DRUG PRIOR AUTHORIZATION COMMITTEE MEETING
MARCH 12, 2009
205 JEFFERSON STREET
JEFFERSON CITY, MO 65101

Committee Members Present
Gene Forrester, RPh
Conrad Balcer, D.O.
Pat Bryant, PharmD
Steven Calloway, RPh
Henry Petry, D.O., Chairman
Morgan Sperry, PharmD, Alternate

Committee Members Absent:
Joe Parks, MD

Contractors in Attendance:
Rick Pope, PharmD, First Health Services
Mark Roaseau , PharmD, ACS-Heritage
Jennifer Kemp-Cornelius, PharmD, ACS-Heritage
Bethany Noble, ACS-Heritage

MO HealthNet Staff Present:
George L. Oestreich, PharmD, Deputy Division Director
Rhonda Driver, RPh, Director Pharmacy Program
Jay Bryant-Wimp, RPh, Clinical Pharmacist
Allison Lauf, RN
Jayne Zemmer, Social Services Manager
Andrew Haslag, Fiscal Manager
Tisha McGowan, Unit Supervisor
Beth McQuaide, Special Assistant
DJ Johnson, Program Development Specialist
Julie Trimble, Medicaid Specialist
Carol Stock, Correspondence and Information Specialist
Debbie Bradley, Medicaid Specialist
Angela Wilson, Medicaid Specialist
Renee Riley, Medicaid Specialist
Lisa Clements, PhD, Clinical Director, Psychology Program

Others Attending:
Todd Houldsworth, OMJ
David Chapman, UCB
Thomas Yuran, AstraZeneca
Peggy Brand, Roche
Eric Blake, Schering-Plough
Matt Dull, Artia Solutions
Don Larsen, Forest
Joe Summers, Takeda
Ron Schnare, Shire
Joan Houster, Centocor
Rick Barbarash, Aztra Zeneca
Steve Moss, Sanofi-Aventis
Lee Marcum, Marcum
Rob Kilo, Pfizer
John Stoner, Astra Zeneca
Hoa Pham, Amgen
Pam Rodgers, Astellas
Josh Cox, Forest
Ted Barden. Alcon
Matt Suorfi, Elsai
M Kunbali, Centocor
Daniel J. Zims, Guest
Dan Riouthieaux, Sanofi-Aventis
Matthew Stafford, Merck
Phil King, Pfizer
Molly Skelsey, Astra Zeneca
Debbie King, Amgen
Dave Case, Astellas
Pam Sardo, Abbott
Lon Lowrey, Novartis
James Osborne, GlaxoSmithKline
Jessica Hurtz, Novo Nordisk
John Valenti, Sanofi Aventis
Brian Miller, GlaxoSmithKline
Cindy Harper, UCB
Randy Beckner, GlaxoSmithKline
Jeff Knappen, Allergan
John Harris, Abbott
Jeff Himmelberg, GlaxoSmithKline
Richard Mesquias, Eli Lilly
Ellen McMahen, Pfizer
Anthony DeFilippo, Novo Nordisk

