

**Drug Utilization Review Board
Meeting Minutes, Open Session
June 15, 2011**

<p>Drug Utilization Review Board Meeting Minutes, Open Session HP Enterprise Services / Forbes Field Capital / Cedar Crest Room Topeka, KS</p>	<p>Members Present: Michael Burke, M.D., Ph.D., Chair Dennis Grauer, Ph.D. Roger Unruh, D.O. Kevin Waite, Pharm.D. John Kollhoff, Pharm.D. Members Absent: Daniel Sutherland, R.ph. Judy McDaniel Dowd, PA-C KHPA Staff Present: Kelley Melton Shelly Liby Dr. Margaret Smith Shea Robinson HP Enterprise Services Staff Present: Deb Quintanilla, R.N. Lisa Todd, R.Ph. Debra Quintanilla, R.N. Nicole Churchwell, Pharm.D. ACS Staff Present: Bethany Noble, C.Ph.T Karen Powell, Pharm.D.</p>	<p>Representatives: Laura Nichols, GSK Phil King, Pfizer Teresa Blair, Amgen Susan Zalenski, J & J Jim Baumann, Pfizer Nick Boyer, AstraZeneca Karen Vandeputte, Astulas Jerry Clewell, Abbott Dan Castor, Pfizer Michelle Terry, Mereck Jeff Plaster, Purdue Julie McDavitt Ann Harty, Endo Scott Maurice, Boehringer Ingelheim Eric Gardner, Vertex</p>
TOPIC	DISCUSSION	DECISION AND/OR ACTION
I. Call to Order	Dr. Burke, Board Chair, called the meeting to order at 10:01 a.m.	
II. Announcements	<p>Nicole Churchwell advised the attendees that the parking spaces in the front of the building (east side) are available for the Board members and that there is additional parking on the west side of the HP office for visitors. Public comments are limited to 5 minutes & you will need to fill out a public disclosure form & return it.</p> <p>Shelly Liby introduced Kelley Melton as the new Pharmacy Manager and Shea Robinson as the Administrative Assistant. She also introduced Bethany Noble, ACS Project Director, and Karen Powell, Pharmacist, for ACS. ACS is the new vendor for the automated prior authorization (PA) system.</p> <p>The DUR meeting will be run differently. Nicole will still lead the meetings and present the medical criteria for HCPCS procedures and ACS will present the criteria for pharmacy PAs.</p>	

<p>III. Old Business</p> <p>A. Review and Approval of June 15, 2011 Meeting Minutes</p> <p>B. Topical Acne Medications (Differin® (adapalene), Epiduo® (adapalene/benzyl peroxide), Azelex® & Finacea® (azelaic acid) , Aczone® (dapson), Retin-A® & Atralin® (tretinoin), Veltin® & Ziana® (tretinoin/clindamycin), and Tazorac® (tazarotene))</p>	<p>No changes made.</p> <p><u>Background:</u> Currently, tretinoin topical agents for acne require prior authorization while other topical acne treatments do not. To ensure consistency, prior authorization criteria for all other agents in this class are being proposed. In April 2011 the DUR Board moved to table this agenda item for further review.</p> <p>The board approved the new Clinical PA Criteria</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> This was presented at the last board meeting and at that time it was decided to table the agenda item until this meeting.</p>	<p>Dr. Waite moved to approve the minutes as written.</p> <p>Dr. Unruh seconded the motion.</p> <p>Motion carried unanimously.</p> <p>Dr. Kollhoff moved to approve the new PA criteria.</p> <p>Dr. Grauer seconded the motion</p> <p>Motion carried unanimously.</p>
<p>IV. New Business</p> <p>A. Retinoids (Targretin (bexarotene), Pancretin (alitretinoin), and Vesanoïd (tretinoin)</p> <ol style="list-style-type: none"> i. Revises Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> The retinoid agents currently require prior authorization. The prior authorization criteria were last revised in August 2000. In April 2011 the DUR board requested this criteria be revised and topical tretinoin products be removed from these criteria and added to the topical acne medications criteria.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Grauer commented that the criteria were much cleaner by splitting the topical acne medications and retinoids products.</p>	<p>Dr. Kollhoff moved to accept the revised PA criteria.</p> <p>Dr. Waite seconded the motion.</p> <p>Motion carried unanimously.</p>

