

**Drug Utilization Review Board  
Meeting Minutes, Open Session  
March 11, 2009**

<p><b>Drug Utilization Review Board</b> Meeting Minutes, Open Session EDS / Forbes Field Capital / Cedar Crest Room Topeka, KS March 11, 2009</p>	<p><b>Members Present:</b> Michael Burke, M.D., Ph.D., Chair John Kollhoff, Pharm.D. Brenda Schewe, M.D. Daniel Sutherland, R.Ph. Roger Unruh, D.O. <b>KHPA Staff Present:</b> LeAnn Bell, Pharm.D. Aimee Grubb Shelly Liby Margaret Smith, M.D. <b>EDS Staff Present:</b> Deb Quintanilla, R.N. Lisa Todd, R.Ph. <b>HID Staff Present</b> Lori Dillehay, Pharm.D. Candace Rief, Pharm.D.</p>	<p><b>Representatives:</b> Jeff Knappen, Allergan Debbie King, Amgen Randy McGinley, Bayer Kelly Golden, Eli Lilly Richard Mesquias, Eli Lilly Don Larsen, Forest Ann Gustafson, GlaxoSmithKline Robert Summers, Johnson &amp; Johnson Dave Walters, Johnson &amp; Johnson Jim Baumann, Pfizer Phil King, Pfizer Joe Summers, Takeda Martin Early, Schering Plough</p>
<b>TOPIC</b>	<b>DISCUSSION</b>	<b>DECISION AND/OR ACTION</b>
I. Call to Order	Michael Burke, Chair called the meeting to order at 10:05 a.m.	
II. Announcements	<p>LeAnn Bell introduced John Kollhoff, Pharm.D. as a new member of the Board. John practices at Patterson Pharmacy in Abilene.</p> <p>Lisa Todd asked the public to fill out the conflict of interest forms if they wanted to speak to the board. There is a limit of five minutes per drug.</p> <p>Dr. Bell introduced Lori Dillehay, Pharm.D. who is employed by HID. She will be housed at EDS.</p>	
III. Review and Approval of November 12, 2008 Minutes	No changes to the minutes.	<p>Brenda Schewe moved that we accept the minutes.</p> <p>Roger Unruh seconded the motion and it carried by a unanimous vote.</p>

<p>IV. Old Business</p> <p>A. Flomax®</p>	<p><b><u>Flomax®</u></b></p> <p>Dr. Burke stated when Uraxotrol® was brought onto the formulary it was by default made available for males only. When Flomax® was brought onto the formulary there was no gender specification.</p> <p>Ms. Todd presented the utilization of Flomax® in female patients. The unique number of female patients over a three year period totaled 101.</p> <p>Dr. Burke clarified there were approximately 30 females on average per year to whom Flomax® was prescribed..</p> <p>Ms. Todd stated that the reason why a gender restriction wasn't placed on Flomax® was because the information obtained from First Data Bank when Flomax® came out didn't have a gender restriction. Since then First Data Bank has updated their information and placed a gender restriction on it, but there was nothing in the system to automatically update a gender restriction. There has been a system change order written to automatically update or flag changes from First Data Bank. Once the system has been changed there shouldn't be an issue like this again. At this time the Board needs to decide whether or not to restrict Flomax® for use in male patients only.</p> <p>Dr. Burke recalled that the Board did not find impressive data to support efficacy of Flomax® in women. He suggested the gender restriction decision should be consist throughout this class of medications. He stated it would affect about 30 patients per year.</p> <p>Dr. Schewe pointed out that it isn't the same 30 patients every year-- which suggests it is not very effective for those patients.</p> <p>Ms. Todd stated time didn't allow her to look at all the age ranges, but at a glance it looked like there were quite a few elderly people being treated with Flomax®.</p> <p>Dr. Burke made the point that the usage in female patients is inconsistent. If we want to take a lead from other pharmacy management programs the direction has been to restrict use based on gender and make these available for males only.</p> <p>Dr. Kollhoff asked if there is any procedure so it could be approved for females. He said that his understanding is that it is not typically used long</p>	<p>Dr. Schewe moved to put hard edit on Flomax® so coverage is for males only.</p> <p>Dr. Unruh seconded and it carried with a unanimous vote.</p>
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	<p>term, but could be beneficial for short term use.</p> <p>Dr. Bell reminded the Board this restriction does not allow for exceptions. She suggested Flomax for use in females could be placed on Prior Authorization (PA) if the Board feels it is appropriate to reimburse for use in females, however then PA would be required for all claims, not just those for females.</p> <p>Ms. Todd stated use in females is not an approved FDA indication. She reminded the Board the state does not promote off label use.</p> <p>Dr. Burke clarified that the physician could make an appeal, but there wouldn't be a prior authorization form that they could fill out.</p> <p>Dr. Burke stated the Board isn't in the position of policing off label use nor are we in the position of driving policy to promote off label use. If a physician wants to provide Flomax<sup>®</sup> for a female it would need to be funded independently.</p>	
<p>V.New Business</p> <p>A. Mental Health Prescription Drug Advisory Committee</p>	<p><b><u>Mental Health Prescription Drug Advisory Committee (MHPDAC)</u></b></p> <p>Dr. Bell gave a general overview of the Mental Health Prescription Drug Advisory Committee (MHPDAC). She noted when the preferred drug list was instituted, a caveat stating mental health medications couldn't be restricted in any way was added. For several years, KHPA has been participating in the Comprehensive Neurosciences project. This project has identified some potentially unsafe prescribing practices, i.e. two or more atypical antipsychotics simultaneously, and many instances of multiple psychotropic medications for children under 18 years of age. Of note psychotropic medications account for about half of the entire Medicaid drug budget. The legislature was approached this year in hopes of being able to add the mental health drugs to our preferred drug list to create safety edits and optimize efficiency of use. Conversations with mental health advocates resulted in a compromise stating these drugs could not be placed on the PDL, but safety edits could be placed on the drugs for children and adolescents under 18 years of age in the Medicaid and SCHIP programs.</p> <p>Dr. Bell stated the MHPDAC members will possess expertise in the mental health field. The makeup of the committee will be specified in law and is still being debated. Currently, the makeup is three psychiatrists, one physician with a psychiatric specialty working in an academic setting, an ARNP with psychiatric specialty, a primary care physician, two</p>	

