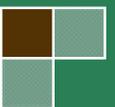




Drug Utilization Review Board

**Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1A
Oklahoma City, Oklahoma 73107
Ponca Room**

**Wednesday
October 13, 2010
6:00 p.m.**





The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY
PHARMACY MANAGEMENT CONSULTANTS

MEMORANDUM

TO: Drug Utilization Review Board Members
FROM: Shellie Keast, Pharm.D., M.S.
SUBJECT: Packet Contents for Board Meeting – October 13, 2010
DATE: October 7, 2010

NOTE: THE DUR BOARD WILL MEET AT 6:00 P.M. THE MEETING WILL BE HELD IN THE PONCA ROOM AT THE OKLAHOMA HEALTH CARE AUTHORITY'S NEW OFFICES IN SHEPHERD MALL. (NORTH ENTRANCE)

Enclosed are the following items related to the October meeting. Material is arranged in order of the Agenda.

Call to Order

Public Comment Forum

Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.

Update on DUR / MCAU Program – See Appendix B.

Action Item – Annual Review of Growth Hormones - See Appendix C.

Action Item – Annual Review of Erythropoietin Stimulating Agents – See Appendix D.

Action Item – Annual Review of Narcotics and 30 Day Notice to Prior Authorize Butrans™, Primlev™, Xolox®, Exalgo™ ER, Rybix™ ODT, and Suboxone® / Subutex® – See Appendix E.

Action Item – Annual Review of NSAIDs and 30 Day Notice to Prior Authorize Vimovo™ – See Appendix F.

Action Item – Annual Review of Ocular Allergy Medications and 30 Day Notice to Prior Authorize Bepreve™ and Lastacaft™ – See Appendix G.

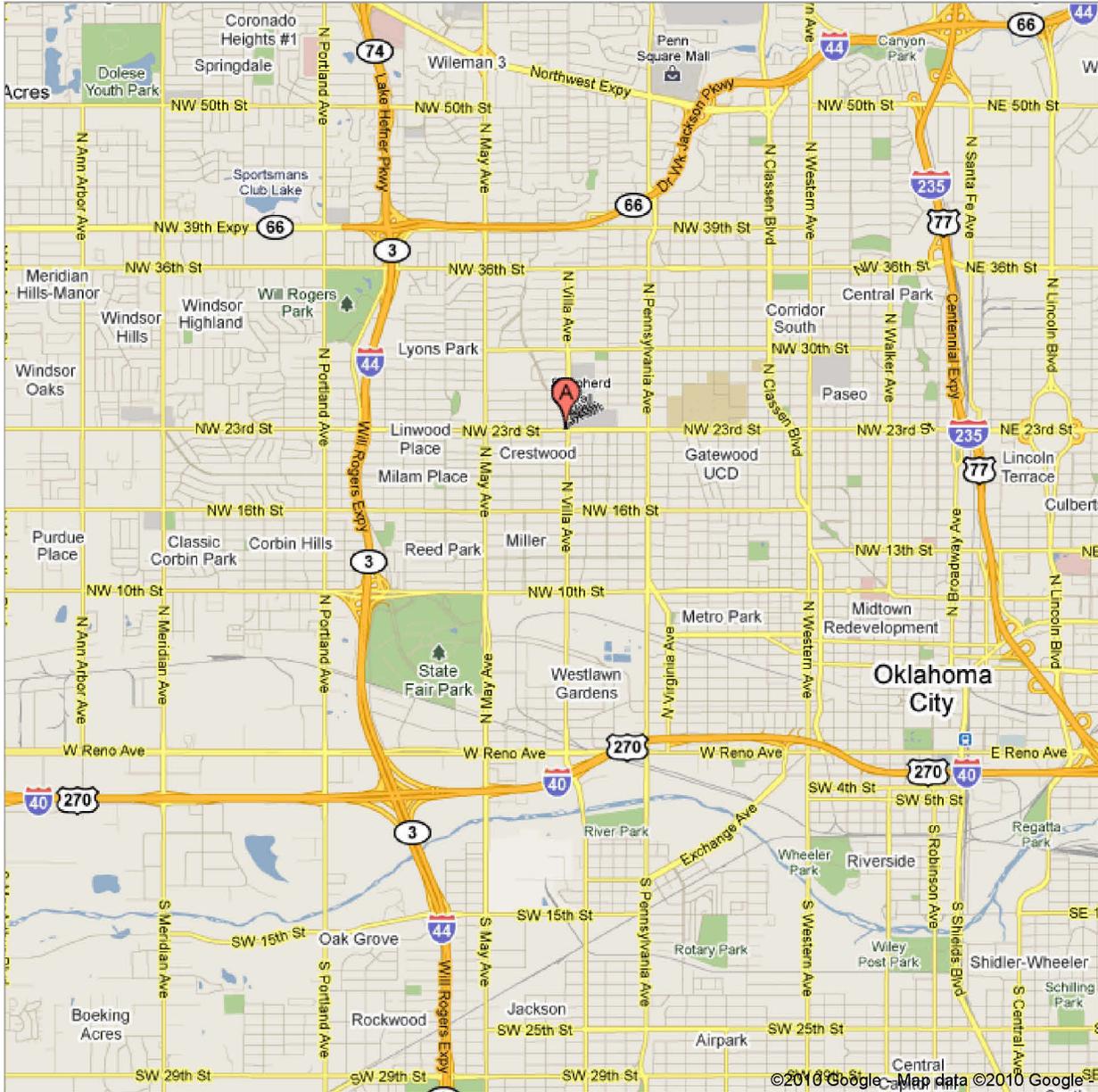
FDA and DEA Updates – See Appendix H.

