DRUG PRIOR AUTHORIZATION COMMITTEE MEETING
January 7, 2011
205 JEFFERSON STREET
JEFFERSON CITY, MO 65101

Committee Members Present

Steven Calloway, RPh.
Conrad Balcer, DO
Pat Bryant, PharmD by Teleconference
Gene Forrester, RPh,
Morgan Sperry, PharmD, Alternate by Teleconference

Committee Members Absent
Joe Parks, MD

Contractors Present

Jennifer Kemp-Cornelius, ACS
Rick Pope, Magellan
Sophie Backes, ACS
Bethany Noble, ACS

MO HealthNet Staff Present

Rhonda Driver, RPh, Director Pharmacy Program
Mark Roaseau, RPh, Clinical Pharmacist
Beth McQuaide, Special Assistant
Jayne Zemmer, Program Manager
Andrew Haslag, Fiscal Manager
Lisa Clements, Clinical Director, Psychology Program
D.J. Johnson, Program Development Specialist
Debbie Bradley, Medicaid Specialist
Angela Wilson, Unit Supervisor
Jenna Twehus, RN
Allison Lauf, RN
Mary Heet, RN
Carol Stock, Correspondence and Information Specialist

Others Attending

Annie Palmer, Taro
Jason Jones, Covidien
Maria Chianta, Coviien
Diane Racicot, Strativa
Michael Kloos, Pfizer
Darcie Ray, Endo
Susan Zalenski, Johnson and Johnson
Peter Michelson, St. Louis Children's Hospital
Todd Houldsworth, OMJ
Jeff Himmelberg, GSK
Raymond Carter, VCG
Patty Miner, Eli Lilly
John Harris, Abbott
Lisa Saake, Covidien
Grant Cale, BMS
Scott Edelhauser, Alcon
Kelly Reed, URL
Eric Gardner, Pfizer
Paul Seilak, Abbott
Charles Marsh, King
Jeff Knappen, Allergan
Cole Linuela, Student
Thomas Holder, Eurand
Eric Blake, Merck
Rick Wardrop, Eisai
Carol Curtis, Astra Zeneca
Jeff Patrick, Covidien

Welcome, Introductions and Opening Remarks	The meeting was called to order by acting chairman, Steven Calloway, RPh at approximately 10:30 a.m. Rhonda Driver, RPh, Director Pharmacy Program addressed the group regarding the recent need to postpone the Committee meeting due to weather and road condition concerns. Ms. Driver noted that this was one of the first times this has been done. She explained the notification process for cancelations. Staff members are able to work from home and e-mails are sent to members, the PhMARA task force, and scheduled speakers. However, when the determination to cancel is made after working hours we have no control over getting this information posted to the Webpage, as Information Technologies staff are not available until the next morning to make updates. A recorded message will be placed on our office voicemail, with cancelation information as well. Please call 573-751-6961, when in doubt of the status of a pharmacy program meeting, for the most current meeting information. Ms. Driver communicated that the membership of the Committee will be changing. Henry Petry, D.O. has resigned effective January 1, 2011, due to health reasons. Dr. Petry had severed on the Drug Prior Authorization Committee since 1992. Ms. Driver expressed the Division's appreciation for his dedicated service. MO HealthNet Division (MHD) will contact appropriate provider organizations for potential replacements for appointment by the Department of Social Services Director. Discussion ensued regarding weather the replacement was required to be a DO. MHD will check the State Statute creating the Committee. (Note: Statute was checked following the meeting. The membership requirement is for 3 practicing physicians, degree is not specified.) Ms. Driver also informed that Joe Parks, MD is resigning effective January 10, 2010. Dr. Park's schedule and Department of Mental Health responsibilities continue to grow making it harder for him to devote time to the Committee. Laine Young-Walker, MD will be appointed to the Committee as his replacement. Dr. Young-Walker's appointment will be effective on January 10, 2011. Dr. Young-Walker is familiar with the MO HealthNet process as she currently serves on the Non Pharmaceutical Mental Health Prior Authorization Committee.
Minutes Approval	Minutes for the meeting held September 16, 2010 were reviewed and approved as submitted.
Pharmacy Program/Budget Update	Andrew Haslag, Fiscal Manager reported that expenditures are in line with what the program was appropriated. He noted the Governor's State of the State Address is scheduled for January 19th. The group was reminded that the MoRx Program is set to sunset on August 31, 2011. Following an extensive review of the program, by a Legislative Oversight Review Team, MHD fully expects the program to be reauthorized and for funding to be a topic of discussion during this legislative session. Mr. Haslag and Ms. Driver answered questions regarding MoRx clawback, membership, and Medicare D annual enrollment, including discussion of the MoRx Preferred Prescription Plans (PDP). Members agree that the program was monies well spent.