<p>B. Rituxan® (rituximab)</p> <ul style="list-style-type: none"> iv. Revises Clinical PA Criteria v. *Public Comment vi. Board Discussion/Action 	<p><u>Background:</u> Indications for Wegener’s Granulomatosis (WG) and Microscopic Polyangiitis (MPA) were approved in April 2011 by the FDA. Prior authorization criteria for Rituxan® was initially approved by the DUR board in January 2010, the criteria is being revised to include the newly approved indications.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke indicated these changes are based on new indications in the package insert.</p>	<p>Dr. Kollhoff moved to accept the revised PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>C. Regranex® (becaplermin)</p> <ul style="list-style-type: none"> i. Revises Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> The package insert for Regranex® was updated in March 2011 and the prior authorization criteria are being revised to reflect the current package insert.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Churchwell indicated there previously were criteria that were not supported in the current package insert. This has been removed (patient’s nutrition status, albumin level, caregiver instructions and the requirement of photos). Dr. Burke commented the board was particularly concerned with safety when the criteria were initially developed. The new criteria are less restrictive and in line with the current package insert. He added that there are not that many unique beneficiaries that use this drug.</p>	<p>Dr. Kollhoff moved to accept the revised PA criteria.</p> <p>Dr. Grauer seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>D. Topical Immunomodulators Elidel® (pimecrolimus) and Protopic® (tacrolimus)</p> <ul style="list-style-type: none"> i. New Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> Elidel® and Protopic® are topical immunosuppressants indicated as second-line therapy for short-term and non-continuous treatment of atopic dermatitis in non-immunocompromised patients who have failed to respond adequately to other topical prescription treatments or when those other treatments are not advisable. Per prescribing information, Protopic® 0.1% ointment should be used only by patients who are 16 years of age or older. The current prior authorization (PA) criteria state that Protopic® 0.1% ointment is approvable for patients over 15 years of age. We recommend changing the wording to 16 years of age or older to match the prescribing information.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke advised this is a straight forward agenda item, but it is the first introduction to the new flow chart format for the ACS/SMART PA system that will be used in future presentations. Circled items reflect what has been changed on the criteria and in this case, the age is changing from greater than or equal to 15 to greater than or equal to 16.</p>	<p>Dr. Kollhoff moved to approve the revised PA criteria.</p> <p>Dr. Waite seconded the motion.</p> <p>Motion carried unanimously.</p>
<p>E. Enbrel® (atanercept)</p> <ul style="list-style-type: none"> i. Revised Clinical PA Criteria ii. *Public Comment 	<p><u>Background:</u> Enbrel® is a tumor necrosis factor (TNF) blocker with several FDA-approved indications, one of which is the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or</p>	<p>Dr. Kollhoff moved to approve the revised PA criteria.</p> <p>Dr. Waite seconded the motion.</p>

<p>iii. Board Discussion/Action</p>	<p>phototherapy. The current Enbrel® prior authorization (PA) criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 diagnosis code. We recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule to allow PA approval at the point-of-sale (POS).</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke indicated that the change is to simply use the general psoriasis diagnosis code (696.1) since there is not a specific ICD-9 code for plaque psoriasis. This will allow the prior authorization to go through the automated SMART PA system. Dr. Smith added that there will most likely be a more specific diagnosis code available with the implementation of ICD-10 codes in October 2013.</p> <p>Dr. Grauer asked what the process was when the diagnosis is not in the beneficiary’s medical history. Dr. Powell explained that the PA could not be automated but the prescriber would need to provide information to the call center to request the PA (which is similar to the current process).</p>	<p>Motion carried unanimously.</p>
<p>F. Humira® (adalimumab)</p> <p>i. Revised Clinical PA Criteria</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion/Action</p>	<p><u>Background:</u> Humira® is a tumor necrosis factor (TNF) blocker with several FDA-approved indications, one of which is the treatment of adult patients with moderate to severe, active plaque psoriasis who are candidates for systemic therapy or phototherapy and when other systemic therapies are medically less appropriate. Two minor revisions to the criteria are recommended.</p> <ol style="list-style-type: none"> 1. While PA approval at the point-of sale (POS) is not possible due to other PA requirements, we recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule for consistency among all agents used for the treatment of plaque psoriasis. 2. In the current prior authorization (PA) criteria for other biologics (e.g., Enbrel, Kineret, Remicade), authorization for more than one biologic is not allowed. While Humira is listed as a biologic in the criteria for other drugs, the limitation of one biologic authorization is not in the current Humira PA criteria. We recommend adding this limitation to the Humira criteria. <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Kollhoff asked about the time frame for no concurrent usage for these agents. Dr. Powell responded that the criteria looks at the past 30 days.</p> <p>Dr. Powell also explained to the board the differences of the flowchart. The flowchart</p>	<p>Dr. Kollhoff moved to approve the revised PA criteria.</p> <p>Dr. Waite seconded the motion.</p> <p>Motion carried unanimously.</p>