Future Business

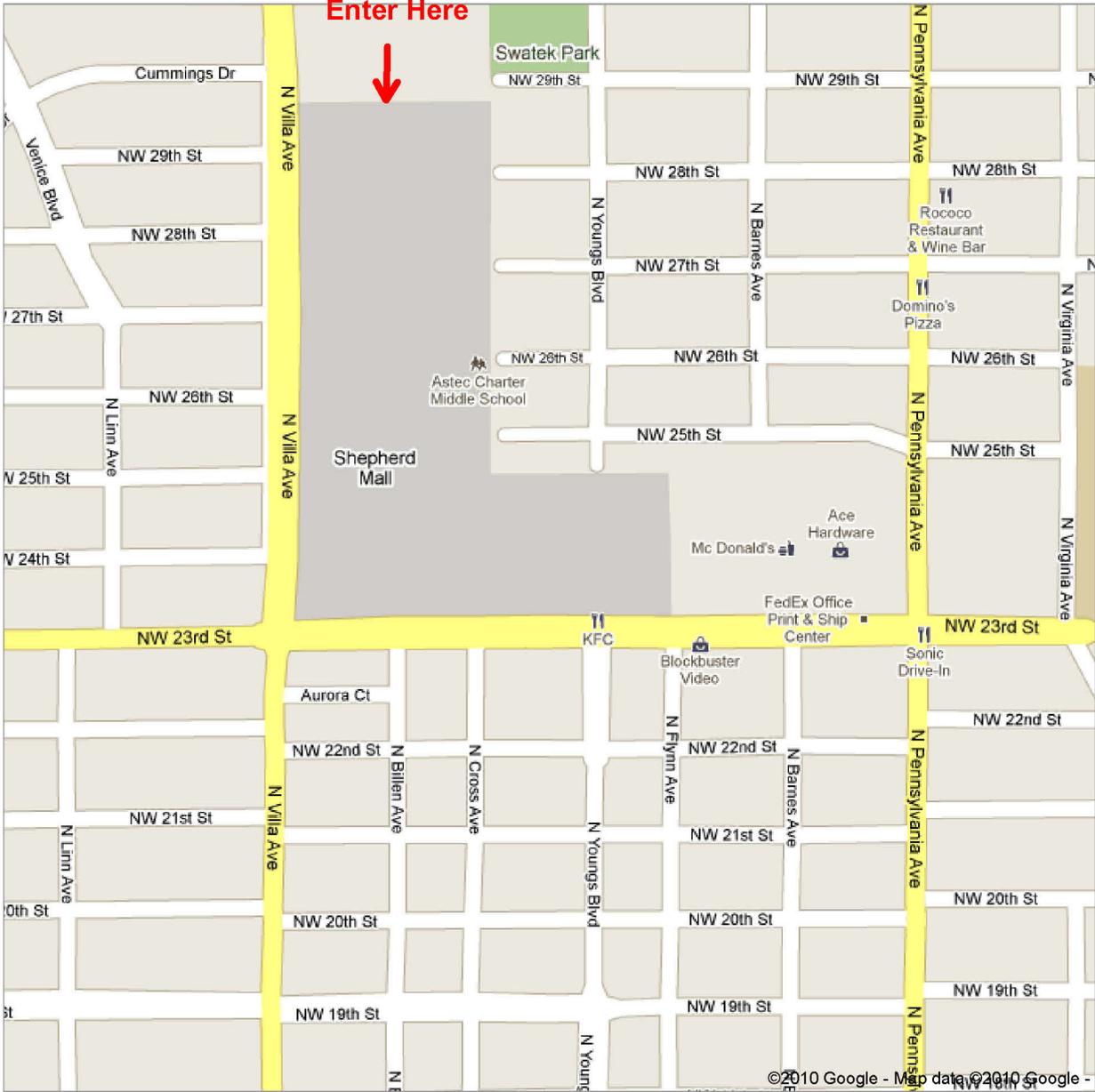
Adjournment

OHCA is now located at the north end of Shepherd Mall, at the intersection of NW 23rd Street and Villa.

Address **2501 NW 23rd St**
Oklahoma City, OK 73107



Please use the entrance on the north side of the building.



Oklahoma Health Care Authority
Drug Utilization Review Board
(DUR Board)
Meeting – October 13, 2010 @ 6:00 p.m.

Oklahoma Health Care Authority
2401 N.W. 23rd Street, Suite 1-A
Oklahoma City, Oklahoma 73107
Ponca Room (North Entrance)

AGENDA

Discussion and Action on the Following Items:

Items to be presented by Dr. Muchmore, Chairman:

- 1. Call To Order**
 - A. Roll Call – Dr. Graham

Items to be presented by Dr. Muchmore, Chairman:

- 2. Public Comment Forum**
 - A. Acknowledgment of Speakers and Agenda Items

Items to be presented by Dr. Muchmore, Chairman:

- 3. Action Item – Approval of DUR Board Meeting Minutes – See Appendix A.**
 - A. September 8, 2010 DUR Minutes – Vote
 - B. September 9, 2010 DUR Recommendation Memorandum
 - C. Correspondence

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman:

- 4. Update on DUR / Medication Coverage Authorization Unit – See Appendix B.**
 - A. Retrospective Drug Utilization Review for August 2010
 - B. Medication Coverage Activity Audit for September 2010
 - C. Help Desk Activity Audit for September 2010

Items to be presented by Dr. Moore, Dr. Muchmore, Chairman:

- 5. Action Item – Annual Review of Growth Hormones - See Appendix C.**
 - A. Current Authorization Criteria
 - B. Utilization Review
 - C. COP Recommendations

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman:

- 6. Action Item – Annual Review of Erythropoietin Stimulating Agents - See Appendix D.**
 - A. Current Authorization Criteria
 - B. Utilization Review
 - C. COP Recommendations

Items to be presented by Dr. Keast, Dr. Muchmore, Chairman

7. **Action Item – Annual Review of Narcotics and 30 Day Notice to Prior Authorize Butrans™, Primlev™, Xolox®, Exalgo™ ER, Rybix™ ODT, and Suboxone® / Subutex® – See Appendix E.**
- A. Current Authorization Criteria
 - B. Utilization Review
 - B. COP Recommendations

Items to be presented by Dr. Patel, Dr. Muchmore, Chairman

8. **Action Item – Annual Review of NSAIDs and 30 Day Notice to Prior Authorize Vimovo™ – See Appendix F.**
- A. Current Authorization Criteria
 - B. Utilization Review
 - C. COP Recommendations

Items to be presented by Dr. Robinson, Dr. Muchmore, Chairman

9. **Action Item – Annual Review of Ocular Allergy Medications and 30 Day Notice to Prior Authorize Bepreve™ and Lastacft™ – See Appendix G.**
- A. Current Authorization Criteria
 - B. Utilization Review
 - C. COP Recommendations

Items to be presented by Dr. Graham, Dr. Muchmore, Chairman

10. **FDA and DEA Updates – See Appendix H.**
11. **Future Business**
- A. Utilization Review of Alzheimer’s Medications
 - B. Utilization Review of BPH Medications
 - C. Annual Review Antihypertensives
 - D. New Product Reviews
12. **Adjournment**



Appendix A

**OKLAHOMA HEALTH CARE AUTHORITY
DRUG UTILIZATION REVIEW BOARD MEETING
MINUTES of MEETING of SEPTEMBER 8, 2010**

BOARD MEMBERS:	PRESENT	ABSENT
Brent Bell, D.O., D.Ph.: Vice-Chairman	X	
Mark Feightner, Pharm.D.		X
Anetta Harrell, Pharm.D.	X	
Evelyn Knisely, Pharm.D.	X	
Thomas Kuhls, M.D.	X	
John Muchmore, M.D., Ph.D.: Chairman	X	
Paul Louis Preslar, D.O., MBA	X	
James Rhymer, D.Ph.	X	
Bruna Varalli-Claypool, MHS, PA-C	X	
Eric Winegardener, D.Ph.	X	

COLLEGE of PHARMACY STAFF:	PRESENT	ABSENT
Metha Chonlahan, D.Ph.; Clinical Pharmacist	X	
Karen Egesdal, D.Ph.; SMAC-ProDUR Coordinator/OHCA Liaison	X	
Ronald Graham, D.Ph.; Pharmacy Director	X	
Shellie Keast, Pharm.D, M.S.; DUR Manager	X	
Chris Le, Pharm.D.; Clinical Pharmacist/Coordinator	X	
Carol Moore, Pharm.D.; Clinical Pharmacist	X	
Neeraj Patel, Pharm.D.; Clinical Pharmacist	X	
Lester A. Reinke, Ph.D.; Associate Dean for Graduate Studies & Research	X	
Leslie Robinson, D.Ph.; PA Coordinator	X	
Jennifer Sipols, Pharm.D.; Clinical Pharmacist	X	
Visiting Pharmacy Student(s): Jack Drakeford, Kshama Kumari	X	

OKLAHOMA HEALTH CARE AUTHORITY STAFF:	PRESENT	ABSENT
Mike Fogarty, J.D., M.S.W.; Chief Executive Officer		X
Nico Gomez; Director of Gov't and Public Affairs		X
Garth Splinter, M.D., M.B.A.; Director of Medicaid/Medical Services	X	
Nancy Nesser, Pharm.D., J.D.; Pharmacy Director	X	
Howard Pallotta, J.D.; Director of Legal Services		X
Lynn Rambo-Jones, J.D.; Deputy General Counsel III		X
Rodney Ramsey; Drug Reference Coordinator	X	
Jill Ratterman, D.Ph.; Pharmacy Specialist	X	
Kerri Wade, Senior Pharmacy Financial Analyst	X	

OTHERS PRESENT:		
Sam Smothers, MedImmune	Frank Folger, MedImmune	Jeff Himmelberg, GlaxoSmithKline
Toby Thompson, Pfizer	Holly Turner, Merck	Penny Harwood, MedImmune
Rob Baxter, MedImmune	Aaron Mays, Alcon	Lance Burcham, MedImmune
Warren Tyes, Merck	Kim Greenburg, Amylin	Frances Bauman, Novo Nordisk
Stephen O'Brien, Novo Nordisk	Adrian Martinez, Pfizer	Jim Dunlap, Lilly USA
John Solem, Lilly USA	Russ Wilson, Ortho McNeil Janssen	Pat Trahan, Taro Pharmaceutical
Mark DeClerk, Lilly	Charlene Kaiser, Amgen	Paul Sparks, NeurogesX Inc.

