were recommended to the current edit. ● Decision - This PDL recommendation was accepted as presented and added to the block vote. (See Roll Call Votes)
Angiotensin II Receptor Calcium Channel Blocker Cominations	<ul style="list-style-type: none"> ● Discussion – Ms. Driver reviewed the criteria document noting a new product addition, Twynsta, to non-preferred status. ● Decision - This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Cox II Inhibitors	<ul style="list-style-type: none"> ● Discussion –Ms. Driver reviewed the criteria document. No change was recommended. She noted the clinical criteria in place. ● Decision - This PDL recommendation was accepted and added to the block vote.(See Roll Call

	Votes)
Hepatitis C Agents	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document noting all products within the class remain as preferred. • Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Amylin Analogs	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document noting no change to the current edit. All products within the class remain preferred; however clinical approval criteria will remain in place to verify a diagnosis of diabetes. • Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
GLP-1 Receptor Agonists	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document including clinical approval/denial criteria to verify a diagnosis of diabetes. Victoza®, a new product, was added in the non-preferred status. A comment from Todd Paulson, Novo Nordisk noted that the denial criteria surrounding end stage renal disease is specific to Byetta® and does not apply to Victoza®. Ms. Driver noted that the edit will be changed to allow transparent approval of Victoza for patients with this diagnosis. • Decision – This PDL recommendation was accepted, with the understanding that changes will be made to allow Victoza® as first line when renal disease is noted in the patient profile, and added to the block vote.(See Roll Call Votes)
DDP-IV Inhibitors	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document including approval/denial criteria. A new product Onglyza® was added to non-preferred status. A clinical criterion is in place to confirm the diagnosis of diabetes. Comments made by the manufacturer of Onglyza®, indicated that the product was the first in the class to undergo more stringent safety reviews and the product has no contraindications or no pancreatitis. The product is not positioned as a first line product by the company. • Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Onychomycosis Antifungals	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document including preferred and non-preferred products. A new product Terbinex® was added to non preferred status. Ms. Driver reminded that this is a class that was moved from strict prior authorization several years ago. • Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Proton Pump Inhibitors	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document including preferred and non-preferred products. The addition of two new products to non-preferred status was noted. Clinical criteria remain in place. • Decision – This PDL recommendation was accepted and added to the block vote.
Ribvirins	<ul style="list-style-type: none"> • Discussion – Ms. Driver reviewed the criteria document noting no change to the current edit. Tablets remain in preferred status with capsules in non preferred status. • Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call

	Votes)
Topical Immunomodulators	<ul style="list-style-type: none"> ● Discussion – Ms. Driver summarized the criteria document noting no change to the current edit was recommended. ● Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
Topical Androgenic Agents	<ul style="list-style-type: none"> ● Discussion – Ms. Driver reviewed the criteria document noting no change to the current edit. ● Decision – This PDL recommendation was accepted and added to the block vote.(See Roll Call Votes)
ACS Healthcare Update	Jennifer Kemp-Cornelius, PharmD, Account Manager for ACS Healthcare Systems was introduced. Ms. Driver explained ACS's history with MHD starting out as a DUR vendor and has grown into our clinical vendor. Retrospective and prospective drug utilization review is a federal requirement. ACS is the company that provides the clinical rules engine and provides the electronic tools that allows the program to edit prospectively. Retrospective interventions are also provided by ACS. Dr. Kemp Cornelius briefly described some of the electronic tools used and their function Dr. Kemp-Cornelius noted that Ms. Driver has requested each member have access to CyberAccess and Cyberformance to allow each member to view actual patient data in hopes of cutting out unnecessary mailings to providers. A demonstration of the tool will be conducted in the executive session so as not to divulge actual patient data in open session. Dr. Kemp-Cornelius reviewed an intervention entitled <i>Diabetes and Statin Use</i> . Another intervention <i>Fall Risk Identification and Prevention</i> was also discussed. Sandra Bollinger, PharmD, explained this intervention was a request of the Pharmacy Association and the Show Me Falls Free Missouri Program.
Preferred Drug List Discussion/Therapeutic Classes	A handout of therapeutic categories to be considered for inclusion on the PDL for the next quarter and meeting was provided in the meeting packet and to all attendees. These categories will be an annual review of products with contracts expiring December 31, 2010. The Division will also post these classes to the Web page.
Program Statistics:	
Top 25 Drugs by Cost	Top 25 drug lists for 2009 and the first three months of 2010 were provided for the Boards' information. These reports were provided by number of claims and amount paid format. Copies were available to all attendees.
Clinical Edit Summary Report	An overview report of the clinical edit and prior authorization request transaction counts for the months of May and June 2009 was provided for all attending. The report detailed total transaction counts as well has information on the outcome (approval or denial) of the request.
Call Center Statistics	A handout illustrating pharmacy help desk call center activity was provided for all attending. Statistics for May and June 2010 were included. Also included for the Boards' information was a CyberAccess™ Report. This report detailed statistics for CyberAccess™ usage from April 2006 through June 2010 and showed how usage has grown overtime and as edits are implemented.
Program Utilization Information/Other Business	A listing of 2011 meeting dates was provided to all attendees.
Adjourn	The DUR Board went into Executive Session for the sole purpose of discussing individual participant

specific medical information. At the conclusion of these discussions the group adjourned entertaining no further business, actions or motions. (See attached roll call vote) The next meeting is scheduled for October 20, 2010.

Roll Call Votes – July 21, 2010

Member	Minutes	Antipsychotic Edit	Poly Pharmacy Edit	SSRS AND SNRII	New Drugs and PDL Recommendations	Closed Session	Adjourn
Susan Abdel-Rahman	Motion	Yeah	Yeah	Motion	Second	Second	Yeah
Randy Beckner	Yeah	Second	Yeah	Yeah	Abstained/Beta Blockers Yeah all other classes	Yeah	Second
Sandra Bollinger	Second	Yeah	Second	Yeah	Yeah	Yeah	Motion
Joy S. Gronstedt	<i>Absent</i>	Absent	Absent	Absent	<i>Absent</i>	<i>Absent</i>	Absent
Kenneth Haller	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Charlene Heyde	Yeah	Yeah	Yeah	Second	Yeah	Yeah	Yeah
Stacy Mangum	Yeah	Motion	Yeah	Yeah	Yeah	Motion	Yeah
Kirk Nelson	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
John Newcomer	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Ginger Nicol	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Jennifer Passanise	Yeah	Yeah	Motion	Yeah	Motion	Yeah	Yeah
Glen Talboy	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Vacant							

EXECUTIVE SESSION
July 21, 2010

DUR BOARD MEMBERS PRESENT

John Newcomer, MD, Chairman
Susan Abdel-Rahman, PharmD
Randy Beckner, PharmD
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Mark Roaseau, MD, PharmD, ACS
Rick Pope, PharmD, Magellan Health Services, Inc.

Minutes Review	Minutes of the April Executive Session were approved as submitted
Case Reviews	Three cases were presented by Jenna Twehaus, RN for review and recommendation by the Board. Members made recommendations for interventions in both cases.
CyberAccess Demonstration	Dr. Kemp-Cornelius demonstrated CyberAccess in more detail allowing members to view what patient data is available through the tool.
Adjourn	Executive session adjourned. (See roll call vote)