DRUG PRIOR AUTHORIZATION COMMITTEE MEETING
MARCH 17, 2011
205 JEFFERSON STREET
JEFFERSON CITY, MO 65101

Committee Members Present
Gene Forrester, RPh**,** Acting Chairman
Conrad Balcer, D.O.
Pat Bryant, PharmD
Laine Young-Walker, MD (by phone)
Morgan Sperry, PharmD, Alternate

Committee Members Absent:
Steven Calloway, RPh

MO HealthNet Staff Present:
Ian McCaslin**,** MD, MPH, Director MO HealthNet
Rhonda Driver, RPh, Director Pharmacy Program
Mark Roaseau, RPh, Clinical Pharmacist
Beth McQuaide, Special Assistant
Mary Heet, RN
Jenna Twehus, RN
Allison Lauf, RN
Andrew Haslag, Fiscal Manager
DJ Johnson, Program Development Specialist
Marguerite Heine, Medicaid Specialist
Debbie Bradley, Medicaid Specialist
Angela Wilson, Unit Supervisor
Emily Antweiler, Pharmaceutical Technician
Joan Klinger, Student Intern

Contractors in Attendance:
Rick Pope, PharmD, Magellen Health Services
Jennifer Kemp-Cornelius, PharmD, ACS
Sophie Bakes, PharmD, ACS

Others Attending:
Jason Kent, Novartis
Dan Keeney, Somaxon
Eric Gardner, Pfizer
John Harris, Abbott
Matt Wessels, Sunovion
Jason Mueller, Novartis
Stephanie Keithly, NNI
Grant Cale, BMS
Kayusen Bala, Novo Nordisk
Patty Minear, Eli Lilly
Pam Rodgers, Astellas
John Robinson, Boehringer Ingelheim
Lon Lowry, Novartis
Heith Durrence, Somaoxon
Jim Cleall, Abbott
Debbie King, Amgen
Gail Teffen, Eisai
Mike Ketcher, Nov Nordisk
Noelle Levy, Pfizer
Dave Sproat, BMS
Scott Edlehouser, Akon
Rita Lakamp, Sanofi Aventis
Eric Blake, Merck
Nathasha Dowd, Shionoji Pharma
Jim McNarara, ViiV Healthcare
Michael Grote, BMS
Terri Hurley, Astra Zeneca
Jan Bassali, Eisai
John Stoner, Azstra Zeneca
Mike Kloos, Pfizer
Susan Zalenski, J & J
Tome McRae, GSK
John Valenti, Sanofi Aventis
Nick Boyer, Astra Zeneca
Andy Becker, Boehringer Ingelheim
Todd Houldsworth, OMJ
James Osborne, GSK
Tim Hutcherson, UMKC, DI
Bryon Goeckner, BMS
Jared Lurk, Novartis
Randy Beckner, GSK
Jeff Knappen, Allergan
Carol Curtis, Astra Zeneca
Jeff, Himmelberg, GSK
Matt Jackson, Astellas
Sandy Dirks, Sunovion
Barbara Green, MD

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

Welcome, Introductions and Opening Remarks	Acting Chairman, Gene Forrester, RPh called the meeting to order at 10:00 a.m. Laine Young-Walker, MD was welcomed as a new member. Dr. Young –Walker replaces Joe Parks, MD on the Committee. Student Intern Joan Klinger was introduced by Rhonda Driver, RPh, Director Pharmacy Program. A folder of correspondence received and responded to during the quarter, pertaining to the agenda topics, was shared with the Committee. A copy of this correspondence is available to Committee members upon request.
Minutes Approval	Minutes of the meeting held January 7, 2011 meeting were reviewed and approved as submitted.
Pharmacy Program/Budget Update	Andrew Haslag, Fiscal Manager stated the pharmacy budget was in line with this fiscal year's appropriation. The process for budgeting next fiscal year is in process and moving through the legislature. Ms. Driver presented slides to update the group on program statistics. These included expenditures compared to budget, participant growth and average prescription costs. Ms. Driver spoke to the sunset of the MoRx Plan which is scheduled for September 2011. Beginning in August 2010 a comprehensive review of the program was completed by the Legislative Oversight Committee. Missouri is one of 26 states who operate a Part D pharmacy assistance benefit plan. At this time there are four bills moving through the General Assembly to reauthorize the Plan. What MoRx is today and the Plan's mission was summarized. Ms. Driver reviewed who qualifies for MoRx and elaborated on the difference between dual and non dual members. Dual members or those who have both Medicare and Medicaid are auto enrolled into one of the preferred drug plans in Missouri, while non-duals must apply and meet income guidelines. Approximately 72% of the membership is dual. Another 17% are considered partially dual; while the non-duals make up the remaining 11% of the membership Ms. Driver discussed the profile of a typical MoRx member. She shared the benefits a member receives from the plan. It was noted that enrollment into the plan began in January 2006 and at the end of December 2010 there were 209,796 members enrolled. Per member per month costs were provided. The program has grown over the years however the level of appropriation has not changed. Ms. Diver noted that changes within the Affordable Care Act are slated to close the coverage gap or doughnut-hole for non-duals over the next several years. Plans to do this include a $250.00 rebate in 2010 for Part D enrollees with spending into the coverage gap, a 50% discount on total cost brand name drugs prescribed in the gap, and over time Medicare will gradually phase in subsidies for brand and generic drugs in gap. MHD is following closely to determine how this will impact MoRx.
DUR Report	Ms. Driver reported the DUR Board reviewed, at their January meeting, and concurred with the recommendations made by the Drug Prior Authorization (PA) Committee at the December meeting. This included the PA Committee's recommendation to hold back the topical analgesic edit and consider other placement of the products as they are rolled into the Preferred Drug List (PDL).
Old Business	