PRESENT FOR PUBLIC COMMENT:		
Agenda Item No. 7:	Stephen O'Brien, M.D.; Novo Nordisk	Carol Nikkel, Amylin
Agenda Item No. 9:	Bill Latton, Ph.D., M.D., P.C. Ed Co, M.D.; Integris Baptist Marsha Dewell, Pharm.D.; GSK Jodi Jensen, UCB	Jeremy Franklin, M.D.; Medimmune Scott Cyrus, M.D. Andrew Thorpe, Pfizer

AGENDA ITEM NO. 1: CALL TO ORDER

1A: Roll Call

Dr. Muchmore called the meeting to order. Roll call by Dr. Graham established the presence of a quorum.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 2: PUBLIC COMMENT FORUM

Dr. Muchmore recognized the speakers for public comment.

Agenda Item No. 7:	Stephen O'Brien, M.D.; Novo Nordisk	Carla Nikkel, Amylin
Agenda Item No. 9:	Bill Latton, Ph.D., M.D., P.C. Jodi Jensen, UCB	Marshall Dewell, Pharm.D.; GSK Andrew Thorpe, Pfizer
Agenda Item No. 11:	Ed Co, M.D.; Integris Baptist Scott Cyrus, M.D.	Jeremy Franklin, M.D.; Medimmune

ACTION: NONE REQUIRED

AGENDA ITEM NO. 3: APPROVAL OF DUR BOARD MINUTES

3A: July 14, 2010 DUR Minutes

Dr. Preslar moved to approve as submitted; seconded by Dr. Knisely.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 4: UPDATE ON DUR/MEDICATION COVERAGE AUTHORIZATION UNIT

4A, B,C: Retrospective Drug Utilization Reviews: March, April, July 2010
4D,E, F, G: Retrospective Drug Utilization Review Responses: January, February, March, April 2010
4H, I: Medication Coverage Activity Audits: July, August 2010
4J, K: Help Desk Activity Audits: July, August 2010

Reports included in agenda packet; presented by Dr. Keast.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 5: VOTE TO PRIOR AUTHORIZE AMPYRA™

Reports included in agenda packet; presented by Dr. Patel.

Dr. Winegardener moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 6: VOTE TO PRIOR AUTHORIZE QUTENZA®

Materials included in agenda packet; presented by Dr. Keast.

Dr. Kuhls moved to approve with criteria addition, "product to be applied in physician's office"; seconded by Dr. Rhymer.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 7: VOTE TO PRIOR AUTHORIZE VICTOZA® AND BYDUREON®

For Public Comment: Stephen O'Brien, M.D.: Thank you. My name's Steve O'Brien. I work for Novo Nordisk. I'm one of the medical scientific directors. I would agree with the College of Pharmacy recommendations to approved Victoza based on prior authorization similar to Byetta and so I'll turn my time back unless you have questions.

For Public Comment: Carla Nikkel: Good evening. My name is Carla Nikkel and I am with the medical development department at Amylin and cover this geography. We noticed that you did have Bydureon on the agenda for approval tonight and I did just want to bring to your attention that this product is currently is still sitting at the FDA waiting for approval, but if you had any questions or would like for me to come back at a later time when we have the full label, I'd be more than happy to answer any questions.

Dr. Muchmore: If you were going to hazard a guess as to when this might be available, what would you guess?

Carla Nikkel: Well all I can tell you is that we're expecting formal feedback October 22nd from the FDA. Any other questions?

Dr. Muchmore: Do you what it's going to cost?

Carla Nikkel: I wish I did but I don't even want to speculate.

Materials included in agenda packet; presented by Dr. Chonlahan.

Dr. Kuhls moved to approve with removal of clinical exception criteria; seconded by Dr. Preslar.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 8: VOTE TO PRIOR AUTHORIZE SPECIAL FORMULATION ANTIBIOTICS

Materials included in agenda packet; presented by Dr. Sipols.

Dr. Bell moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 9: VOTE TO PRIOR AUTHORIZE ANTICONVULSANT MEDICATIONS

For Public Comment: Bill Latton, Ph.D., M.D.: I'm Bill Latton. I'm a solo practice neurologist in Muskogee, Oklahoma. I'm here tonight acting as an advocate for my patients. In the last several years, there have been newer anticonvulsants become FDA approved. Many of those have unique mechanisms of action. I have been able to achieve better seizure control for many patients using these medicines. When I achieve better seizure control in these patients, their quality of life improves. Sometimes what we overlook are the other effects that occur with better seizure control. I order less laboratory studies. My patients end up in the emergency room fewer times and I have less hospitalizations, particularly for status epilepticus. Another use of the anticonvulsants is a rational and acceptable alternative to narcotic pain control for pain management. In reviewing the agenda tonight, I have three issues of concern. First, many medications including the anticonvulsants have a number of FDA approved utilizations. As I read the agenda, prior authorization for anticonvulsants will require a diagnosis of seizures. How will this affect the non-epilepsy utilization of these medications? Second, with these guidelines passed for the medications that require prior authorization, will there be guidelines available? If a criterion is lack of seizure control, that means different things to different people. Will that be defined? Will the side effects the medicine has on the patient be considered? And finally, purely will the number of anticonvulsants used to control a patient be an issue than can be considered for a prior authorization medication? And the third issue is, if prior authorization is established, will there be a hierarchy that I must follow? In other words, when I require prior authorization, will I be forced to use "medicine A" and if it fails, "medicine B", or will there be a uniform distribution and I can request any prior authorization medicine? I'd really like the Board, for my patients to consider, that there are other issues than the direct cost of the medicine that you're providing for your clients and my patients, and I hope you'll consider this in making your recommendations. Thank you.

Dr. Kuhls: I'm a little confused and maybe we can kind of, maybe we can understand each other together, because maybe you and I don't understand it. To me, what these guidelines say is that if there is a generic, right, then use the generic before you use the brand name. Isn't that what we're basically talking about? But I don't think this Board or anybody else has had any discussion to sit there and say in some of these newer drugs where there is no generic, that you can't use these or there's a hierarchy of medicines or those kind of things. It was my understanding that these guidelines are more to just say that if there is a generic available, use the generics or the same drug. Is that right or am I missing something?

Dr. Muchmore: That's the way I understand it.

Dr. Kuhls: That's how I understand it. And I think we've looked at a lot and I think looking at antiseizure medications, I don't think that this Board's ever discussed a hierarchy in medicines, or you can't get this medicine or you have to go through these medicines before that medicine at all. I think what these guidelines say is that if there is a generic available of the same medication, use the generic.

Dr. Winegardener: Dr. Kuhls on 1a, it says "all brand-name anticonvulsants will require prior authorization".

Dr. Knisely: It doesn't say just

Dr. Kuhls: Well I have some concern about that too, because that's my understanding too.

Dr. Knisely: See that, number 1, I think does say what you want to say, but having all brand name require a PA, that's

Dr. Winegardener: With a generic equivalent.

Dr. Kuhls: All brand names with a generic equivalent

Dr. Knisely: Yeah, that's what it needs to say.

Dr. Harrell: It reads confusingly.

Dr. Kuhls: So I think maybe the wording's wrong, okay. But I don't think anybody's telling you that, I think what we're trying to do is use generics. And I don't, I think that to be open from my readings and understandings of others is that some day down the road when there's enough studies done comparing drugs, that maybe at a time in neurology for seizure medications, there may be a hierarchy, but I don't think we're anywhere close to that. I don't think there's enough science and enough good studies to compare one drug versus the others to do that.

Dr. Muchmore: We're in the situation now where there's a plethora of generic seizure medications much better than what we had to deal with say thirty years ago, and as I read this, is that it's expected that you will make a proper attempt to control the seizures with the available generics and that if you have a reason to go to a brand name, that it will require prior authorization, but people who are already stabilized on brand

Dr. Graham: People who are already stabilized can stay on it.