pharmacists, one social worker, and four members of the public (two of which must be consumer or parent of consumer). The membership will be approved at the KHPA Board Meeting on 3/17/09.

Dr. Bell noted the DUR Board will be affected by creation of this new committee. Any MHPDAC recommendations incorporating prior authorizations will be presented to the DUR Board for their approval. This is similar to the current process with the Preferred Drug List Committee.

Margaret Smith stated that this has not gone through the legislature yet and is still in committee. She noted for the MediKan population that cost effectiveness and safety will be addressed. KHPA will institute the committee whether the Medicaid and SCHIP proposal comes out of the legislature.

B. Health Information Designs (HID)

**Health Information Designs (HID)**

Ms. Todd introduced Health Information Designs (HID) as the new subcontractor that is replacing ACS Heritage. They will provide the Retro DUR services, which will include five interventions, 30 academic detailing visits and four newsletters per State Fiscal Year. Lori Dillehay, Pharm.D., will be the HID pharmacist and located at EDS. Ms. Todd also introduced Candace Rieth, Pharm.D., also with HID, to provide an overview of HID and their services. Additionally, Dr. Rieth will provide clinical support services to Kansas Medicaid as needed.

***HID Company Overview***

- 27 Years Experience in Providing RDUR and Other Pharmacy Management Services
- RDUR provider in sixteen State Medicaid Programs
- Work with four State Health Department Programs
- Provide services for several commercial Pharmacy Benefit Management (PBM) Organizations
- Home office in Auburn, Alabama
- Two offices in Mississippi
- Staff in Alabama, Arkansas, Connecticut, Kansas, Maryland and Mississippi

***Pharmacy Support Services Provided by HID***

- Retrospective Drug Utilization Review

- Lock-In
- Prior Authorization
- Preferred Drug List Development and Management
- CMS and Supplemental Rebate Management
- DUR Board and P&T Committee Support
- Electronic Health Record Systems & Management
- Prescription Drug Monitoring Programs
- Disease Management Programs
- Academic Detailing and Physician Education Services
- Electronic Prescribing
- Data Warehouse and Decision Support Systems
- Fraud and Abuse Detection Systems
- Research and Statistical Analysis

***HID's Medicaid "Footprint"***

- 12 million covered lives (21% of national total)
- States served by HID have total Medicaid expenditures of \$87 billion dollars (28% of national total)
- Operating in 16 states (32% of national total)

***Clinical/Technical Staff for Kansas DUR Program***

- Lori Dillehay, Pharm.D. – Clinical Account Manager
- Candace Rieth, Pharm.D. – Clinical Support Services
- John Williams, R.Ph. – Pharmacy and Prescriber Inquiries
- Pam DeRuiter, R.Ph. – Criteria Manager
- Clif Fisher – Data Systems Analyst