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

Welcome, Introductions and Opening Remarks	Chairman, Henry Petry, D.O. called the meeting to order at 10:00 a.m. 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 the Members upon request. George L. Oestreich, PharmD, Deputy Division Director thanked the Committee for their flexibility in allowing the meeting date change.
Minutes Approval	Minutes of the meeting held December 18, 2008 were reviewed and approved with corrections to the attendee list.
Pharmacy Program/Budget Update	Due to a lengthy agenda Dr. Oestreich did not present the usual PowerPoint program update slides. He did provide a brief update on the pharmacy budget, noting the program lapsed dollars again this fiscal year and that discussions were underway in the legislature for next year. He also updated the attendees on the status of the Administrative Services Organization (ASO) expansion and the position of the Chronic Care Improvement Program (CCIP) during these budgetary discussions. Dr. Oestreich summarized discussions with the Centers for Medicare and Medicaid Services (CMS) surrounding the pharmacy provider tax. He discussed the status of the Clinical Services Unit following statewide personnel cuts and how the Unit plans to shift workloads. Dr, Oestreich also explained that several of the Preferred Drug List (PDL) classes scheduled for review had been selected for extension of existing contracts, creating a third annual review group. This will decrease the number of products requiring annual review each quarter. The fourth quarter will be used to add new classes to the PDL. He noted that the Unit is working on developing a separate page on the Division's Web page to devote to the advisory groups and meeting information and will continue to work toward getting this information posted as timely as possible.
DUR Report	Tisha McGowan, DUR Coordinator 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.
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. This schedule may be found on the MHD web page at http://dss.missouri.gov/mhd/cs/pharmacy/impsched.pdf
New Business	
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. Questions surrounding compounding were addressed. A more in depth discussion will be planned for a future meeting, following the release of Centers for Medicare and Medicaid recommendations. • **Public Hearing –** No public testimony was entered. • **Decision –** 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 2009 Recommended changes to the current edits were bolded on the criteria documents presented (See Meeting Packet), for easy identification.

Antiemetics-Oral	• **Discussion –** Ms. Driver reviewed the criteria document pointing out clinical criteria that will remain in place for these products. One new product (Sancuso®) was added to the non preferred agents with no other changes recommended for this class. • **Public Hearing-** No public comment was entered. • **Decision –**Members voted to accept the edit 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 pointing out the movement of Albuterol Sulfate (generic Accuneb®) to preferred status and a trial and failure of 2 preferred agents to reach a non preferred agent transparently. • **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 the movement of one product to the preferred agent side (Proventil HFA®) and the addition of a new product (Relion Ventolin HFA®) to non preferred status. Dr. Oestreich and Ms. Driver responded to questions from the Committee regarding these changes. • **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)
Hematopoietic Agents	• **Discussion –** Ms. Driver reviewed the proposed criteria document, including approval and clinical edit criteria in place. The movement of two products one from non preferred to preferred status (Epogen®) and the other from preferred to non preferred status (Procrit®) was noted. • **Public Hearing-** Maureen Kubacki, PharmD, MBA, Senior Manager Outcomes Research for Centocor Ortho-Biotech addressed the Committee in support of Procrit®. Dr. Kubacki discussed the product's indications and efficacy. She noted it is the only product within the class with the indication for HIV patients undergoing transfusion as well as for anemic patients scheduled for non vascular surgeries. Safety information was reviewed for the entire class and significant changes for the labeling of these products were discussed. Dr. Kubacki requested consideration for preferred status for Procrit®. • **Decision –** In response to Committee questions Ms. Driver explained that the clinical criteria can be updated as product labeling changes occur. Members approved the edit to allow approval for pediatric dosing for the non preferred product. MHD will request a literature review on this class from Oregon Health and Sciences University-Drug Effectiveness Review Project (DERP) (See Roll Call Vote)
Inhaled Corticosteroids	• **Discussion –** Ms. Driver reviewed the criteria document. The addition of a new product (Alvesco®) to non-preferred status was noted. Symbicort® was being recommended for movement to preferred status.