Dr. Muchmore: Yeah, which I think is exceedingly generous. I don't think other

Dr. Graham: We're not we're grandfathering everybody that's on

Dr. Muchmore: Yeah, that's exceedingly generous. But it's certainly

Dr. Rhymer: Any of the brands?

Dr. Graham: A1, or 1a right below brand name medications.

Dr. Muchmore: But if somebody's a brand new seizure and somebody wants to start out with a brand name, they're going to have to give a reason and ask for a prior authorization and there may be reasons.

Dr. Kuhls: So I think we have to be careful. I think that the way this plan, at least the way I interpret it, is that for most of the seizure medications now, even the newer ones, or many of the newer ones, they've already gone generic, and so to me, it's mostly using generic medications, but if you have a patient that you think needs a branded medicine, nobody's saying you can't get that medicine for your patient. I think and I think that the pharmacy crew has to have somewhat of an open view of how all this works and realize that there's patients with seizure medications, there's not a lot of science to say you have to use one drug versus the other because they're equal. So, I don't disagree with you much, but I think the way this is written is to try to control costs, especially since most of the seizure medicines have gone generic. I don't disagree with anything you say.

Dr. Muchmore: Just a few years ago, some of those that are now available generically were at high cost and you know, you couldn't argue that they weren't excellent medications that needed to be used.

Dr. Graham: Also for multiple purposes, too they were marketed wrong, too.

Dr. Kuhls: Does that answer some of your questions of how the Board thinks or?

Dr. Latton: Yes it does, and I supposed that I misinterpreted that.

Dr. Kuhls: Well I think that we have to change the wording a little bit. I think that the wording wasn't perfect. I agree.

Dr. Latton: Thank you very much.

For Public Comment: Marshall Dewell, Pharm.D.: Good evening. My name is Marshall Dewell. I'm from the medical affairs department of GlaxoSmithKline. In followup to testimony last month in regards to my colleague Michael Jones, I'm just here as a courtesy to the Board to be available to answer any questions or concerns, otherwise I yield my time.

For Public Comment: Andrew Thorpe: Thank you very much. My name is Andrew Thorpe and I'm with Pfizer's medical affairs division. I'm a regional medical and research specialist for this region and for the other region. I'd like to thank you for the time. Thank you for the clarification of this agenda item, I do appreciate that. I would just like to state that as you know, there's no generic for Lyrica. Lyrica has four FDA approved indications. It's an adjunctive therapy for adults with partial onset seizures, as an indication for neuropathic pain associated with DPN, as indication of a frequent PHN and is also indicated by the FDA for the treatment of fibromyalgia. I would just like to address any questions you may have, otherwise I give my time up to the agenda.

For Public Comment: Jodi Jensen: Good evening. Thank you for your time. I'm with medical affairs department of UCB which is a Belgian based pharmaceutical company with a US headquarters in Atlanta, and we specialize in drugs for treatment of epilepsy. I just wanted to make a few comments in general about epilepsy. It's a complex disease with an incidence of around 50 per 100,000 persons per year despite the availability of over twenty anti-epileptic drugs on the market. Approximately 30 or 40% of patients with epilepsy still have uncontrolled seizures or intolerable side effects on their current therapy. This represents a great unmet need for the patients and their caregivers and more therapeutic options are needed. There is no one AED or combination of anti-epileptic drugs that have been shown to meet the needs of patients with epilepsy, as the response to the therapy of individual patients is highly unpredictable. I'm here today to talk about Vimpat which has a generic, lacosamide, and I'd like to point out just a few things regarding Vimpat that differentiate it from other drugs in this class. It's indicated for adjunctive therapy in the treatment of adults with partial onset seizures and the drug is available as an oral solution, tablets, or an IV formulation. Having an IV formulation available is extremely beneficial for seizure patients, especially those that are well controlled in the community and get hospitalized and become NPO for some reason. You know, basically if the drug that they're well controlled on doesn't have an IV formulation, there is no alternative but to try to start something new and titrate them up to get them controlled, so having that IV is a huge advantage. In our pivotal studies, we studied the drug in combination with virtually every other anti-epileptic drug currently available, and regardless of which combination or which drug it was paired with, we saw additional efficacy, so if we've got patients who are currently uncontrolled on their current therapy, this can be added to any currently available drugs. Pharmacokinetically, the drug is different. As you all know, these drugs can be difficult to manage. The pharmacokinetics of Vimpat are proportional and linear. There's no known clinically relevant pharmacokinetic drug interactions. It has a low plasma protein binding and no blood level monitoring is needed. It has a novel mechanism of action. It's the first new drug in ten years with a novel mechanism of action and there is no generic equivalent available for this now. I did forget to mention that the gelous conversion between the orals formulations and the IV is a one to one conversion, so there's no need to mess with trying to calculating appropriate dose. In closing, I'd like to just say a few words about our company. UCB is considered to be the epilepsy company. We have an AEB portfolio that includes Keppra, Keppra XR, as well as Vimpat and additional pipeline compounds within this therapeutic area. We have pre-clinical as well as clinical investigators working specifically in epilepsy. Our sales force is dedicated to insuring proper utilization of these products and as such, they only call on neurologists and they only call on as well, epileptologists. In addition, we've developed several strategies to demonstrate our commitments to patients and their caregivers. We sponsor a company called Canine Assistants which is based in Atlanta and we support full training and lifetime care of epilepsy assistance dogs. We have an epilepsy advocate program where we train patients with epilepsy in public speaking, things like that, where they're able to go out and meet with newly diagnosed patients and kind of help them navigate the challenges of their illnesses, and lastly, we have an extensive scholarship program available, and that's both to the patients as well as their siblings, because we recognize what kind of impact this illness could have on the entire family. That's it. Any questions?

Materials included in agenda packet; presented by Dr. Sipols.

Discussion regarding quantity/dosage limits for medications that have FDA approved non-anticonvulsant applications; generic versus brand name therapeutic levels; PA requests for dual/multiple dose packs under one PA for adults

Dr. Kuhls moved to approve as modified (1a: All brand-name anticonvulsants with generic equivalents); dual/multiple dose packs for adults; seconded by Dr. Winegardener.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 10:

VOTE TO PRIOR AUTHORIZE PROCENTRA® AND SECOND OPINIONS PROCESS FOR ADHD/NARCOLEPSY CATEGORY

Reports included in agenda packet; presented by Dr. Le.

Dr. Bell moved to approve as submitted; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 11:

ANNUAL REVIEW OF SYNAGIS®

For Public Comment: Jeremy Franklin, M.D.: Thank you very much. As he mentioned, my name is Dr. Jeremy Franklin. I am board certified in general pediatrics as well as pediatric infectious disease. Currently I serve as the medical science director for MedImmune, which is of course the manufacturer of Synagis. First I'd like to review the fact that RSV is the leading cause of infant hospitalization in this country every year. There is no treatment or vaccine available. The only product that is available to prevent RSV hospitalization that's been proven safe and effective is of course Synagis, which is a monoclonal antibody. In a pivotal trial that actually led to the FDA approving Synagis, there was a 55% reduction in RSV related hospitalizations compared to the placebo group and if you look specifically at the late pre-term group in the 32 to 35 week gestation group, without congenital I'm sorry chronic lung disease, there was actually an 82% reduction in RSV related hospitalizations. Of course as you know, the AAP Committee on Infectious Disease put out new guidelines for the use of Synagis last year about the end of June, and these changes have caused some considerable concern for those who care for children. One of the big concerns is in the late pre-term group because several significant changes were made, apparently without any clinical data to support these changes and they were based strictly on expert opinion. And in some cases, these changes actually are in direct opposition to published clinical data, the FDA approved package insert and twelve years of clinical experience. Tonight I want to specifically talk about the truncated dosing regimen that was introduced in the 2009 guidelines that states basically infants 32 to less than 35 weeks gestational age should receive prophylaxis only until they turn three months of age and receive a maximum of three monthly doses. The first thing I want to remind you of, these infants are not normal healthy infants. These infants receive less than half of the maternal antibody that a term infant would receive. They also have decreased lung volume, decreased surface area for gas exchange, as well as increased thickness of the alveolar wall. In addition to these anatomic differences, they also have physiologic decreases in lung function. These decreases in lung function have been demonstrated to persist at least until twelve months of age and in some studies even longer than that. They do not spontaneously revert to having normal lungs at three months of age. Several studies have been published that have shown significant risk exists beyond three months of age for RSV hospitalization in this group. Three that I would point to are studies by McCormick, et. al.; Rush, et.al.; and Rossi, et.al. Also I'd briefly like to mention that the pharmacokinetics of Synagis do not support a truncated dosing regimen. Half life is only approximately twenty days so this requires monthly dosing throughout the RSV season to provide protection for these infants. I would also mention there are absolutely no published studies to support the safety or efficacy of this truncated dosing regimen or any other dosing regimen that does not continue through the entirety of the RSV season. I have also mentioned that RSV guidelines published by the AAP Committee on Infectious Disease were published again in June of last year and still to this day, they have not provided any data to support this truncated dosing regimen. This lack of clinical data has caused significant concern and dissension in the pediatric world. Numerous physicians and physician groups have published alternate guidelines or local standard of care documents. Earlier this year, the National Perinatal Association actually published its' evidence-based guidelines in the Journal of Neonatal Intensive Care. I would also mention that the National Medical Association has voiced their concern with this truncated dosing regimen. I would also bring up the fact that approximately half of all state Medicaid in the country have not fully adopted the COID 2009 guidelines and that actually one state that adopted the guidelines last year had decided to revert back to previous guidelines for immunoprophylaxis. The last point I would bring up is that the CDC has actually formed a working group on RSV immunoprophylaxis. This group contains in its' membership experts in RSV disease, scientists and economists from the CDC, members of the FDA as well as liason members from the AAP and the American Academy of Family Physicians. This working group has been specifically tasked with developing RSV immunoprophylaxis guidelines based on a review of all of the available clinical evidence and it is expected that these guidelines will be published by this working group sometime in 2011. In conclusion, I urge this group to not adopt the truncated dosing regimen as proposed in the 2009 guidelines due to lack of supporting evidence and the significant on-going controversy. I would also ask that the committee continues protecting vulnerable infants in this state by maintaining current RSV immunoprophylaxis guidelines which includes dosing throughout the entirety of the RSV season, and I'd be happy to answer any questions that anyone has.

Dr. Kuhls: Well, I have a question. You're saying that half the states did the the American Academy of Pediatrics new recommendations?

Dr. Franklin: At the last count, we had 25 states that had adopted.

Dr. Kuhls: Half didn't.

Dr. Franklin: Correct, not fully.

Dr. Kuhls: So last year, what is the data that RSV was so much horrible in the 25 states that changed to the new guidelines?

Dr. Franklin: Sure, that data is currently being selected by a lot of different researchers as well as MedImmune and I am aware of a particular state where a group of neonatologists it was Colorado where a group of neonatologists in their initial

quality improvement review noted approximately, I think it was 98% increase in documented RSV hospitalizations year over year.

Dr. Muchmore: Were those increases in a group with the truncated regimen?

Dr. Kuhls: And were those in 32 to 34 weeker?

Dr. Franklin: I don't have all the details of this data because it has not been published yet. This is data that was presented at, again, as part of a quality improvement project by this group of neonatologists in Colorado.

Dr. Kuhls: So really there's no data at all that says that the states that believed in the American Academy of Pediatrics, that their expert opinions, that the new recommendations, you don't have any data that, oh my God, those people really screwed up and made a mistake by going to the new guidelines.

Dr. Franklin: There, to my knowledge there is also new data to prove that there has not been increases. The data's, as I said, being collected and analyzed at this time. The problem is, a lot of this data takes, there's a significant lag in the time from the end of the season until the time the data has actually been collected, analyzed, submitted for publication, these types of things. Particularly if you're looking at claims based database kind of reviews

Dr. Kuhls: Come on, we were trained the same. You know that there's abstracts, you know there's meetings, you know that states look at it. You know that you're only talking about state Medicaid's, but mostly all the insurance companies have gone to the, commercial companies have gone to AAP guidelines, and so we should have some feeling going into the next year that, oh my God, these guidelines are so terrible that we need to go back. I haven't heard that from you.

Dr. Franklin: To my knowledge, there again, the data's being collected, there has been one state already that has reversed its' decision based on its' concern regarding

Dr. Kuhls: What state was that?

Dr. Franklin: It was Wyoming. They recently decided to go back to guidelines that were more consistent with the 2006 Redbook guidelines. Again a lot of this data, there's significant lag time between end of season and the time that it can be collected, analyzed and published. Again, the only data that I'm aware of that's looked at this, that I have access to currently that I can discuss is the data that was presented from the Colorado quality improvement project, that group of neonatologists, and there is further, obviously, data collected and analysis being done again by physicians who were interested in what happened with changes in the guidelines as well as MedImmune is looking at the issue on-going, prospective fashion also.

Dr. Knisely: You mentioned the CDC committee, can you elaborate on that? What's the reason that they're going to review it?

Dr. Franklin: One of the things that came out of the significant concern and controversy because certainly not every member of the American Academy of Pediatrics agrees with these guidelines. Not every pediatric or patient disease physician agrees with these guidelines, not even every RSV expert agrees with these guidelines. There's significant concerns about the lack of data or the lack of available data in terms of published data. And so this is the first time ever that the CDC advisory committee on immunization practices has considered this issue, but they're considering it because of the concerns and controversies that were generated after these guidelines were published. And again, this committee is composed of people who are experts in the field of RSV. You have scientists as well as economists from the CDC who have the resources to really look at this in a proper fashion. You have officials from the FDA, you have liaison members from the American Academy of Pediatrics, and you have liaison members from the American Academy of Family Physicians. So this is a, certainly multidisciplinary team that's been put together, and again, their task was to review all of the available literature and make recommendations for immunoprophylaxis guidelines based on all of the available data.

Dr. Knisely: And when was this? When do we expect this?

Dr. Franklin: We expect that those guidelines will be posed by that working group sometime next year, 2011.

Dr. Knisely: Early, late, do you have a feel?

Dr. Franklin: I don't know, I don't know, sorry. They were just formed this year towards the end of last year, first part of this year, and again, in response to the commotion and controversy that was generated by these new recommendations.

For Public Comment: Ed Co, M.D.: Good evening. My name is Dr. Edward Co. I'm a neonatologist at Integris Baptist Medical Center and also the chairman of pediatrics at the Integris Southwest Medical Center. I also, I'm here today as a patient advocate more than a physician. I have founded two nonprofit organizations. One is the Oklahoma Family Network which deals with families with special needs kids and also the Neonatal Quality Initiative Network which deals with a lot of education with regards to neonatal issues. And also lately we also have a grassroot operation known as the Oklahoma Infant Alliance which is an organization that is, was developed principally to tackle the problems of the late pre-term infants. I would like to thank you for your decision last year to allow, to allow a compromise on the modification, for the qualification on the use of Synagis prophylaxis guidelines extending number of doses to the maximum of six doses for infants less than 35 weeks. I'm here again today to ask the Board to extend and not to change the dosing guidelines until there is sufficient outcome data to show that it is safe to discontinue therapy early. I'm not aware of any new data to support a change in dosing and dose less than 35 weeks gestation infants. Although the AAP COID has recommended last year to decrease or limit doses of Synagis, there really has not been any sufficient efficacy or safety data to support such a truncated dose. As we all know by now, there has been a big push by the American Academy, American College of Obstetrics and Gynecology, and American Academy of Pediatrics, and CHD and the JCAHO to late pre-term births. The main reason is that late pre-term infants are at high risk for morbidity and mortality and including rehospitalizations compared to those term babies. It is due to the fact that these late pre-term infants have lower IGD levels and maternal anti-RSV antibodies up to the first six months of age. Their immunity are compromised and can easily catch infections such as RSV. Many of the national organizations including the National Perinatal Association has been voicing their opposition to the AAP guidelines and has been working with the CDC, ACIP committee on immunization practices to develop a new RSV guideline based on evidence-based medicine and outcome data. It is therefore my suggestion that the Board should keep the same regimen for the RSV prophylaxis that you have so generously agreed last year and wait for these new CDC

guidelines, possibly by next year they should be able to come up with some guidelines. And I know that I'm doing the right thing by being present here today and I hope you can make the right decision and your kind understanding and consideration will be appreciated by our patients.