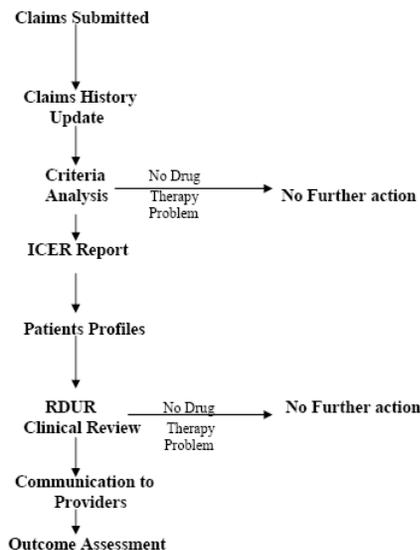
***Kansas DUR Program: Responsibilities of HID***

- DUR support
- Criteria development
- 1,000 monthly profile evaluations
- Access to HID's data mining tool, RxExplorer®
- Quarterly provider newsletter
- Quarterly academic detailing visits
- Standardized reports
- Ad hoc reports
- Data analysis support

Dr. Burke asked what kind of support falls under DUR support. Dr. Rieth stated that she will show areas where they will work together throughout the formal presentation.

### ***RDUR Process***

- Criteria developed
- Criteria presented to DUR Board
- Criteria implemented
- Initial criteria exception report (ICER) created which comes from the claims history being run against the criteria. All the hits the patient has will show up on the ICER report.
- Topics for profile review selected from ICER
- Patient profiles selected and reviewed
- Letters will be sent to providers with a response form and self-addressed return envelope that will be returned to HID
- Provider responses entered into database
- Quarterly report presented to DUR Board demonstrating impact of interventions.



### ***Criteria Development***

- HID maintains a comprehensive list of approved criteria that all claims are run against each month.

- The criteria include drug/drug interactions, drug/disease contraindication and precautions, over utilization, under utilization, disease state management, black box warnings, and cost savings.
- Criteria are defined as minor, moderate or severe based on gender, age, number of physicians and pharmacies the patient has visited.
- Criteria are added, deleted or modified per instructions from the DUR Board. Additions and changes are presented to the committee each meeting for approval.
- All drug classes are reviewed periodically for the addition of new drugs and new drug-drug interactions, precautions, and contraindications.
- FDA site is reviewed daily for new drugs.
- Existing criteria are reviewed for needed updates and/or modifications. Criteria alert messages and references are reviewed for new and/or additional information.
- Disease State Management topics and nationally-recommended guidelines are reviewed for possible new criteria.

A sample of the criteria, ICER report, basic patient profile, provider letter, and provider survey were presented. Dr. Burke stated the provider survey was not a service provided by ACS Heritage and will be new to the Board. Dr. Rieth explained that the surveys are helpful.

***Data Mining Tool, RxExplorer®***

- RxExplorer® is a pharmaceutical decision support system that provides the user with desktop access to the entire prescription claims database for patient profiling, provider (physician/pharmacist) profiling, and demographic analyses
- The product is user-friendly with pre-defined reports, and, more importantly, offers a wide array of ad hoc reporting capabilities
- RxExplorer® is Internet browser based
- Includes standardized and ad hoc reporting

Several screenshots of RxExplorer® were shown.

***Role of HID***

- DUR support
- Criteria development
- 1,000 monthly profile evaluations

C. DUR plus (+) Demonstration

- RxExplorer®
- Quarterly provider newsletter
- Quarterly academic detailing visits
- Standardized reports
- Ad hoc reports
- Data analysis support

Dr. Reith clarified that once the criteria is developed it will be run against the total pharmacy claims in the database. Historically, 5 intervention topics are selected per year which could generate more than 1,000 profile reviews. HID expects a 30-40% return of provider feedback surveys.. The DUR Board will need to review criteria and materials used by HID.

**DUR Plus (+) Demonstration**

Dr. Bell provided introduction to DUR+, a new KHPA initiative, to automate many parts of our prior authorization process. DUR+ is required to be up and running before starting the MHPDAC.

Debra Quintanilla presented the following overview:

DUR+ is an automated Prior Authorization system that is integrated within the interChange MMIS (the claims processing system utilized by Medicaid). It uses established clinical criteria and claims data from the MMIS to evaluate whether a pharmacy claim meets prior authorization criteria at the point-of-sale (POS). If the criteria are met, then a system-generated PA is created and the claim is paid.

As with any automated PA process, some claims may not meet the automated criteria. In these cases, the pharmacist receives the same message that they have always received – “NDC requires Prior Authorization.” At this point, the pharmacy contacts the PA unit to obtain a Prior Authorization. The PA nurse works with the provider using the standard PA processes currently in place today.

At this time there are 41 drug categories entered into the DUR+ system; these include most of the PDL drugs. Each of these drugs have specific criteria requirements as noted in the existing PA criteria utilized currently by the PA nurses.