DUR Report	Ms. Driver reported the DUR Board had met in October to review the recommendations made by the Drug Prior Authorization (PA) Committee at their September meeting. The Board concurred with all recommendations made by the PA Committee and the annual PDL review discussed was implemented on January 6th.
Old Business	
Implementation Schedule	An updated copy of the Proposed Implementation Schedule for Edits was included in the members' meeting packet and as a handout to all attendees. The schedule had been updated with all edits approved at the last quarter's meeting. This included the implementation following the annual review of half of the PDL done in September and October. Ms. Driver noted that all three psychotropic medication edits have been implemented however implementation was shortly delayed from the previously scheduled dates as coding and call center issues were addressed. MHD will plan to provide feedback on all three psychotropic medication edits. The schedule may be found on the MHD Web-site at http://dss.missouri.gov/mhd/cs/pharmacy/imsched.pdf.
Selzentry Clinical Edit	●Discussion-A copy of the clinical edit document was provided in the meeting packet and all attendees. Changes under recommendation were bolded for easy identification. Mark Roaseau, RPh, clinical pharmacist reviewed the document noting additions to approval criteria to address a new low viral load trofile test for the product sensitivity. ●Public Hearing-No Comments were entered. ●Decision- The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Ranexa Clinical Edit	●Discussion-A copy of the clinical edit document was provided in the meeting packet and all attendees. Mr. Roaseau explained additions to both approval and denial criteria. These changes were bolded on the document for easy identification. MHD previously required a trial and failure on a CCB, ACE Inhibitor, Beta Blockers and angiotensin receptor blocker or nitrates. The new criterion only requires concomitant therapy with one of the classes. Criteria to limit the dosing of Ranexa® to 500 mg twice daily for patients taking diltiazem, verapamil or cyclosporine was also added. ●Public Hearing-No Comments were entered. ●Decision- The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Botulinum Toxin Type A Clinical Edit	●Discussion-A copy of the clinical edit document was provided in the meeting packet and to all attendees. Changes under recommendation were bolded for easy identification. Ms. Driver reviewed the document noting the addition of two products to the edit as well as new approval diagnosis codes for Botox therapy. ●Public Hearing-Jeff Knappen, Allergan thanked MHD for their work on this edit which he

	stated was most appropriate and evidenced based. He requested consideration of removal of type A from the title of the edit as well as within the edit, as the classes has recently gone under a nomenclature change from the FDA. This change will make the title of the edit a little more generic should other products be introduced. He indicated that there were additional diagnosis codes under spastic hemiplegia that should be considered for approval. He also requested codes for late effects of cardio vascular disease monoplegia of upper limb. Ms. Driver indicated that spactic hemiplegia codes will be added however more research will be conducted on codes associated with cardio vascular disease. Mr. Knappen will follow up with an e-mail to MHD regarding these requests. No further comments were entered. ●Decision- The Committee voted to accept the recommendation as presented MHD will revise with the addition of appropriate codes for Botox following additional review and will report back to the Committee. (See Roll Call Votes)
Human Papilloma Virus (HPV) Clinical Edit	●Discussion-A copy of the clinical edit document was provided in the meeting packet and all attendees. A new product was added to the edit. Ms. Driver summarized the document and noted the addition of males under approval criteria for the product Gardasil. ●Public Hearing-Eric Blake, Merck Pharmaceuticals commented that the edit was very appropriate; however a very recent new indication was approved for Gardasil. Ms. Driver will ensure this is incorporated into the criteria. ●Decision- The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
New Business	
New Drug Review	● Discussion - Drug Monographs were available for review at http://www.heritage-info.com/mohealthnet/ for all new products reviewed this quarter. A listing of products detailing MHD's recommendations for open access, clinical edit, as a PDL product or for continued prior authorization was provided in the Members' meeting packets for discussion and action. This listing was also provided as a handout to all in attendance. Ms. Driver reviewed the recommendations and responded to Committee questions. ● Public Hearing –A copy of correspondence from Greg Hoke, Reckitt Benekiser Pharmaceuticals was shared with the Committee, as Mr. Hoke was unable to attend in person. The correspondence expressed support for appropriate clinical edits, to ensure appropriate utilization, while mitigating potential abuse or misuse, for the product Suboxone® Film. The letter offered the following recommendations for inclusion in the edit: approval with a diagnosis of opioid dependency or abuse only and no approvals for pain diagnosis, prescribers should be certified under the Drug Addiction Treatment Act of 2000, maximum daily dose of 24 mg per day, documented treatment protocols and allow subutex approval only for patients who are pregnant or have a documented allergy to naloxone. Diane Racicot, MBA, RD, Strativa