	• **Public Hearing-**Rick Barbarash, PharmD, Astra Zeneca, presented slides discussing the development of and indications for Symbicort as well as a new product indication recently approved. Efficacy and safety data were discussed. Dr. Barbarash stated the product demonstrates an onset of action within 15 minutes. • **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 pointing out the preferred and non-preferred agents. No change to the current edit was recommended. • **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 with out change. (See Roll Call Vote)
Ophthalmic NSAIDS	• **Discussion –**Ms. Driver reviewed the criteria document noting no change to the current edit. • **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. No change to the class was recommended. • **Public Hearing-** No public testimony was entered. • **Decision -** Members approved the recommendation with out change. (See Roll Call Vote)
Statins (HMG Co-A Reductase Inhibitors	• **Discussion –**Dr. Oestreich reviewed the preferred and non-preferred agents outlining significant changes to the edit. Changes to the edit included the recommendation for Altoprev® as a preferred agent; Crestor® and Lipitor® were both recommended for non preferred status. Approval criteria included a trial and failure on 2 or more preferred agents before transparent approval of a non preferred agent. Members were provided a drug class review completed by Oregon Health and Sciences University-Drug Effectiveness Review Project (DERP) and a DERP P&T Committee Brief on this class for their review. Discussion ensued regarding the number of preferred products required to trial and fail on prior to approval of a non preferred agent. Integration of the lab values into the clinical edit process will be of great benefit to this edit, however system work will take at least another year. Dr. Oestreich responded to a question from the audience surrounding the ability to edit by provider specialist. MHD would like to build edits using this criteria however the quality of the provider database and the specialty codes within it is not optimal. • **Public Hearing-**Molly Skelsey, PhD, Regional Scientific Manager with Astra Zeneca presented a PowerPoint slide presentation on the product Crestor®. Dr. Skelsey noted the product has been on the market for 5 ½ years she discussed the products efficacy and several studies/trials including the Jupiter trial, Stellar and Meteor Studies. Adverse events and laboratory values were reviewed as well as data on new

	onset diabetes in Statin outcome trials. She requested consideration for preferred status the product. Pfizer Pharmaceuticals addressed the Committee in support of preferred status for the product Lipitor. Dr. Ellen McMahon reviewed clinical outcomes in several studies and indicated that 6 of 10 of these studies (Ascot, Sparkl, Cards, Prove-It, TNT, and OACIS) formed the basis to change clinical guidelines. Product safety and drug-drug interaction information were outlined. The product has been on the market for over 10 years and safety demonstrated in over 400 trials. Adverse effects, ease of use and tolerability in respect to compliance were stressed. A new indication for the product was recently added as a result of the TNT Study. Dr. McMahon discussed myocardial infraction (MI) risk reduction and hospitalization risk for congestive heart failure (CHF). The members were asked to consider this information and consider the product for preferred status. John Stoner, Astra Zeneca and as a member of the National Lipid Association, asked the Committee to consider lowering the need to fail on 2 low potency agents before reaching a non preferred agent. • **Decision –** Following this discussion the members recommended the trial and failure criteria be lowered to one (1) or more preferred agent before transparent approval of any non preferred agent. The PDL recommendation was accepted with this change. (See Roll Call Vote)
Triglyceride Lowering Agents	• **Discussion –**Ms. Driver reviewed the criteria document, noting several changes to the edit. A new product (Trilipix®) was introduced to this class and was recommended for preferred status. Fenofibrate was moved into preferred status while Antara® was recommended for movement to non preferred status. A trial and failure of 3 or more preferred agents was proposed in order for a non preferred agent to be transparently approved. Discussion surrounding available options to lower triglycerides and active ingredients for the preferred products ensued. Lab data integration will be valuable to this edit as well and MHD will revisit this edit when the data is available. The level of usage, including number or requests while the product was under new drug review, for Lovasa® was provided in response to a Member's question. • Public Hearing-Randall Beckner, PharmD, representing GlaxoSmithKline addressed the Committee in support of Lovasa®. He described the product as unique and a medical miracle. Dr. Beckner indicated this product's safety profile was exemplary. The package insert has no warnings, contraindications or drug-drug interactions. He requested the Committee consider Lovasa® for preferred status. • **Decision –**The group recommended the trail/fail number of preferred products be reduced to 1 for transparent approval of a non-preferred agent. With this change the group approved the edit as presented. The Committee would like to revisit this class three months post implementation.(See Roll Call Vote)
Urinary Tract Antispasmodics	• **Discussion –** Ms. Driver reviewed the criteria document. No change to the current edit was recommended. • **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. No product status changes were recommended. Members were reminded that clinical edit criteria will remain in place as well. • **Public Hearing-**No comments were entered. • **Decision –** Members approved the edit as presented. (See Roll Call Vote)
Androgen Hormone Inhibitors	• **Discussion –**Ms. Driver reviewed the criteria document. No changes were recommended to the current PDL edit or criteria. • **Public Hearing-**No comments were entered.