Implementation Schedule	An updated copy of the Proposed Implementation Schedule for Edits, 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 which will be implemented in April, May and June 2011. This schedule may be found on the MO HealthNet Division's (MHD) Web page at http://dss.missouri.gov/mhd/cs/pharmacy/impsched.pdf
New Business	
Short Acting Narcotics Single Agent Clinical Edit	• **Discussion –** Ms. Driver provided background surrounding the decision to begin editing these drugs. Previously only methadone was edited by the program. Input from the provider community regarding the potential for fraud and abuse of these products prompted a look at these classes. In order to be more consistent and in line with the editing placed on long acting narcotics, MO HealthNet developed edit criteria for short acting narcotics as well. Ms Driver reviewed the criteria noting approved diagnosis codes and product daily dosing limitations. She noted that the Division will strive to identify acute pain diagnosis codes in order to allow transparent approval for acute situations. Ian McCasin, MD, MPH, Director MO HealthNet remarked that comments were welcome and plenty of room for input exists as the presentation of the criteria rolls through both advisory groups. He spoke to the intent of the edit and expressed the state's support of providing treatment and counseling for those with substance abuse problems. MHD will address concerns that Codeine use for cough will hit the edit. • **Public Hearing –**No comments were entered. • **Decision –** Members voted to accept the recommendation as presented, (See Roll Call Vote)
Short Acting Narcotics Combination Therapy Clinical Edit	• **Discussion –**Ms Driver reviewed the criteria noting approved diagnosis codes and product daily dosing limitations • **Public Hearing –** No comments were entered. • **Decision –** Members voted to accept the recommendation as presented, (See Roll Call Vote)
New Drug Review	• **Discussion –** A listing of products recommended for open access, clinical edit, as a preferred drug list (PDL) product or continued prior authorization was provided in the Members' meeting packet for discussion and action. This listing was also provided as a handout to all attending. Ms. Driver reviewed MHD recommendations. For drugs identified as new through a unique GCN in October, November and December 2010. Ms Driver noted that the FDA has recently removed a large amount of cough and cold products from the market. MHD is currently reviewing and at the June meeting a revised cough and cold products listing will be presented for discussion. In response to a question Ms. Driver explained the process that has removed these products and the steps MHD is taking to identify what is still available. • **Public Hearing –** Sandy Dirks, PharmD, Sunovion Pharmaceuticals, Inc. presented slides to overview the product Latuda. Dr. Dirks discussed the treatment and impact of medications used to treat schizophrenia. Indications and dosing were reviewed. Uniqueness of the product was discussed. Registration Studies and a food affect study were summarized. Efficacy, adverse reactions, including discontinuation rates no greater than 2% and safety data was shared. Metabolic affects for 6, 9 and 12 month data were discussed. Bryon Goeckner, BMS spoke in support for Kombiglyeze XR. Dosing was