	Pharma addressed the group in support of the produce Zupelnz®. She requested for patients unable to tolerate tablets a step edit for approval of the product. Michael Kloos, PharmD, Pfizer provided information and handouts on Aricept 23®. He provided an overview of a head to head, double blind clinical trial in patients with moderate to severe Alzheimer's Disease. Product efficacy compared to Aricept 10 was summarized. Dr. Kloos asked the group to consider moving patients on higher doses of Aricept 10 for at least 30 days to Aricept 23 as opposed to the standard trial and failure model. ● Decision – Following this discussion the Committee voted to accept the new drug recommendations as presented. (See Roll Call Votes)
Clinical Edits	
Stadol NS/butophanol	●Discussion-A copy of the proposed clinical edit document was provided in the meeting packet and to all attendees. This edit would allow the removal of the product from the prior authorization process currently in place. Mr. Roaseau reviewed the document which included approval and diagnosis criteria to ensure use for an appropriate diagnosis, age limits and to not exceed maximum recommended doses. Grandfathering will not apply to this edit so an appropriate diagnosis will need to be on file once the criteria are implemented. ●Public Hearing-No Comments were entered. ●Decision- The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Provigil/Nuvigil	●Discussion-A copy of the recommended clinical edit document was provided in the meeting packet and to all attendees. Mr. Roaseau reviewed the document which will move the products from prior authorization to a transparent clinical edit process. Approval criteria included extensive diagnostic criteria for each approved indication. Denial criteria limited the product to those 18 years and older and will not allow patients with a history of ventricular hypertrophy or mitral valve prolapse transparent approval of the products. Discussion ensued surrounding the type of prescriber seen using these products. ●Public Hearing-No Comments were entered. ●Decision- The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Ampyra	●Discussion-A copy of the proposed clinical edit document was provided in the meeting packet and to all attendees. Ms. Driver explained that this product was unique in the treatment of Multiple Sclerosis (MS) specific to gait and the improvement of walking and therefore had not been included in the existing MS PDL edit. She reviewed approval criteria, which requires a trial on 2 preferred PDL agents. Therapy will be denied if the patient has a history of seizures or renal insufficiency. Discussion ensued surrounding how to identify renal insufficiency and members recommended requiring a base line lab prior to approval. Members understood this

	requirement would not be transparent. ●Public Hearing-No Comments were entered. ●Decision- The Committee voted to accept the recommendation with the requirement of a baseline CrCl lab prior to approval. (See Roll Call Votes)
PDL Edits	Five new classes were presented for inclusion in the PDL. Discussion for each class is detailed below.
Antihyperuricemics	● Discussion – Ms. Driver reviewed the criteria document provided as a meeting handout. Preferred and non-preferred agents were summarized. Ms. Driver clarified that a product no longer on the market was still included in the edit due to the lag in claims submission. The Committee felt due to this products inclusion approval for a non preferred agent should be allowed after a trial and failure of 2 preferred agents versus 3 as was being recommended by MHD. ● Public Hearing – Kelly Reed, PharmD, URL Pharmaceuticals presented a PowerPoint presentation on the product Colcrys®. Dr. Reed provided statistics on the number of persons in the United States affected by Gout and results of flares of the disease. Clinical trials were summarized and comparison with NSAID therapy discussed. Dr. Reed presented safety and efficacy data for the product. Members also requested a clinical arm be incorporated into the edit to ensure a trial on NSAID therapy to allow transparent approval of Colcrys for an acute attack following this presentation. ● Decision – The Committee voted to accept the recommendation with changes detailed in above discussion. (See Roll Call Votes)
Bile Salts	● Discussion – Ms Driver reviewed the criteria document, noting preferred and non-preferred agents and approval/denial criteria. It was noted that this is a generics first edit. Ms. Driver responded to utilization questions from the Committee. ● Public Hearing – No comments were entered. ● Decision – The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Inhaled Antibiotics	● Discussion – Ms. Driver reviewed the criteria document provided as a meeting handout. Both products in the class were recommended as preferred agents. ● Public Hearing – No comments were entered. ● Decision – The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Pancreatic Enzymes	● Discussion – Ms. Driver reviewed the criteria document noting recommendations for preferred and non-preferred agents. Approval and denial criteria were reviewed as well. ● Public Hearing – Peter Michaelson, MD, St. Louis Children's Hospital spoke in support of all products being equally available. Dr. Michaelson discussed symptoms of Cystic Fribrosis and