	• **Decision –** The edit was approved as submitted. (See Roll Call Vote)
Non-Ergot Dopamine Receptor Agonists	• **Discussion –**Ms. Driver reviewed the criteria document. Changes recommended included the addition of Ropinirole and Requip® XL to preferred agents and Rquip® to non preferred status. • **Public Hearing-** No public testimony was entered. • **Decision –** The Committee approved the edit as submitted. (See Roll Call Vote)
Low Molecular Weight Heprins	• **Discussion –**Ms. Driver reviewed the criteria document. No changes were recommended to the current PDL edit or criteria. • **Public Hearing-**No comments were entered. • **Decision –** The recommendation was accepted as presented. (See Roll Call Vote)
Skeletal Muscle Relaxants	**Discussion –**Ms. Driver reviewed the criteria document. No changes were recommended to the current edit, including the clinical criteria which will remain in place for transparent approval and duration of therapy limits. Discussion surrounding this criteria ensued, however members report no difficulties in their practices. • **Public Hearing-** No public testimony was entered. • **Decision –** The recommendation was accepted as presented. (See Roll Call Vote)
Benzoyl Peroxide /Clindamycin Topical Agents	**Discussion –**Ms. Driver reviewed the criteria document. No changes were recommended to the current PDL criteria. Both products for this class remain preferred agents. • **Public Hearing-**No comments were entered. • **Decision –** The recommendation was accepted as presented. (See Roll Call Vote)
Platelet Inhibitor Agents	**Discussion –**Ms. Driver reviewed the criteria document. No changes were recommended to the current PDL criteria. A diagnostic clinical criterion remains in place as well. • **Public Hearing-** No public testimony was entered. • **Decision –** The recommendation was accepted as presented. (See Roll Call Vote)
Preferred Drug List Discussion/Therapeutic Classes	MHD elected to defer solicitation and subsequent finalization of several therapeutic classes originally scheduled to be reviewed at this meeting. These deferred classes will be reviewed at the June 18, 2009 Committee meeting. First Health Services, Inc. will contact the appropriate pharmaceutical manufacturers in April for these products. Manufacturers who had already submitted bids during the current review may choose to retain that bid or submit a replacement at that time. A handout listing the drug classes affected was provided in the meeting packet and to all attendees. This handout will also be posted to the Division's Web page at http//:www.dss.mo.gov.mhd. Dr. Oestreich responded to questions from the Committee regarding the merger or sale of companies and how supplemental contracts were affected.
Program Utilization Information	
Top 25 Drugs by Cost	Top 25 drug list for dates of service from the 4th quarter of 2007 through 3rd quarter of 2008 was provided for the Committees' information. This report was provided in two formats; ranked by number of claims and ranked by amount paid. Dr. Petry suggested the group monitor the recent FDA discussions surrounding propoxyphene and determine if action is required. 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 month of February 2008 was provide for all attending. The report provided total transaction counts as well has information on the outcome (approval or denial) of the request.
Call Center Statistics	A handout detailing pharmacy help desk call center activity was provided for all attending. Statistics for

	February 2009 were included. Information regarding CyberAccess™ Logging was provided. Jennifer Kemp-Cornelius, PharmD, ACS HealthCare, Inc. summarized the report for the group. Information provided was from April 2, 2006 to February 28, 2009. Dr. Kemp-Cornelius provided an update on the progress of bringing e-prescribing live. She stated ACS is ready to pilot e-prescribing.
Other Discussion	Lon Lowry, Novartis representing PhRMA commented on the information available through the ePocrates tool. Ms. Driver acknowledged that the language used by the tool was geared to the commercial payer and affirmed discussion with ePocrates was on going to encourage them to add terminology more appropriate for Medicaid programs, including the use of PDL and clinical edit. She stated the comments section is the key to using the tool for the MO HealthNet program. Matthew Stafford, Merck commented that his company was working with their sales representatives to help them understand and train providers on the MO HealthNet pharmacy program and were placing a significant emphasis on using CyberAccess. He encouraged others in the industry to assist in this win-win opportunity.
Adjourn	The next meeting is scheduled for June 19, 2008. 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 12, 2009