	discussed. Advantages including spray coating technology which allows the addition of Onglyza to metformin without increasing the size of the tablet were noted. Two large trials to demonstrate efficacy were summarized. Side effects were reviewed. Preferred status was requested for the product. Ms. Driver clarified the terminology "under solicitation" in response to a question. A letter from the Gateway Chapter of the National Multiple Sclerosis (MS) Society, in support of new product Gilenya, was shared with the Committee. The letter stressed the importance of an oral medication in this class. Barbara Green, MD spoke in support of Gilenya. Dr. Green is the director of a MS Center in St. Louis and shared her experiences in the treatment of MS. She discussed the affect of break through medications on the treatment of the disease since their introduction in 1993. She also stressed the value of the first oral medication in this class and discussed its dosing and unique mechanism of action. She summarized two trials, and efficacy of the product. • **Decision –** Following discussion and presentation(s) members voted to accept the new drug recommendations as presented, (See Roll Call Vote)
Preferred Drug List (PDL) Annual Review:	Products under review this quarter are currently on the PDL. Contracts will expire in June therefore an annual review of these classes was conducted. Approved changes will be implemented in July 2011. Recommended changes to the current edits were bolded on the criteria documents presented (See Meeting Packet), for easy identification.
Androgen Hormonal Inhibitors	• **Discussion –** Ms. Driver reviewed the criteria document .The new product Jalyn® was added to the edit in non preferred status. Uroxatral was moved into preferred status. • **Public Hearing-** No public comment was entered. • **Decision –**Members voted to accept the edit as presented. (See Roll Call Vote)
Antiemetics-Oral	• **Discussion –** Ms. Driver reviewed the criteria document pointing out clinical criteria that will remain in place for Lotronex® and Emend® however much of the clinical criteria was removed last year. Three new products were added to non preferred status (Sancuso®, Zuplenz® and Metozolov ODT®) The edit is a generics first edit. • **Public Hearing-** No public comment was entered. • **Decision –**Members voted to accept the edit as presented. (See Roll Call Vote)
Benzoyl Peroxide /Clindamycin Topical Agents	**Discussion –**Ms. Driver reviewed the criteria document noting the addition of one new product, Acanya® to non-preferred status and the movement of Duac CS® to the non-preferred side. • **Public Hearing-**No comments were entered. • **Decision –** The recommendation was accepted as presented. (See Roll Call Vote)
Beta Adrenergic Agents Long Acting	• **Discussion –**Ms. Driver reviewed the criteria document. MHD was recommending no change to the edit. Both products within the class are preferred agents. • **Public Hearing-** No public testimony was entered. • **Decision –** The Committee voted to accept the edit as presented. (See Roll Call Vote)

Beta Adrenergic Agents Nebulized	• **Discussion –**Ms. Driver reviewed the criteria document. A trial on one preferred agent will allow transparent approval of a non-preferred agent. No changes were recommended. • **Public Hearing-** No public testimony was entered. • **Decision –** The edit was accepted as presented. (See Roll Call Vote)
Beta Adrenergic Agents Short Acting	• **Discussion –**Ms. Driver reviewed the criteria document noting no change was recommended to the current edit. • **Public Hearing-** No public testimony was entered. • **Decision –** Members voted to accept the edit as presented. (See Roll Call Vote)
COPD Anticholinergics	• **Discussion –** Ms. Driver reviewed the criteria document and approval recommendations, including a trial and failure on three preferred agents for transparent approval of a non-preferred agent. No product status changes to the current edit were proposed. • **Public Hearing-** No public testimony was entered. • **Decision –** The Committee approved the edit as presented. (See Roll Call Vote)
Growth Hormones	• **Discussion –**Ms. Driver reviewed the criteria document. Members were reminded that clinical edit criteria will remain in place as well. Two new products were added to the class. Increlex® (preferred status) and Egrifta® (non preferred status) are growth hormone releasing agents. Additional clinical criteria were added to the edit for these products. • **Public Hearing-**A scheduled presentation by Pfizer was waived. No comments were entered. • **Decision –** Members approved the edit as presented. (See Roll Call Vote)
Hematopoietic Agents	• **Discussion-** Ms. Driver reviewed the proposed criteria document, including clinical edit criteria that will remain in place. All products remain preferred. • **Public Hearing-** No public testimony was entered. • **Decision –** The Committee approved the edit as presented. (See Roll Call Vote)
Inhaled Corticosteroids	• **Discussion –** Ms. Driver reviewed the criteria document noting the addition of a new product, Dulera® to preferred status. Approval criteria, looking for appropriate diagnosis was noted. • **Public Hearing-** A scheduled presentation by Astra Zeneca was waived. No comments were entered**.** • **Decision –** The edit recommendation was approved as presented. (See Roll Call Vote)
Insulins	• **Discussion –** Ms. Driver reviewed the criteria document. No changes were recommended. • **Public Hearing-** No public testimony was entered. • **Decision –**Members approved the edit as recommended. (See Roll Call Vote)
Long Acting Insulins	•**Discussion –**Ms. Driver reviewed the criteria document. No change was recommended and all products in this category remain as preferred agents. • **Public Hearing-** No public testimony was entered. • **Decision –** The edit was approved as presented. (See Roll Call Vote)