	the need for these enzymes with all meals and snacks. He expressed fear that limiting choice will result in long term health concerns for patients. Previous problems with generic substitution requirements of some insurers were detailed. Dr. Michaelson responded to questions on the how the practitioner would choose to initiate which agent for a specific patient. Ms. Driver explained the definition of failure and grandfathering as well as the compliance model. Mr. Calloway explained the unique editing process in Missouri and the effort for transparency, but also the ability for not only the physician but also the pharmacy to call the help desk for approvals and overrides. ● Decision –The Committee voted to accept the recommendation as presented. (See Roll Call Votes)
Topical Analgesics	● Discussion – Ms. Driver reviewed the criteria document noting recommendations for preferred and non-preferred agents. Discussion ensued regarding the disparate grouping of products in this class. It was pointed out that most of the products are targeted to specific indications. Ms. Driver commented the next step would be to tie coding to each product within the edit. Members suggested that the products might be better suited within their oral comparator edits. Ms. Driver indicated provider push back was of concern when patches were included in the oral edits. Members felt the edit process should be used to guide providers toward supported appropriate usage. ● Public Hearing –Charles Marsh, PharmD, King Pharmaceticals spoke in support of preferred status for Flector ® Patch. Dr. Marsh discussed reasons why topical non steroidals are coming into play. Benefits of limited systemic absorption were discussed. Clinical trials data was reviewed. Safety, efficacy and adverse effects were reviewed. Maria Chianta, PharmD, Medical Science Liaison for Covidein Pharmaceuticals presented slides in support of Pennsaid Topical Solution. Dr. Chianta discussed the unique delivery agent and mechanism of the product. Clinical trials data was summarized. Osteo Arthritis treatment guidelines were compared. Pennsaid safety and efficacy data were reviewed. ● Decision –The Committee voted to reject this edit and look at more appropriate placement for these products. (See Roll Call Votes)
Preferred Drug List Announcement	A handout of therapeutic categories for the annual review of one third of 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. The posting will be updated with MHD recommendations prior to the March meeting of the Committee.
Program Utilization Information	A listing of the top 25 drugs for dates of services for the 4th quarter 2009 through 3rd quarter 2010 was provided for the Committees' Information. This report was provided in two formats: ranked by number of claims and ranked by amount paid. Copies were available to all attendees.

Clinical Edit Summary Report	An overview of clinical edit and prior authorization transactions was provided for the month of November 2010. The report provided total transaction counts as well as information on the outcome (approval or denial) of the requests. CyberAccess active count reports for the month of November were also provided for the Committee's information and review.
Call Center Statistics	A handout detailing pharmacy help desk call center activity was provided for all attending. Statistics were for the month of November 2010.
Adjourn	The next meeting of the Committee is scheduled for March 17, 2011**.** The Drug PA Committee 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 Roll Call Votes)

January 7, 2011 ROLL CALL VOTES

Member	Selzentry	Ranexa	Botox	HPV	New Drugs	Stadol NS/ butorphanol	Provigil/ Nuvigil	Ampyra	Antihyeuricemic	Bile Salts
VACANT										
GENE FORRESTER	**SECOND**	**SECOND**	YEAH	**SECOND**	YEAH	**SECOND**	**SECOND**	YEAH	**SECOND**	YEAH
STEVE CALLOWAY	YEAH	YEAH	YEAH	YEAH	YEAH	YEAH	YEAH	YEAH	YEAH	YEAH
PAT BRYANT	YEAH	YEAH	**SECOND**	YEAH	**SECOND**	YEAH	YEAH	**SECOND**	YEAH	**SECOND**
CONRAD BALCER	**MOTION**	**MOTION**	**MOTION**	**MOTION**	**MOTION**	**MOTION**	**MOTION**	**MOTION**	**MOTON**	**MOTION**

Member	Inhaled Antibiotics	Pancreatic Enzymes	Topical Analgesics	Closed Session	Adjourn
VACAN T					
GENE FORRESTER	**SECOND**	**SECOND**	**SECOND**	**SECOND**	**MOTION**
STEVE CALLOWAY	YEAH	YEAH	YEAH	YEAH	YEAH
PAT BRYANT	YEAH	YEAH	YEAH	**MOTION**	YEAH
CONRAD BALCER	**MOTION**	**MOTION**	**MOTION**	YEAH	**SECOND**
JOE PARKS	ABSENT	ABSENT	ABSENT	ABSENT	ABSENT

EXECUTIVE SESSION
January 7, 2011

Committee Members Present

Steven Calloway, RPh.
Conrad Balcer, DO
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Andrew Haslag, Fiscal Manager
Jenna Twehus, RN
Mary Heet, RN

MINUTES REVIEW	Minutes of the September 2010 Executive Session were approved as submitted.
CASE REVIEWS	No cases were presented for review.
ADJOURN	The meeting adjourned at approximately 2:00 p.m. (See Roll Call Votes)