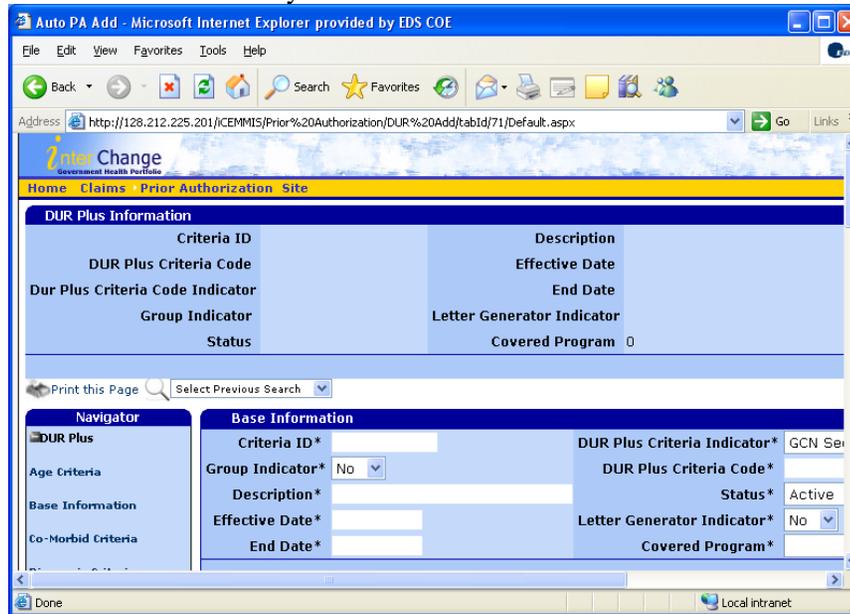
This new system allows KHPA pharmacy staff to look at other drugs that could be managed through the automated PA process without having to

add administrative staff. The PA nurses can then be used to evaluate more clinically and technically advanced criteria as well as answering provider questions.

PA staff, Pharmacy and KHPA Pharmacy staff worked closely to review current pharmacy criteria to see what could be incorporated into DUR+ without modification of criteria. Drug categories were identified as appropriate for creation of an AutoPA from the data available through MMIS claims (physician, inpatient, outpatient, etc.) and reference files. Certain PA staff members are responsible for entering data into the DUR+ criteria panels which enable Auto PAs to be created through the Point of Sale (POS) submission. The data required to allow the creation/completion of these panels is obtained from criteria reviewed and accepted by the DUR Board members and approved by KHPA Pharmacy staff.

PA staff will continue to work closely with pharmacy staff regarding setting up National Drug Code (NDC) or Generic Code Number (GCN) groups and with Medical Policy staff to establish diagnosis groups in the reference files. This will allow the DUR+ panels to pull information directly from the necessary reference files.

Panels from the DUR+ system are shown below:

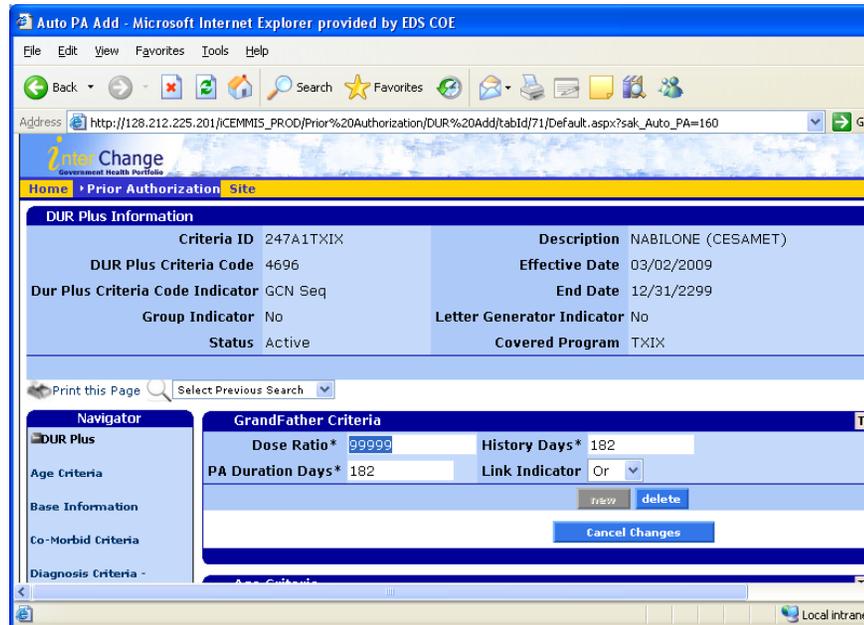


Ms. Quintanilla explained the technical details of the DUR+ system.

She stated the DUR+ Information section is populated from the Base Information panel. The criteria ID number is keyed manually using the specific assignment code established in the manual PA process. Additional numbers are added to that assignment code to track changes to criteria. If changes are made through DUR then adjustments will be made so that the history is there.