Rapid Acting Insulins	•**Discussion –**Ms. Driver reviewed the criteria document noting no recommended changes. • **Public Hearing-** No public testimony was entered. • **Decision –** The edit was approved as presented. (See Roll Call Vote)
Insulins-Mix	•**Discussion –**Ms. Driver reviewed the criteria document. No change was recommended. • **Public Hearing-** No public testimony was entered. • **Decision –** Members approved the recommendation without change. (See Roll Call Vote)
Low Molecular Weight Heprins	• **Discussion –**Ms. Driver reviewed the criteria document. Generic Lovenox®, Enoxaparin, was added to non-preferred status. • **Public Hearing-**A scheduled speaker for Eisai Pharmaceuticals passed. No public comments were entered. • **Decision –** The recommendation was accepted as presented. (See Roll Call Vote)
Non-Ergot Dopamine Receptor Agonists	• **Discussion –**Ms. Driver reviewed the criteria document. Ms. Driver noted this edit is turning into a generics first edit with both generics in preferred status and name brand products non-preferred. • **Public Hearing-** No public testimony was entered. • **Decision –** The Committee approved the edit as submitted. (See Roll Call Vote)
Ophthalmic NSAIDS	• **Discussion –**Ms. Driver reviewed the criteria document noting no changes to current edit. • **Public Hearing-** No public testimony was entered. • **Decision –** The edit was approved as presented.(See Roll Call Vote)
Platelet Inhibitor Agents	**Discussion –**Ms. Driver reviewed the criteria document. Warfarin was moved into the category and placed in the preferred status. Ms. Driver clarified the addition of this product. Pradoxa®, a new product, was also added to preferred status. A recommendation to re-title this edit was made. • **Public Hearing-** No public testimony was entered. • **Decision –** The edit was approved as presented.(See Roll Call Vote)
Sedative Hypnotics	• **Discussion –**Ms. Driver summarized the criteria document including approval/denial criteria. It was noted that for patients with diagnostic history of substance abuse a trial of one preferred agent vs. three will allow transparent access to non-preferred agents. Zaleplon® was recommended for movement from non-preferred to preferred status and Lunesta® from preferred to non-preferred status. Two new products Zolpimist® and Zolpidem ER® were added in non-preferred status. Discussion ensued regarding limitations on long term use for products not recommended for over 6 to12 weeks of therapy. The effect on the call center and lack of an alternative other than life style changes were considered. The Committee requested duration of therapy study for clinical consideration. • **Public Hearing-** Heith Durrence, PhD, Somoaxon presented slides on the product Silenor®. Dr. Durrence provided statistics on insomnia. Indications were discussed. The product has no short term restriction. He also noted co-morbidities of insomnia and focused on the reduction of pain threshold. The presentation focused on sleep maintenance and in particular early morning awakenings without residual sedation. He discussed the differences of the product from dyphenhydromine. Studies were summarized. Efficacy, safety, and comparison of adverse events data was shared. Dr. Durrence noted the trials of Silenor® showed no evidence of abuse potential or no effect with discontinuance.