	<p>outlines the steps the call center uses to manually process a PA request. Each box is a question or part of the criteria that must be answered. Blue boxes are questions that cannot be answered systematically via pharmacy or medical history and must be provided either by fax or phone by the provider. An example of this is the results from a lab test. The system can verify a test was received but not the outcome of the test.</p> <p>Dr. Burke said the board previously wanted to be safe by requiring specialty prescribers to prevent adverse reactions. He wondered what the impact was for beneficiaries that did not have access to the required specialist. Dr. Smith responded that most often the beneficiary will receive an evaluation by the specialist and follow up once a year.</p>	
<p>G. Remicade® (infliximab)</p> <ul style="list-style-type: none"> i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> Remicade® is a tumor necrosis factor (TNF) blocker with several approvable indications, one of which is the treatment of adult patients with chronic, severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The current Remicade prior authorization (PA) criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 code. We recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule to allow PA approval at the point-of-sale (POS).</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke added that this is similar to the previous agenda item. There was no further board discussion.</p>	<p>Dr. Waite moved to approve the revised PA criteria.</p> <p>Dr. Grauer seconded the motion.</p> <p>Motion carried unanimously</p>
<p>H. Amevive® (alefacept)</p> <ul style="list-style-type: none"> i. New Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> Amevive® is a recombinant, immunosuppressive fusion protein indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy. The current Amevive prior authorization (PA) criteria require the prescriber to manually provide the specific diagnosis of plaque psoriasis since there is no corresponding ICD-9 code. While PA approval at the point-of sale (POS) is not possible due to other PA requirements, we recommend using the general ICD-9 code for psoriasis (696.1) in the SmartPA rule for consistency among all agents used for the treatment of plaque psoriasis.</p> <p><u>Public Comments:</u> Karen Kluczykowski from HP asked if the changes made on these drugs also impact the existing physician administered criteria utilized by HP. Deb Quintanilla explained that these approved changes are being made for the Smart PA system but her staff can still look for the plaque psoriasis diagnosis because it's a manual step that can be required by the physician's office when billed using the HCPCS code.</p>	<p>Dr. Grauer moved to approve the revised PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>Motion passed unanimously.</p>

Shelly Liby stated the ACS criteria will be applied to both medical and pharmacy criteria but Dr. Smith indicated that if we could get more specific with our criteria, we should. Dr. Kollhoff asked how often this drug is used off-label. Deb Quintanilla responded that is not currently known at this time because the criteria is specific and providers know they won't get it without the plaque psoriasis diagnosis because that is how it's been since 2005. The outcome of the discussion was that there can be two sets of criteria for a drug if the manual process by HP can be more specific than ACS' point of sale criteria.

Dr. Waite asked for clarification regarding whether the changed diagnostic criteria for SmartPA was for renewal purposes only (look for psoriasis only) and not the initial PA request (that would look for plaque psoriasis). Lisa Todd acknowledged that this was not the case and that any diagnosis of psoriasis would allow the PA. These drugs are infusions and most won't go through the pharmacy (with the exception of Humira®).