Dr. Schewe asked if Flomax<sup>®</sup> would be entered in this system. Ms. Todd stated the gender restriction discussed earlier is a different process in the system and would not involve AutoPA.

Dr. Burke asked who sees this application. Ms. Quintanilla said that Nancy Perry (pharmacy prior authorization supervisor), the Pharmacy team and she would see this application. Dr. Burke wanted to clarify that when a pharmacy POS claim is submitted that the end users do not have to review the detailed information panel. Ms. Quintanilla agreed and said she will explain how a claim is processed.



The Grandfather Criteria allows AutoPAs to be generated based on past usage of the same medication within a certain timeframe in history. For example, if a patient has obtained prior authorization for a non-preferred

drug within the last six months and the PA has expired for that drug, then an AutoPA will be created for the same medication.

Ms. Quintanilla emphasized the grandfather criteria will only work if the patient has already been on the medication. If a claim is submitted for a medication that the patient has never taken before or hasn't taken within the "history" timeframe, then the system will not set up an AutoPA. The claim will default to the traditional PA process.

Dr. Burke asked if most of the PAs are good for 12 months. Ms. Quintanilla stated most PAs are good for 12 months, but some are good only for 6 months. Dr. Schewe asked how a PA is renewed. Ms. Quintanilla explained that as long as there is a POS claim submitted within 60 days of the end date of the PA, it will automatically renew.

Mr. Sutherland asked how quickly it works. Ms. Quintanilla said five seconds. The patient and pharmacist receive a follow-up letter stating the approval and duration of the PA.

The Age Criteria is another panel in the Auto PA system. This criteria panel allows restrictions relating to minimum and maximum age, dose ratio, and duration of the PA .to be built into the criteria.

There is also a link indicator available on all of the specific criteria panels.

These can be set to “and” or “or” to indicate to the system how to apply the criteria to the claim.

The screenshot displays a web application interface for adding primary and secondary diagnosis criteria. It features two main panels, each with a 'Link Indicator' dropdown menu set to 'And'. The 'Primary' panel includes fields for 'Primary Diagnosis', 'Diagnosis 1', 'Diagnosis 2', 'Diagnosis 3', 'Diagnosis Type', 'Dose Ratio', and 'PA Duration Days'. The 'Secondary' panel includes fields for 'Secondary Diagnosis', 'Diagnosis 1', 'Diagnosis 2', 'Diagnosis 3', 'Diagnosis Type', 'Dose Ratio', and 'PA Duration Days'. Both panels have 'new' and 'delete' buttons at the bottom.

There are two panels available regarding diagnosis. The existence of two panels enables criteria to be built to include certain diagnoses while excluding other diagnoses. For example, if a drug was indicated for acne, but was contraindicated in pregnancy the panels could be set to require an acne diagnosis while excluding a pregnancy diagnosis. Therefore, the AutoPA would not be created for a pregnant patient with acne in this example. The claim would deny and go to the traditional PA process.

Dr. Schewe asked if this will negate having to do the paperwork. Ms. Quintanilla said yes. Dr. Burke said we would still need to know the patient’s diagnosis. Ms. Quintanilla explained the diagnosis will be retrieved from the physician claims in the patient’s history. Dr. Bell said the only caveat is that it is time limited so if a physician sees a patient for the first time and sends the patient off with a prescription, the physician’s claim won’t be available yet so the paperwork will have to be filled out initially.

Dr. Schewe asked how far back the claims history goes. Ms. Todd said 15 months.

**Other Drug Therapy 1 Criteria** Top Nav ? A Min

Type data below for new record.

Other Therapy 1 Drug  Criteria Indicator GCN Seq

Criteria 1  [ Find... ] Criteria 2  [ Find... ]

Criteria 3  [ Find... ] Group  [ Find... ]

Criteria Count  History Days

Other Therapy Days  Dose Ratio

PA Duration Days  Link Indicator And

There are two panels relating to Other Drug Therapy. The existence of two panels enables criteria to be built to require certain medications to have been used in the past while excluding certain medications. These panels screen for other drugs the patient has filled to allow for verification of appropriate previous or concurrent therapy.

**Co-Morbid Criteria** Top Nav ? A Min

Type data below for new record.

Co-Morbid Diagnosis  Diagnosis 1  [ Find... ]

Dose Ratio  Diagnosis 2  [ Find... ]

PA Duration Days  Diagnosis 3  [ Find... ]

Link Indicator And  Diagnosis Type  [ Find... ]

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**Provider Type/Specialty** Top Nav ? A Min

Type data below for new record.