	• **Decision -** Members approved the recommendation with the movement of Silenor® into the arm allowing transparent approval following trial and failure on one preferred agent. Clinical criteria will be discussed at a future meeting when information on duration of therapy is available. (See Roll Call Vote)
Skeletal Muscle Relaxants	• **Discussion –**Ms. Driver the criteria document. The addition of Metaxolone to non-preferred status was the only recommended change. • **Public Hearing-** No public testimony was entered. • **Decision -** Members approved the recommendation without change. (See Roll Call Vote)
Statins (HMG Co-A Reductase Inhibitors	• **Discussion –**Ms. Driver reviewed the preferred and non-preferred agents and outlined the approval criteria to allow first line access to high potency statins. The addition of Livalo® to non-preferred status was noted. • **Public Hearing-**A scheduled presentation was waived by Astra Zeneca. • **Decision –** Following this discussion the members approved the PDL recommendation without change. (See Roll Call Vote)
Triglyceride Lowering Agents	• **Discussion –**Ms. Driver reviewed the criteria document, noting no changes to the edit. • **Public Hearing**-No public comment was entered. • **Decision –**Following discussion and presentations the Committee approved the edit as recommended. (See Roll Call Vote)
Urinary Tract Antispasmodics	• **Discussion –** Ms. Driver reviewed the criteria document. Three additions to non- preferred status were discussed. (Trospium, Flavoxate, and Urogesic Blue®). Ms. Driver also pointed out the approval criteria includes a transparent option to reach the approved product for pediatric patients. • **Public Hearing-** Scheduled presentations by Astellas and Pfizer were waived by each company. • **Decision -** The Committee approved the edit as presented. (See Roll Call Vote)
Preferred Drug List Discussion/ Therapeutic Classes	A handout of therapeutic categories for review and inclusion in the PDL during the next quarter was included in the meeting packet and to all meeting attendees. This listing will be posted to the Division's Web page at http://www.dss.mo.gov.mhd.
Program Utilization Information	
Top 25 Drugs by Cost	Top 25 drug list was provided for the Committees' information. This report was provided in two formats; ranked by number of claims and ranked by amount paid and detailed all quarters of 2010. Copies were available to all attendees.
Clinical Edit Summary Report and Call Center Statistics	A handout detailing pharmacy help desk call center activity was provided for all attending. Statistics for February 2011 were included. Information regarding CyberAccess™ Logging was provided. Jennifer Kemp-Cornelius, PharmD, ACS HealthCare, Inc. summarized the report in detail for the group. Information provided was from January 1, 2004 to February 28, 2011.
Adjourn	The next meeting is scheduled for June 16, 2011. The Drug PA committee went into Executive Session for the sole purpose of discussing individual recipient specific medical information. At the conclusion of these discussions the group adjourned entertaining no further business, actions or motions. (See attached roll call).

Roll Call Votes – March 17, 2011

Member	***Minutes***	***New Drug Review***	***Short Acting Narcotics***	***Androgen Hormone***	***Anti-emetics***	***Benzoyl***	***Betas***	***COPD***	***Growth Hormone***	***Hematopoietic***	***Inhaled Corticosteroids***
Steven Calloway, R.Ph.	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Gene Forrester, R. Ph.	**Yeah**	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Pat Bryant, Pharm.D.	**Second**	**Second**	**Second**	**Second**	**Motion**	**Second**	**Motion**	**Second**	**Motion**	**Second**	**Second**
Conrad Balcer, D.O.	***Motion***	***Motion***	***Motion***	***Motion***	**Second**	***Motion***	**Second**	***Motion***	**Second**	***Motion***	***Motion***
Laine Young-Walker	Absent	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Morgan Sperry, Pharm.D.											

Member	***Insulins***	***Low Molecular Weight Anticoag***	***Non Ergot Dopamine***	***Ophth NSAIDS***	***Platelet Inhibitor***	***Seditive Hypnotics***	***Skeletal Muscle Relaxant***	***Statins***	***Trigly Lowering Agents***	***UTA***	***Closed Session and adjourn***
Steven Calloway, R.Ph.	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Gene Forrester, R. Ph.	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Pat Bryant, Pharm.D.	**Second**	**Second**	**Motion**	**Motion**	**Second**	**Second**	**Second**	**Motion**	**Motion**	**Motion**	**Second**
Conrad Balcer, D.O.	***Motion***	***Motion***	**Second**	**Second**	***Motion***	***Motion***	***Motion***	**Second**	**Second**	**Second**	***Motion***
Laine Young-Walker	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Morgan Sperry, Pharm.D.											

EXECUTIVE SESSION
March 17, 2011

Committee Members Present
Gene Forrester, RPh**,** Acting Chairman
Conrad Balcer, D.O.
Pat Bryant, PharmD
Laine Young-Walker, MD (by phone)
Morgan Sperry, PharmD, Alternate

Committee Members Absent:
Steven Calloway, RPh

Contractors in Attendance:
Rick Pope, PharmD, Magellen Health Services
Jennifer Kemp-Cornelius, PharmD, ACS
Sophie Bakes, PharmD, ACS

MO HealthNet Staff Present:

Rhonda Driver, RPh, Director Pharmacy Program
Mark Roaseau, RPh, Clinical Pharmacist
Beth McQuaide, Special Assistant
Mary Heet, RN
Jenna Twehus, RN
Allison Lauf, RN
Andrew Haslag, Fiscal Manager
DJ Johnson, Program Development Specialist
Marguerite Heine, Medicaid Specialist
Debbie Bradley, Medicaid Specialist
Angela Wilson, Unit Supervisor
Emily Antweiler, Pharmaceutical Technician
Joan Klinger, Student Intern

	EXECUTIVE SESSION
Minutes Review	Minutes of the January 7, 2011 Executive Session were approved as submitted
Case Reviews	No cases were presented for review.
Adjourn	Executive session adjourned. (See roll call vote)