The state's goal is to automate the criteria but in most cases with these agents, the flowchart requires interaction with the call center. Automating the psoriasis question will allow the ACS system to process as many steps as possible before manual intervention is required. It's possible to keep the plaque psoriasis diagnosis in the ACS workflow to be consistent with HP's process. Dr. Grauer asked if there was a situation where one call center approves and the other doesn't. Deb Quintanilla responded that the systems are linked so the MMIS will know if there is an existing PA. Dr. Waite responded that as long as the outcome is the same, then it's ok if the processes or workflow is different.

Dr. Burke said the blue boxes in the ACS criteria will require the prescriber to provide information. Dr. Churchwell pointed out the difference is that Enbrel® could get approved before they are required to call for PA to answer other questions – this is the only biologic that can be fully automated when allowing the general diagnosis of psoriasis. Dr. Smith recommended taking out the look back for oral therapy and ask if the person is a candidate for oral therapy which will put everyone through the call center at the end of the work flow. This offers consistency across the agents.

The board recognized that the goal of implementing ACS was to provide more automation and the discussion is short-circuiting that effort. Dr. Kollhoff recommended updating the criteria to be more specific when the ICD-10 diagnosis codes become available. The conversion to ICD-10 will require future changes be made.

Dr. Waite asked that the changes stand as approved and utilization data is reviewed in six to 12 months to look for outliers of how these changes have impacted PA. The risk is minimal enough to try to streamline it for the majority of the patients.

It was determined that ACS point of sale criteria will use the general psoriasis diagnosis and the ACS call center step will be the same as HP's and ask for a plaque psoriasis diagnosis.

	<p>This will be the case for Enbrel®, Humira®, Remicade® and Amevive®.</p> <p>Susan Zalenski, Johnson & Johnson, asked if the approval criteria for the call centers would be listed on the web site. Shelly Liby responded the criteria will not be listed on the web site; it is for internal processes only. The criteria reflects what is in the package insert so as long as providers are prescribing as indicated in the package insert, it will meet the PA criteria. Dr. Smith added the prior authorization form will be listed on the web site, as it currently is.</p> <p>Jim Baumann, Pfizer, wanted to clarify what will be required by the providers – phone call or fax and who those will be directed to. Authorization for physician administered drugs will be requested through HP using the fax form on the KDHE website. Outpatient drugs will be handled either through the point-of-sale transaction (if criteria can be automated) or by ACS through a phone call or fax (if manual processing is required).</p> <p>Dr. Grauer asked about the possibility of putting the criteria on the web site. Dr. Churchwell responded that there is the risk of having a small number of providers answer PA questions based on the criteria alone. That could be happening currently anyway but it was discussed that potentially not all criteria should be posted (narcotics) and to be consistent we do not post. Susan Zalenski indicated other states list their criteria and will send some examples for Dr. Melton to consider.</p> <p><u>Board Discussion:</u> No discussion regarding Amevive specifically.</p>	
<p>I. Forteo® (teriparatide)</p> <ul style="list-style-type: none"> i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> Forteo® is a recombinant human parathyroid hormone analog indicated to treat postmenopausal women with osteoporosis at high risk for fracture, increase bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture and treat men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture. The current Forteo prior authorization (PA) criteria require failure of or intolerance to conventional osteoporosis therapy which is defined as bisphosphonate therapy. We recommend expanding the definition of conventional osteoporosis therapy to include calcitonin products and raloxifene (Evista®).</p> <p><u>Public Comments:</u> Karen Kluczykowski clarified that because this can be administered by a physician, HP should ensure their criteria are updated as well as the ACS workflow. Dr. Burke note d when there are criteria changes that affect both contractors, both sets should be presented at the meeting.</p> <p><u>Board Discussion:</u> There was no board discussion.</p>	<p>Dr. Waite moved to approve the revised PA criteria.</p> <p>Dr. Grauer seconded the motion.</p> <p>Motion passed unanimously.</p>