Provider Type 1  [ Find... ] Provider Specialty 1  [ Find... ]

Provider Type 2  [ Find... ] Provider Specialty 2  [ Find... ]

Provider Type 3  [ Find... ] Provider Specialty 3  [ Find... ]

Provider Group  Dose Ratio

PA Duration Days

The Co-Morbid Criteria panel is another diagnosis panel that can be used if there are more diagnoses to either include or exclude.

The Provider Type/Specialty panel can be used to limit a drug to a specific provider type and specialty.

Dr. Burke pointed out if a specialty provider prescribes a drug but doesn't write for refills and the PA is good for a year, then their PCP writes for a refill, it will go through because it will be under the original 12 months that was initiated by the specialty provider. Dr. Bell said that is the way it happens currently and will continue to happen with AutoPA.

Ms. Quintanilla explained once a POS claim is submitted for payment to the MMIS it goes through the initial claims editing to ensure beneficiary number, provider number, NDC, etc. are without errors and that the claim is payable but requires a PA. The MMIS claims engine performs a PA search. Since DUR+ is activated real-time, if an available and appropriate PA already exists on the MMIS for that beneficiary, provider and NDC, it is used. If no active PA is found then the claim continues through the process. If the NDC being processed is subject to DUR+ criteria, the claim is processed against the DUR+ rules set up on the panels and applicable to that NDC, GCN or these types of groups.

Mr. Sutherland asked in a scenario where a non-preferred drug is prescribed how will the system proceed. Ms. Quintanilla said that with an initial prescription that is non-preferred the system will deny and say the NDC requires PA. If there is a PA in place for the non-preferred drug that has expired, it will set the AutoPA because it was grandfathered. If there is a six month lapse since the non-preferred drug was filled the claim will be denied stating "PA required". Mr. Sutherland asked if the initial PA will require submission of the paperwork to support the need for a non-preferred drug. Ms. Quintanilla said yes. Dr. Schewe gave an example where a patient was prescribed Prevacid<sup>®</sup>, then Omeprazole OTC<sup>®</sup>, and then Nexium<sup>®</sup> (which is non-preferred). The system will deny and a paper PA will be required. Ms. Quintanilla said that is how it works now, but it is possible to reconfigure the system for future use.

The claims engine pulls paid claims for pharmacy and professional claims in history within the past 120 days (or other date range limitations as established by KHPA). For DUR+, inpatient, outpatient and crossover claims paid within the last 120 days are considered. This enables more robust diagnosis and procedure code searches to aid in the DUR+ criteria

decision process.

Ms. Quintanilla mentioned several benefits of DUR+:

- A more robust, cost effective pharmacy program through the placement of more drugs on prior authorization without increased administrative staff
- Provider satisfaction with a more cost-effective pharmacy program that eases the administrative burden
- Faster delivery of medications to the beneficiary
- An integrated solution
- As drugs become more expensive, sophisticated, and indicated for targeted populations (in addition to the FDA issuing more and more ‘Black Box’ warnings), this increases the need for Medicaid to assure appropriate use.
- The DUR+ automated PA solution can assist in helping KHPA maximize pharmacy benefit dollars and promote appropriate use.

Dr. Unruh asked if this is a program unique for Kansas. Dr. Bell stated that the DUR+ system is used in Oklahoma and Delaware. Dr. Unruh then asked if the other states show a decrease in the administrative costs to offset the potential long term use of medicines that may fall off PA. Patrice Ticehurst said she doesn’t think Oklahoma maximizes it to the extent we are and Delaware just recently began using the system.

Dr. Burke asked if there would be a letter sent to providers to alert them about the updates to our system. Dr. Bell stated that we sent bulletins to pharmacy providers. The Kansas Pharmacy Association suggested sending letters to physicians as well. Ms. Todd stated that there was a bulletin published on the KMAP website for all providers to view.

**Serevent® and Foradil®**

Ms. Todd stated Serevent® and Foradil® are long acting beta agonists (LABA). A FDA panel was convened to discuss asthma-related drugs. The panel expressed concern about the use of Serevent® and Foradil® without an inhaled corticosteroid for the treatment of asthma. There have been reports of asthma related deaths in patients taking a LABA not in conjunction with an inhaled corticosteroid. The FDA did say that these drugs can be used alone for COPD. The PA criteria for each of these drugs is shown below:

D. Serevent® and Foradil®

i. Public Comment

ii. Board Discussion/Action

Dr. Schewe moved to accept the PA criteria for both Serevent® and Foradil®.

John Kollhoff seconded and it carried with a unanimous vote.