Member	*New Drug Review*	*Anti-emetics*	*Long Acting Betas*	*Short Acting Betas*	*Nebulized Betas*	*COPD*	*Hematopoietic*	*Inhaled Corticosteroids*	*Insulin*
Henry Petry, D.O.	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Steven Calloway, R.Ph.	**Second**	***Motion***	Yeah	**Second**	***Motion***	***Motion***	***Motion***	Yeah	**Second**
Gene Forrester, R. Ph.	Yeah	Yeah	***Motion***	Yeah	Yeah	**Second**	Yeah	***Motion***	Yeah
Pat Bryant, Pharm.D.	Yeah	**Second**	Yeah	***Motion***	**Second**	Yeah	Yeah	Yeah	**Motion**
Conrad Balcer, D.O.	***Motion***	Yeah	**Second**	Yeah	Yeah	Yeah	**Second**	**Second**	Yeah
Joe Parks, M.D.	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Lindsey Schnabel Pharm.D.									

Member	*Long Acting*	*Rapid*	*Mix*	*Ophth NSAIDS*	*Sed Hypnotics*	*Statins*	*Trigly Lowering Agenst*	*UTA*	*Growth Hormones*
Henry Petry, D.O.	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Steven Calloway, R.Ph.	Yeah	Yeah	**Second**	***Motion***	Yeah	Yeah	Nay	Yeah	***Motion***
Gene Forrester, R. Ph.	Yeah	***Motion***	Yeah	Yeah	***Motion***	Yeah	**Second**	**Second**	Yeah
Pat Bryant, Pharm.D	**Second**	Yeah	***Motion***	Yeah	**Second**	**Second**	Yeah	Yeah	**Second**
Conrad Balcer, D.O.	***Motion***	**Second**	*Yeah*	**Second**	Yeah	***Motion***	***Motion***	***Motion***	***Yeah***
Joe Parks, M.D.	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Lindsey Schnabel Pharm.D.									

Member	*Androgen Hormone*	*Non Erogot Dopamine*	*Low Molecular Weight Anticoag*	*Skeletal Muscle Relaxant*	*Topical Benzoyl Peroxide/ Clindamycin*	*Platelet Inhibitors*	*Closed Session*	*Adjourn*
Henry Petry, D.O.	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah	Yeah
Steven Calloway, R.Ph.	**Second**	Yeah	Yeah	**Second**	Yeah	**Second**	Yeah	Absent
Gene Forrester, R. Ph.	Yeah	***Motion***	Yeah	Yeah	***Motion***	Yeah	***Motion***	**Second**
Pat Bryant, Pharm.D	***Motion***	**Second**	**Second**			Yeah	Yeah	Yeah
Conrad Balcer, D.O.	Yeah	Yeah	***Motion***	***Motion***	**Second**	***Motion***	**Second**	***Motion***
Joe Parks, M.D.	Absent	Absent	Absent	Absent	Absent	Absent	Absent	Absent
Lindsey Schnabel Pharm.D.				Yeah	Yeah			

EXECUTIVE SESSION
March 12, 2009

Committee Members Present
Gene Forrester, RPh
Conrad Balcer, D.O.
Pat Bryant, PharmD
Joe Parks, MD
Henry Petry, D.O., Chairman
Morgan Sperry, PharmD, Alternate
Steven Calloway, RPh

Committee Members Absent
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Debbie Bradley, Medicaid Specialist
Angela Wilson, Medicaid Specialist
Renee Riley, Medicaid Specialist
Lisa Clements, PhD, Clinical Director, Psychology Program

	EXECUTIVE SESSION
Minutes Review	Minutes of the December 2007 Executive Session were approved as submitted
Case Reviews	No cases were presented for review.
Adjourn	Executive session adjourned. (See role call vote)