<p>J. Weight Loss Drugs (Xenical® & Alli® (orlistat) and Adipex-P® (phentermine))</p> <ul style="list-style-type: none"> i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> This group of drugs includes orlistat (Xenical®, Alli®) and phentermine (Adipex-P®); sibutramine (Meridia®) is no longer on the market. The criteria for orlistat and phentermine allow for approval in pediatric patients (orlistat >= 12 years) as long as the Body Mass Index (BMI) and other criteria are met. BMI is reported for people over 20 years of age and Body Mass Index percentiles for age are typically reported for those 2-20 years of age. While PA approval at the point-of sale (POS) is not possible due to other PA requirements, we recommend adding the ICD-9 for BMI that is greater than or equal to the 95th percentile for age (V85.54) to the BMI criteria to better assess overweight or obese pediatric patients who might be eligible for these medications. The current package insert for phentermine states that the safety and effectiveness in pediatric patients has not been established therefore it is being recommended the age criteria for phentermine be changed from ≥ 16 years of age to ≥ 18 years of age.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Grauer asked if there is anything in the package insert that recommends the 95th percentile. Dr. Powell responded no, this is a way to translate the current criteria for pediatric patients that are obese into the appropriate percentiles.</p> <p>Dr. Burke asked, in regards to Dr. Grauer’s question, can a physician appeal if they have a patient in the 90th percentile but is overweight. Dr. Smith answered, yes they can appeal.</p> <p>Dr. Unruh stated the BMI criteria are skewed. BMI plots on the percentile and can be misleading for some patients.</p>	<p>Dr. Unruh moved to approve the revised PA criteria.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>Motion passed unanimously.</p>
<p>K. Long-Acting Opioids (Butrans® (buprenorphine), Duragesic® (fentanyl), Embeda® (morphine/naltrexone), Opana ER® (oxymorphone), Kadian® (morphine), Avinza® (morphine), MS Contin® (morphine), Oramorph® (morphine))</p> <ul style="list-style-type: none"> i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> Hydromorphone ER (Exalgo®) and Oxycodone SR (Oxycontin®, generics) were incorporated into the Meperidine/Hydromorphone/Oxycodone SR proposal and Tramadol ER (Ultram ER®, generics, Ryzolt®) was incorporated into the Narcotics/Tramadol/Skeletal Muscle Relaxants proposal. This was an operational change to improve efficiency and allow claims for these agents to flow through a single rule incorporating all clinical criteria and audit limits.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Kollhoff asked about the 28 day supply. If someone gets a prescription on the first of the month, do they have to wait until the 29th for the next prescription/claim? Dr. Powell replied there is a limit to the number of patches they can get in a month. Day 29 would be the reset date. It was noted this is more stringent than the normal refill allowance of 80%.</p>	<p>Dr. Waite moved to approve the revised PA criteria.</p> <p>Dr. Unruh seconded the motion.</p> <p>Motion passed unanimously.</p>