***Serevent***<sup>®</sup>

Must meet all of the following:

Patient must be 4 years of age or older

AND

- Diagnosis of chronic obstructive pulmonary disorder (COPD)

OR

- Diagnosis of asthma
- Patient must be concurrently using an inhaled corticosteroid with Serevent<sup>®</sup>

Length of Prior Authorization: 1 year

***Foradil***<sup>®</sup>

Must meet all of the following:

Patient must be 5 years of age or older

AND

- Diagnosis of chronic obstructive pulmonary disorder (COPD)

OR

- Diagnosis of asthma
- Patient must be concurrently using an inhaled corticosteroid with Foradil<sup>®</sup>

Length of Prior Authorization: 1 year

**WARNING:** Foradil<sup>®</sup> may increase the risk of asthma-related death.

Ms. Todd stated that both of these drugs would be perfect to put on AutoPA.

Dr. Schewe asked if the physician could write the diagnosis on the prescription and the pharmacist enter it at the POS to get an AutoPA. Ms. Todd said we could do that, but it is built into a different part of our claims engine and would require a diagnosis on every prescription for Serevent<sup>®</sup> and Foradil<sup>®</sup>. Diagnosis codes submitted on the pharmacy claim is not currently something DUR+ is designed to do. Dr. Bell stated that KHPA can look into this for a future modification of the DUR+ system.

No public comment.

Dr. Burke stated that for the diagnosis of asthma the patient must be on an inhaled corticosteroid.

Dr. Schewe asked if there be a requirement that the patient would have to have the inhaled corticosteroid filled in the last 30 days. Ms. Quintanilla said yes.

**Oral Contraceptives**

Dr. Bell stated that the oral contraceptives were reviewed at the PDL committee meeting in November. The committee deemed that “oral contraceptives are clinically equivalent based on the chemistry and dosage in a particular formulation and that all sub classes categorized as monophasic, biphasic, triphasic, and progestin only should be represented on the preferred drug list.” Dr. Bell created some tables that separated the oral contraceptives out by various ingredients and dose range. One or two agents out of each category will be chosen as preferred and the rest of the agents will be non-preferred. The forms are drafts only. The preferred agents have not been chosen yet.

No public comment.

Dr. Burke stated this is the second time the PDL Committee had looked at this class of drugs. The committee did receive input from active Ob/Gyn practitioners. Their position was that if the components are the same and the dosages of the components are the same then one product doesn't have advantages over another. They also felt strongly that there needed to be representatives from all the major classes of oral contraceptives on the preferred drug list.

Dr. Burke presented the standard PA that is used when a drug class is added to the Preferred Drug List. He emphasized that a goal of the PDL

- E. Oral Contraceptives
  - i. Public Comment
  - ii. Board Discussion/Action

Daniel Sutherland moved to accept the PA forms for oral contraceptives.

Dr. Schewe seconded and it carried with a unanimous vote.

process is to maintain access for consumers and providers. It is the Board's job to make sure the PA forms provide ease of use and access to needed therapies for prescribers and consumers.

F. Erythropoiesis-Stimulating Agents

- i. Public Comment
- ii. Board Discussion/Action

**Erythropoiesis Stimulating Agents**

Dr. Bell stated this class was evaluated at the PDL Committee meeting in November. The committee determined that all of the erythropoiesis stimulating agents are clinically equivalent. The PA forms were provided for the Board's approval. The preferred agents have not been chosen.

Debbie King, Amgen, highlighted some featured benefits of Aranesp®. It comes in prefilled syringes and can be used with extended dosing. In most cases physicians use it for the chemotherapy induced anemia of patients in oncology and chronic renal failure patients, both on dialysis and non-dialysis. It is administered at the hospital or doctor's office, but there are some cases where it can be self administered because the patient lives in a rural area. Aranesp® provides less frequent dosing. Chronic renal failure patients can be dosed for up to two weeks. Chemotherapy induced anemia patients can be dosed up to three weeks.

Dr. Burke stated that Aranesp® does come in the prefilled syringes which offers an advantage. He pointed out that even if Aranesp® was a non-preferred medication a PA would provide a mechanism to access the drug.

G. Mozobil®

- i. Public Comment
- ii. Board Discussion/Action

**Mozobil®**

Dr. Bell stated this medication is newly approved by the FDA. It is approved for use in non-Hodgkin's lymphoma and multiple myeloma for stem cell transplant. There are some safety concerns with it and it is expensive (e.g., \$40,000 for a single course of therapy). The PA criteria are based on the package insert with the exception of the third bullet

It was pointed out that in resource material reviewed by the board; a recommendation was that Mozobil would only be appropriate for use in heavily pre-treated patients or patients who have failed prior attempts at stem cell transplants. Dr. Bell couldn't find a finite definition of "heavy pre-treatment". Therefore, we must rely on the oncologist's judgment to determine whether the patient has met this criterion.

No public comment.

Dr. Kollhoff moved to accept the PA criteria for Erythropoiesis Stimulating Agents.