Dr. Kuhls: Next year. I don't think this is going to happen. But next year, MedImmune, say they get their new product approved. Then what does the new recommendations, what is it going to mean?

Dr. Co: Not too familiar with the new product.

Dr. Kuhls: Well they just had their product denied by the FDA, similar compound, and so that one's still in the waiting. Do you want to make a Dr. Franklin, do you want to make a comment about that?

Dr. Franklin: Sure, actually it was not denied. We received a CRL, complete response letter from the FDA. That's currently being evaluated by our company, and where you have on-going discussions with the FDA.

Dr. Kuhls: Okay, so if that product gets approved, what is the CDC committee going to do? Because it really doesn't make a difference because you're going to take Synagis off the market anyways, right?

Dr. Franklin: Is this a question or a statement, sir?

Dr. Kuhls: No, it's a question.

Dr. Franklin: Okay. I cannot speak for what the CDC committee is going to do, that's totally out of my purview.

Dr. Kuhls: But the plan would be for MedImmune to phase out Synagis anyways, right?

Dr. Franklin: I have no idea what the plans from the marketing commercial side of the organization as I am strictly medical scientific affairs.

Dr. Kuhls: Okay. (further opinion statement regarding CDC recommendation, new MedImmune product and withdrawal of Synagis from the market) Would you like to talk about the new product a little bit, since you're much more of an expert than me?

Dr. Franklin: Because we're in on-going negotiation and discussions with the FDA I can't really speak much to motavizumab, the product you're discussing, apparently.

For Public Comment: Dr. Scott Cyrus, M.D.: Good evening. I'm Scott Cyrus. I'm a pediatrician from Tulsa. I've been in solo practice on staff at six hospitals there, chief of pediatrics for Southcrest Hospital and been giving Synagis in my office for years and years; taking care of a lot of special needs children that are vent dependent and have other needs. What I have seen over the years is a reduction in hospitalizations in my own particular practice. When you all, you know, set out the guidelines last year and you really kind of came in a very superior way of looking at the AAP guidelines and you moved into a guideline that says we're going to, you know, kind of hit middle ground. It gave us a lot of things to work with. This is a very fragile group of kids. Even at the 34 or less than, if you will, 35 weeks of age, this is a fragile set of children and we all understand that. They're at a particular risk when they are in the SoonerCare population. We understand that. We're sitting here trying to debate over something that we have a very fragile at-risk group of children. You've taken the stand to move into the, move away from the AAP guidelines into a middle ground. It was a great move, it was an excellent move; and what we see is, if we maintain that, that we give our children who are at-risk for RSV, decreased hospitalizations are going to be our reward on that situation. So this is what I see. The other thing that was really amazes me about the COVID guidelines is you know, we look at all the time at evidence-based medicine. We look at it all the time. We base our whole judgement on evidence-based medicine. It is the buzzword of right now. And what we did was we came up with guidelines with no evidence. All we did was, we had expert opinion. These guys are smart. These people are smart and I agree with that. But when we look at evidence-based medicine, we look at the guidelines of what we're doing. Let's stick with that. It has served us well. It has taken things off the market, it has proved drugs to be valuable and really, not so valuable. So why don't we stick with that? The Oklahoma Health Care Authority, you know, the DUR Board has come up with this guideline that has served us well and to keep that guideline exactly where it is gives us pediatricians, the pulmonologists, the ID's, another tool in their armamentarium to help these children that are at risk the most. And when we do that I think that you'll find that overall, the admissions will be the best they can be for the at-risk population. When you, you know, you say, you look at studies, there's been one study that Dr. Chang, we've been very, very fortunate in the Tulsa area to have received Dr. Chang just recently. He's an ID guy from out of Texas and he looked at one of the studies out of the Dallas area where we have seen an increased amount of RSV in the area; 3,000 hospital admissions, over 600 of them have been into the ICU; on average about a week on mechanical ventilation for a fifth of those patients; so when you see that you can use, that's a lot of revenue, that's a lot of money going into caring for this at-risk group. The median age, 34 weeks, for gestation. The median age for admission, four months of age. So it is outside the three months. It's inside that 35 weeks area. So that's where we sit right now is that we are at a perfect guideline to me, for the State of Oklahoma. Especially now that I've learned about the new, what the new CDC guidelines, or you know, committee's trying to form, it's a great way to keep things where they are. We've had a balance basically between the use of Synagis and what the impact on budget is and waiting to see what's going on with the CDC. So I think what you've done last year was commendable. It was, it showed that we had the ability to step out, do what's best for Oklahoma children, especially this huge at-risk population, and I don't see we can do this the same this year. I'd be more than happy to answer questions.

Dr. Graham: I've got a question for you Dr. Do you agree that compliance is probably the most important thing in this, right?

Dr. Cyrus: Uh-huh.

Dr. Graham: Do you follow the patients after you give them the initial injection, make sure they get all their doses?

Dr. Cyrus: Yes sir. I call every month the day before. I have called them numerous times the day of. I've had them if they've missed the day of, I call them that day until I track them down. I actually am one of the very few pediatricians that see patients in the hospital, see them in the nursery and see them in the office. So, yes sir, I do. If they get sick, they see me at 5:00 in the morning.

Dr. Kuhls: Yeah, so it's in your best interests to call them?

Dr. Cyrus: Yes, it is in my best interests to call them, because it decreases my hospitalization and keeps me from having to make rounds. This morning I was up at 4:30 making rounds because I had three hospitals to hit.

Materials included in agenda packet; presented by Dr. Moore.

PA and appeals turnaround time was discussed and noted to be within 24 hours, and also that questionable cases are referred to the OHCA neonatologist, Dr. Lopez, for approval or denial.

Correction noted to recommendation B date changed to November 1, 2010 through March 31, 2011.

Dose pooling clarification – per the FDA, the vial is a single-dose vial.

Discussion to note on PA approvals for 32-34 weekers that approval is for three doses and also state special considerations for additional doses are to be returned to PMC/College of Pharmacy for a maximum five dose approval.

Board members were also advised of OHCA's care management department and upcoming discussion regarding Synagis compliance, maximization of dosing and other issues.

Dr. Kuhls moved to approve with date change for recommendation B (approval dates November 1, 2010 through March 31, 2011), and special considerations message on PA's; seconded by Ms. Varalli-Claypool.

ACTION: MOTION CARRIED

AGENDA ITEM NO. 12: FDA & DEA UPDATES

Materials included in agenda packet; presented by Dr. Graham.

ACTION: NONE REQUIRED

AGENDA ITEM NO. 13: FUTURE BUSINESS

Materials included in agenda packet; submitted by Dr. Graham.

A: Annual Review of Growth Hormones

B: Annual Review of Narcotics

C: Annual Review of ESAs

D: New Product Reviews

ACTION: NONE REQUIRED

AGENDA ITEM NO. 14: ADJOURNMENT

The meeting was adjourned at 8:18 p.m.