	Dr. Burke clarified this update moves hydromorphone, oxycodone and tramadol ER out of the long-acting opioid criteria and puts them into separate criteria (see next agenda item). The criteria itself is not changing.	
L. Demerol® (meperidine), Dilaudid® (hydromorphone), Exalgo® (hydromorphone ER) and OxyContin® (oxycodone) i. Revised Clinical PA ii. *Public Comment iii. Board Discussion/Action	<u>Background:</u> The long-acting opioid criteria were incorporated into the Meperidine/Hydromorphone/Oxycodone SR criteria to apply to hydromorphone ER (Exalgo) and oxycodone SR (OxyContin, generics). There were no public comments. <u>Board Discussion:</u> Dr. Burke noted that this will be more consistent with other criteria for indications for terminal illness. Deb Quintanilla also said that it's likely these beneficiaries with cancer will be enrolled with hospice; therefore, HP will be handling these requests. It won't be necessary for HP to update their criteria because the only change was to move these drugs from one set of criteria to another.	Dr. Unruh moved to approve the revised PA criteria. Dr. Kollhoff seconded the motion. Motion passed unanimously.
M. Narcotics, Tramadol, and Skeletal Muscle Relaxants i. Revised Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action	<u>Background:</u> The long-acting opioid criteria for Tramadol ER (Ultram ER®, generics, Ryzolt®) were incorporated into the Narcotics/Tramadol/SMR criteria along with the Preferred Drug List (PDL) criteria for Muscle Relaxants. This was an operational change to improve efficiency and allow a claim to flow through a single rule incorporating all clinical criteria, audit limits, and PDL requirements. There were no public comments. <u>Board Discussion:</u> There was no board discussion.	Dr. Waite moved to approve the revised PA criteria. Dr. Unruh seconded the motion. Motion passed unanimously.
N. Arcalyst® (rilonacept) i. New Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action	<u>Background:</u> Arcalyst® is an interleukin-1 blocker indicated for the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS). The other agent in this class, Ilaris® (canakinumab) was approved for prior authorization in October 2009 by the DUR board, to remain consistent among the class prior authorization criteria for Arcalyst is being proposed. There were no public comments. <u>Board Discussion:</u> Dr. Burke noted that this was modeled after the Ilaris ® PA criteria.	Dr. Grauer moved to approve the new PA criteria. Dr. Kollhoff seconded the motion. Motion passed unanimously.
O. Makena® (hydroxyprogesterone) i. Quantity Limits, Diagnosis Restrictions & New Clinical PA Criteria ii. *Public Comment iii. Board Discussion/Action	<u>Background:</u> Makena® was recently approved to reduce the risk of preterm birth in women with a singleton pregnancy with a history of singleton spontaneous preterm birth. Treatment with Makena® should begin between 16 weeks, 0 days and 20 weeks, 6 days and can be continued until week 37 (through 36 weeks, 6 days) of gestation or delivery. Prior to the approval of Makena® pharmacies compounded hydroxyprogesterone powder for this use at a price much lower than the cost of Makena®.	Dr. Kollhoff moved to approve the new diagnosis restrictions and quantity limits. Dr. Unruh seconded the motion. Motion passed unanimously.

	<p>Multiple limits are being proposed for Makena® including: quantity limits, diagnosis restrictions and prior authorization criteria. Quantity limits will ensure that the proper length of therapy is being used; prior authorization criteria are being proposed to ensure women have the indicated risk factors for preterm labor for use of Makena®. Diagnosis restrictions are also being proposed to ensure women have the indicated risk factor for preterm labor for use of Makena® since these restrictions can be implemented quicker than prior authorization criteria. The diagnosis restrictions will provide a stop-gap until the prior authorization can be implemented.</p> <p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke indicated this was a two step process – approve the quantity limit and diagnosis restriction now and implement the prior authorization after legislative approval. The drug comes in a multi-dose vial so the limit would be one vial every five weeks with a total of five vials per pregnancy. Dr. Burke said there are other cases like this currently in place where there is a quantity limit and a PA in place (ex: Actiq).</p> <p>The PA criteria reflect the diagnosis restriction and quantity limitations. Dr. Grauer asked how the PA department would know how far along the patient was. Dr. Churchwell said that the call center would need to get this information from the doctor.</p> <p>Dr. Waite asked what the beneficiaries had access to before Makena® was available. The compound product was and still is available to these patients. Prescribers can choose to prescribe the compounded product or Makena®. The PA is only for Makena® and the compounded agent does not require PA.</p> <p>Karen Kluczykowski provided some background on API and excipient coverage through the Medicaid program. There was a coverage issue earlier in the year where the compound was not available for a short period of time. That issue has been resolved.</p>	<p>Dr. Waite moved to approve the new PA criteria</p> <p>Dr. Unruh seconded the motion</p> <p>Motion passed unanimously.</p>
<p>P. Pradaxa® (dabigatran)</p> <ul style="list-style-type: none"> i. Day Supply Limits & Quantity Limits ii. *Public Comment iii. Board Discussion/Action 	<p><u>Background:</u> Pradaxa® is a direct thrombin inhibitor indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation; it was approved by the FDA in October 2010. The package insert states that Pradaxa® should be dispensed and stored in the original bottle to protect the product from moisture. Storage and handling information state that once the package is open the product must be used within 30 days. Currently there are 15 beneficiaries receiving Pradaxa®, 4 of them are receiving the 150 mg strength at quantities less than #60. Pradaxa® is indicated for twice daily dosing and is available in 75 mg & 150 mg strengths. Quantity and day supply limits are being proposed for Pradaxa®.</p>	<p>Dr. Grauer moved to approve the new limitations.</p> <p>Dr. Kollhoff seconded the motion.</p> <p>Motion passed unanimously.</p>

	<p>There were no public comments.</p> <p><u>Board Discussion:</u> Dr. Burke pointed out the utilization data provided in the packet. There have been a couple patients that have been receiving quantities of less than a bottle which wastes product. This limitation will prevent those situations from happening.</p>	
<p>Q. State Fiscal Year 2012 Retro-DUR Intervention Topic Selection</p> <p>i. Intervention Topic Selection</p> <p>ii. *Public Comment</p> <p>iii. Board Discussion/Action</p>	<p>The DUR board needs to select 2-3 topics for Intervention in SFY 2012, the remaining topics will be selected at the October DUR board meeting.</p> <p>The list of topics are below:</p> <ol style="list-style-type: none"> 1. Appropriate Migraine Headache Therapy 2. Drug Interactions in Patients with Seizure Disorders 3. NSAIDS and Cardiovascular Disease 4. Adverse Cardiometabolic Effects of Antipsychotic 5. Therapeutic Duplication 6. Non-Adherence to Antihypertension Regimen <p>Dr. Churchwell provided a refresher of the process:</p> <ul style="list-style-type: none"> • The claims data is entered in the data mining tool, RxExplorer • The claims data hits against the clinical criteria • An exceptions report is generated for review to determine which topics should be presented to the board • Board selects five topics as interventions • New exception reports are generated for each five topics using the most recent claims data • Profiles are then selected and reviewed to determine if the provider should be lettered • Provider letters are generated and mailed which include the alert message, patient profile and provider survey <p>Dr. Grauer asked about the intervention response rate. Dr. Churchwell indicated it was about 30%. Providers don't always change how they prescribe but they do indicate the information is useful (about 50%). Some of comments have been that they are not aware what other drugs are being prescribed for their patient.</p> <p>Dr. Kollhoff asked if medical claims were considered. Dr. Churchwell responded that the overall cost was included but the specific service is not considered.</p> <p>Dr. Unruh asked Dr. Churchwell that keeping mind what's best for the patient but also considering the state's economic situation, which interventions would have the most favorable economic impact. She responded that therapeutic duplication should be considered because if patients are taking two overlapping therapies it's not only a safety issue but also a cost issue.</p>	<p>Dr. Waite moved to approve the two topics for the SFY2012 Intervention topics.</p> <p>Dr. Grauer seconded the motion.</p> <p>Motion passed unanimously.</p>

	<p>The cardiometabolic effects of antipsychotic drugs category was discussed by the board, which felt that it may not save a lot of money but it may save lives. Seizure disorders were looked at closer, as well as, anticonvulsants. A previous vendor looked at anticonvulsants but it focused on off-label use. Dr. Kollhoff asked if tramadol had been included and Dr. Churchwell responded that it was recently reviewed so she excluded it so as not to review the same patients again. Dr. Waite commented that the overall health impact would be greater using the seizure disorder category.</p> <p>The following two topics chosen were:</p> <ol style="list-style-type: none"> 1. Adverse Cardiometabolic Effects of Antipsychotic 2. Drug Interactions in Patients with Seizure Disorders <p>Dr. Burke mentioned he would like to have a binder at future meetings in which we keep a brief summary of the results from the previous intervention topics.</p>	
R. Additional Public Comments	<p>Dr. Smith announced that the Kansas Health Policy Authority will become the Kansas Department of Health and Environment, Division of Health Care Finance in July.</p> <p>Jim Baumann, Pfizer , announced that multiple surrounding states publish SMART PA criteria. He request that it be considered as it improves transparency and patient care.</p>	
S. Adjourn	<p>The meeting was adjourned.</p> <p>The next DUR Board meeting will be on Wednesday, Oct. 12, 2011, beginning at 10:00 am at the HP Enterprise Services Office.</p>	<p>Dr. Waite made the motion to adjourn.</p> <p>Dr. Unruh seconded the motion</p> <p>Motion passed unanimously.</p>