The University of Oklahoma

Health Sciences Center

COLLEGE OF PHARMACY

PHARMACY MANAGEMENT CONSULTANTS

Memorandum

Date: September 9, 2010

To: Nancy Nesser, Pharm.D., J.D.
Pharmacy Director
Oklahoma Health Care Authority

From: Shellie Keast, Pharm.D., M.S.
Drug Utilization Review Manager
Pharmacy Management Consultants

Subject: DUR Board Recommendations from Meeting of September 8, 2010

Recommendation 1: Vote to Prior Authorize Ampyra™ (dalfampridine)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorizing Ampyra™ (dalfampridine) with the following criteria:

- Member must have a diagnosis of Multiple Sclerosis
- Kurtzke Expanded Disability Status Scale (EDSS) score between 4 and 7.5
- A 90 day trial will be approved. If member has responded well to treatment and physician states that the member has shown improvement or the drug was effective, member may receive authorization for one year
- Quantity limit of 60 for 30 days

Recommendation 2: Vote to Prior Authorize Qutenza® (capsaicin) 8% Patch

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends pharmacy and medical prior authorization of Qutenza® (capsaicin) 8% patch with the following criteria:

1. FDA approved diagnosis (Postherpetic Neuralgia).
2. Provide documented treatment attempts at recommended dosing or contraindication to at least one agent from each of the following drug classes:
 - a. Tricyclic antidepressants
 - b. Anticonvulsants
 - c. Topical lidocaine
3. Quantity limit of no more than 4 patches per treatment every 90 days.
4. **Product must be administered by a healthcare provider.**

Recommendation 3: Vote to Prior Authorize Victoza® (liraglutide) and Bydureon® (exenatide LAR)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends placing a prior authorization on Victoza® (liraglutide) and Bydureon® (exenatide long-acting), when it becomes available. Approval is based on prior authorization criteria similar to that required for Byetta® (exenatide):

1. Diagnosis of Type 2 Diabetes.
2. Therapy with metformin, sulfonylurea, thiazolidinediones, or a combination, for at least 90 days within the last 180 days, that has not yielded adequate glycemic control.
3. ~~Clinical exception may be allowed if medication is prescribed by an endocrinologist.~~

Recommendation 4: Vote to Prior Authorize Special Formulation Antibiotics

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends pharmacy prior authorization of these special formulation antibiotics with the criteria as follows:

Moxatag® (extended-release amoxicillin) criteria:

1. FDA-approved diagnosis of tonsillitis and/or pharyngitis secondary to *Streptococcus pyogenes*, confirmed by clinical testing, in members 12 and older.
2. Must provide a clinical reason why the member cannot take immediate-release forms of penicillin, amoxicillin, or amoxicillin/clavulanate.

Augmentin XR® (amoxicillin/clavulanate potassium) criteria:

1. FDA-approved diagnosis of community-acquired pneumonia or acute bacterial sinusitis due to confirmed or suspected β -lactamase-producing pathogens (i.e. *H. influenza*, *M. catarrhalis*, *H. parainfluenzae*, *K. pneumoniae*, or methicillin-susceptible *S. aureus*) and *S. pneumoniae* with reduced susceptibility to penicillin (i.e. penicillin MICs = 2 mcg/mL, but not indicated if MICs \geq 4 mcg/mL).
2. Must provide a clinical reason why the member cannot take immediate-release forms of penicillin, amoxicillin, or other forms of amoxicillin/clavulanate.

Oracea® (extended-release doxycycline) criteria:

1. FDA-approved diagnosis of rosacea with inflammatory lesions in adults 18 and older.
2. Must provide a clinical reason why the member cannot take immediate-release forms of doxycycline.

Doryx® (extended-release doxycycline) criteria:

1. FDA-approved diagnosis.
2. Must provide a clinical reason why the member cannot take immediate-release forms of doxycycline.

Oravig® (miconazole buccal tablets) criteria:

1. FDA-approved diagnosis of oropharyngeal candidiasis in adults age 18 and older.
2. Recent trials (within the last month) of the following medications at recommended dosing and duration of therapy:
 - a. Clotrimazole troches, AND
 - b. Nystatin suspension, AND
 - c. Fluconazole tablets
3. Contraindication(s) to all available alternative medications.

The College of Pharmacy also recommends the prior authorization of drugs on the market that are reformulations of existing anti-infectives. Member must have a clinically significant reason why the existing formulation and/or other cost effective therapeutic equivalent medication(s) cannot be used.

Recommendation 5: Vote to Prior Authorize Anticonvulsants

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends prior authorization of the anticonvulsant category under the scope/utilization PA program.

1. Anticonvulsants will be included in the current mandatory generic plan.
 - a. All brand-name anticonvulsants (**with a generic equivalent**) will require prior authorization.
 - i. Brand-name medications (**with a generic equivalent**) will be approved for all members who are currently stable on these medications and have a seizure diagnosis.
2. Prior authorization will be required for certain non-standard dosage forms of medications when the drug is available in standard dosage forms.
 - a. Members 12 and older must have a documented medical reason demonstrating need for non-standard dosage forms.
 - b. Criteria for approval of extended-release formulations:
 - i. Previously stabilized on the short-acting formulation.
 - ii. Dosing is not more than once daily.
 - iii. Member must provide a reason why the short-acting formulation is not adequate.
 - c. Dosepacks will not be approved if standard dosage forms are available.
3. Quantity limit restrictions will be placed on lower strength tablets and capsules. The highest strengths will continue to have no quantity restrictions unless a maximum dose is specified for a particular medication.
4. Felbamate will require prior authorization with the following criteria:
 - a. Initial prescription written by a neurologist.
 - b. Member has failed therapy with at least three other medications commonly used for seizures.

Recommendation 6: Vote to Prior Authorize Procentra® (dextroamphetamine) and Second Opinion Process for ADHD/Narcolepsy PBPA Category

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends inclusion of the ADHD/Narcolepsy PBPA category in the Second Opinion Program for all SoonerCare members aged 0-4. The current Second Opinion Process, which provides a response to both the pharmacy and the prescriber within 24 hours of receipt of the petition, will be utilized.

The College of Pharmacy also recommends the addition of ProCentra® (dextroamphetamine) to Tier 3 of the PBPA category. The current criteria for the category will apply. In addition, a clinical reason necessitating the need for the liquid formulation must be provided.

Recommendation 7: Annual Review of Synagis® (palivizumab)

MOTION CARRIED by unanimous approval.

The College of Pharmacy recommends modification of the existing Synagis® (palivizumab) authorization criteria as recommended by the American Academy of Pediatrics (AAP) guidelines.

A. Member Selection. Members must be included in one of the following age groups at the beginning of the RSV season:*

1. Infants and children less than 24 months old with Chronic Lung Disease (CLD) (formerly bronchopulmonary dysplasia) who have required medical treatment (O₂, bronchodilator, corticosteroid, or diuretic therapy) for CLD in the 6 months prior to RSV season.
2. Infants up to 24 months old with moderate to severe pulmonary hypertension, cyanotic heart disease, or those on medications to control congestive heart failure.
3. Infants less than 12 months of age, born at 28 weeks gestation or earlier
4. Infants less than 6 months of age, born at 29-31 weeks gestation.
5. Infants less than 12 months of age, born before 35 weeks gestation, with congenital abnormalities of the airway
6. Infants less than 12 months of age, born before 35 weeks gestation, with severe neuromuscular disease
7. Infants, up to 3 months old at the start of RSV season, born at 32-34 weeks gestation, who have one of the following risk factors: **(up to three doses only)**
 - a. Child care attendance
 - b. Siblings younger than 5 years of age

* Treatment is authorized for the entire RSV season **(as indicated) except for members meeting criteria #7, in which case, a maximum of 3 doses will be authorized. Prescribers may request**

special consideration for additional doses (up to the end of the RSV season as indicated) on an individual patient basis for members meeting criteria #7.

B. Length of treatment. Synagis[®] is approved for use only during RSV season. Approval dates will be November 1 through March 31.

C. Units authorized. The maximum duration of therapy is five (5) doses, with a dose to be administered no more often than every 30 days. Infants born at 32-34 weeks gestation will receive a maximum of three doses. Members given doses more frequently than every 30 days will not be authorized for additional doses. Doses administered prior to the member's discharge from a hospital will be counted as one of the approved total.

D. Dose-pooling. To avoid unnecessary risk to the patient, multiple patients are not to be treated from a single vial. Failure to follow this recommendation will result in referral of the provider to the Quality Assurance Committee of the Oklahoma Health Care Authority.

Scott S. Cyrus, DO, FACOP
Children & Adolescent Medical Services, Inc.
8803 South 101st East Avenue, Suite 200
Tulsa, OK 74133

September 7, 2010

Oklahoma Health Care Authority (OHCA)
Drug Utilization Review Board (DUR)

RE: Synagis (palivizumab) Guidelines for 2010-2011 RSV season

Dear Board Chair:

I have had the opportunity to treat many of Oklahoma's special needs children and other infants that have required Synagis (palivizumab) during the Respiratory Syncytial Virus (RSV) season. The 2009 Red Book guidelines for the use of Synagis (palivizumab) changed and the DUR board advised the OHCA to change the age requirements but more importantly allowed the physicians of Oklahoma to continue to treat infants that have met the guidelines throughout the RSV season. I understand the DUR board again this year is considering changing the guidelines to Synagis (palivizumab) that may in fact place the infants of Oklahoma at risk and cost the OHCA an increased number of hospitalizations.

RSV exposure avoidance and Synagis (palivizumab), a RSV monoclonal antibody, are key strategies in the prevention and hospitalization of premature infants with RSV. It is a well known fact that sixty five percent of all births in Oklahoma are covered by SoonerCare and many of those are preterm or extremely preterm. Supportive care is the key treatment option for most term infants who contract RSV. Those infants born prior to 35 weeks who have chronic lung disease, bronchopulmonary dysplasia, congenital heart disease, compromised respiratory or immune systems have higher rates of re-hospitalization due to RSV. They will have these conditions throughout the RSV season and therefore would benefit from Synagis (palivizumab) throughout the season. The RSV season severity varies from year to year as well as the peak time for RSV. For infants born at 32-35 weeks gestation, the Redbook guidelines recommend a maximum of 3 doses and dosing Synagis (palivizumab) only to 3 months of age. The severity and variation of the season, as well as the infant's condition will impact the true bottom line and so consequently maintaining the guidelines in their current status would benefit the infants of Oklahoma.

The selection process for the guidelines and use of Synagis (palivizumab) is a very arduous task, one that admittedly requires much deliberation and study. I can understand the difficulties balancing the budget demands with the health of Oklahoma's premature babies. I can propose to you the use of the current guidelines and feel they are superior to other guidelines. They will benefit the children of Oklahoma and provide the best opportunity to prevent unnecessary admission which would avoid taxing the already strapped budget. I appreciate your time in this most critical matter and please feel free to contact me should any additional information be required or requested.

Sincerely,



Scott S. Cyrus, D.O., FACOP



www.BreatheASAP.com

7125 South Braden Avenue
Tulsa, OK 74136

918.481.8100 Office
918.481.0159 Fax

August 31, 2010

Ron Graham, D. Ph.
Director of Pharmacy Management Consultants
1122 NE 13th
Oklahoma City, Oklahoma 73117

Dear Dr. Graham:

It has been brought to my attention that the Oklahoma DUR board plans on reviewing the criteria for RSV prophylaxis on September 8th. I agreed with the decision last year not to adopt the abbreviated dosing regimen of Synagis as outlined by the AAP COID for the 32 0/7 to 34 6/7 GA infants. The literature does not offer clinical support for a limited dosing regimen. The NPA (National Perinatal Association) recently published RSV prophylaxis guidelines and confirmed that there is not sufficient evidence for this particular change. I would also point out, as the NPA did, that this is against the FDA approved labeling. I would recommend that the DUR board maintain the current policy to dose the 32 0/7 to 34 6/7 GA infants throughout the entire RSV season.

Sincerely,

T. L. Carey, M.D., FAAP, FAAAAI, FACCP
Pediatric Pulmonology/Allergy/Immunology



Michael Lee Chang, M.D.
Pediatric Infectious Diseases
6151 South Yale Avenue
Suite 1303
Tulsa, OK 74136
(918).502.2700

Oklahoma Health Care Authority
Drug Utilization Review Board
2401 N.W. 23rd St.
Suite 1A
Oklahoma City, OK 73107

To the Members of the Oklahoma Medicaid Drug Utilization Review Board:

I am writing this letter regarding the issue of prophylaxis with palivizumab against respiratory syncytial virus (RSV) infection for infants in the state of Oklahoma. There has been much debate amongst pediatricians, pulmonologists, and neonatologists about the appropriate use of palivizumab since the American Academy of Pediatrics (AAP) Committee on Infectious Diseases (COID) published revised indications for administration of palivizumab in late 2009. As a new member of the Oklahoma physician community with specialization in pediatric infectious diseases, I would like to share my opinion.

I am in agreement with the AAP COID on the majority of the revised indications, with the exception of the final portion of the following recommendation:

“Prophylaxis may be considered for infants from 32 through less than 35 weeks’ gestation (defined as 32 weeks 0 days through 34 weeks 6 days) who are born less than 3 months before the onset or during the RSV season and for whom at least 1 of the 2 risk factors is present. Infants in this gestational-age category should receive prophylaxis only until they reach 3 months of age and should receive a maximum of 3 monthly doses; many will receive only 1 or 2 doses before they reach 3 months of age. Once an infant has passed 90 days of age, the risk of hospitalization attributable to RSV lower respiratory tract disease is reduced. Administration of palivizumab is not recommended after 90 days of age”

Specifically, infants over 90 days of age may still be at significant risk for severe disease due to RSV. Retrospective analysis of approximately 3,000 patients admitted (approximately 650 to intensive care) to a large free-standing tertiary referral pediatric hospital in Dallas over 7 years (2001/2002 to December 2007) demonstrated the following findings:

- 1) The number of admissions due to RSV disease actually increased significantly over this time period. Approximately 1 in 5 patients required intensive care.
- 2) Most infants admitted for bronchiolitis or lower respiratory tract infection (LRTI) due to RSV were actually of term gestational age. Among the pre-term infants (estimated gestational age less than 37 weeks), the median gestational age was 34 weeks.
- 3) The median age at the time of admission of infants admitted to the hospital for RSV disease was 4 months. For infants requiring intensive care, the median age was 69 days. However, nearly 42% of patients admitted to the ICU were over the age of 3 months at the time of admission. More importantly, when examining pre-term infants admitted to the ICU, 22% were between the ages of 3 months and 6 months.
- 4) Nearly 66% of pre-term infants admitted to the ICU for RSV disease required intubation and mechanical ventilation with the median length of intubation lasting 7 days. The median length of total days of hospitalization was 10 days.

As you can see from the data (which has been presented at the annual meetings for American Pediatric Society/Society for Pediatric Research in 2009 and the Infectious Diseases Society of America/Interscience Conference on Antimicrobial Agents and Chemotherapy in 2008), the burden of RSV disease is still increasing. Infants with an estimated gestational age of 34 weeks and over 90 days of age make up a significant proportion of patients requiring hospital admission and intensive care. Further, the majority of patients in intensive care due to RSV disease require mechanical ventilation for 1 week, utilizing significant hospital resources during RSV season. Taken together, it is my opinion that discontinuing administration of palivizumab at 90 days of age for infants with gestational age of 32 to 35 weeks during the annual RSV epidemic is not an optimal dosing regimen for RSV prophylaxis and infants that are at high risk for severe disease will not be protected.

Being new to Oklahoma, I am not as familiar with the epidemiology of RSV disease in this state and the data presented were collected in north Texas. As a retrospective analysis the results presented above may not reflect future trends. However, the very large number of patients included from a region with similar climate and RSV seasonality lends significant relevance to the analysis for Oklahoma.

Overall, I agree with the majority of the revised indications for palivizumab from the AAP COID. I believe that the revised indications may actually result in increased doses of palivizumab for infants since the guidelines actually lower the number of risk factors necessary to qualify for palivizumab (to 1) for infants 32 to 35 weeks gestational age. However, I disagree with stopping administration at 90 days of age for infants who meet initial criteria to qualify for RSV prophylaxis based on the above data. It would be my recommendation to continue and complete 5 doses of palivizumab for the RSV season for those infants

between 32 and 35 weeks gestational age to provide optimal protection for these infants that continue to be at high risk for severe disease due to RSV.

Thank you for your time and consideration on this important issue.

Sincerely,

Michael L. Chang, M.D.
Pediatric Infectious Diseases
The Children's Hospital at St. Francis