Dr. Schewe seconded and it carried with a unanimous vote.

Dr. Schewe moved to accept the PA criteria for Mozobil® with the modification of length of authorization time.

Dr. Kollhoff seconded and it carried with a unanimous vote.

Dr. Kollhoff asked if that means they have had treatment failure with other courses. Dr. Burke said the patient would have had unsuccessful trials of chemotherapy, radiation therapy, or any of the traditional therapies and bone marrow transplant was now being recommended.

Dr. Burke presented the draft PA criteria.

Must meet all of the following:

- Diagnosis of non-Hodgkin's lymphoma or multiple myeloma
- Prescribed by an oncologist
- Must have either a prior stem cell collection failure or history of heavy pre-treatment
- Mozobil must be given in combination with granulocyte-colony stimulating factor (G-CSF)
- Patient must be 18 years of age or older
- Must NOT have a diagnosis of leukemia
- Must NOT be pregnant or become pregnant during treatment
- Female patients with reproductive potential need to use effective contraceptive methods during Mozobil use

Length of Prior Authorization: 1 year

Dr. Burke said it isn't unprecedented to have a PA on a new product, particularly one that has significant adverse effects, and to monitor it during that first post marketing year of use. The need for PA can be eliminated or modified at a later time. In seeking expert opinion the board was informed by an oncologist, Dr. Moore, who specializes in transplantation. His position was that the PA criteria made sense to him. He didn't foresee a run on inappropriate use of Mozobil<sup>®</sup> as a first line approach. He did point out that although \$40,000 may seem expensive for a round of treatment, alternatives which may include hospitalization, other growth stimulating agents, and transfusions would also be expensive. In terms of the indications for treatment of non-Hodgkin's lymphoma and multiple myeloma, Dr. Moore thought there wouldn't be other diagnoses that would lend themselves to this treatment or that off label use would be an issue.

Dr. Kollhoff asked about the length of the PA. He stated that there probably wouldn't be a need for more than 30 days. Essentially if a round of treatment fails, then it will be six months before you can do it again. Dr. Burke said that there may be more than one round of Mozobil<sup>®</sup>; every

case is different. Dr. Bell said one year is our standard, but six months would be fine.  
Dr. Schewe asked if a treatment could be PA'd to something other than time (e.g., authorize four doses). Ms. Quintanilla said not on a pharmacy PA. Ms. Quintanilla said that the reason for the time span is that something may happen. For example, The patient may get sick and they don't get it right away. The open time period allows for this situation so patient can obtain the medication within that time period.

Dr. Burke stated since this is a new product and it isn't all about the cost that the PA time period be set at six months and the board could revisit use in a year. .

**Marinol®**

Dr. Bell stated she ran a utilization report on Marinol®. Claims data shows many prescriptions filled for doses greater than 20mg per day, which is the FDA recommended daily dose. Total cost is about \$600,000 just for the patients that are getting more than 20mg. Dr. Bell discussed options to limit doses over 20mg daily. One option would be to put in a hard edit.

Dr. Schewe asked Dr. Bell if she had looked at the number of unique providers prescribing for those patients. Dr. Bell said not yet and Dr. Schewe indicated there are probably very few.

Dr. Bell spoke with Dr. Sweet, an HIV specialist, Dr. Sweet suggested sending a letter to providers to make them aware that they are prescribing above the FDA recommended max daily dose and then in a few months put it on PA or hard edit. Dr. Bell said Dr. Sweet also stated that there may be instances when more than 20mg/day is needed and a hard edit that couldn't be overridden may not be the best solution. A PA would allow more than 20mg/day in specific situations. Dr. Schewe asked what those situations would be. Dr. Bell paraphrased Dr. Sweet's recommendations that patients must have a BMI of less than 27, intractable nausea, trial of less than 20mg/day, etc. Dr. Schewe said that a BMI of 27 is normal size; that less than normal is a BMI of 21. Dr. Schewe suggested we use a BMI of 20.

No public comment

Dr. Burke stated HIV patients are frequently prescribed Marinol®, but it

H. Marinol®

i. Public Comment

ii. Board Discussion/Action

Dr. Schewe moved to send education letters regarding daily dose and alerts providers on future PA and LeAnn will bring PA criteria for review to our next meeting.

Mr. Sutherland seconded and it carried with a unanimous vote.

isn't used exclusively in that population. Looking at the clinical trial data the 20mg/day maximum dose came from a study that showed doses above 20mg/day provided no additional benefits in terms of antiemetic effects. Doses above 20mg/day also increased adverse effects. The recommendation now is, rather than cut people off, start with a letter to providers that would say that the clinical trial data supports 20mg/day as the maximum dose in terms of benefit and doses higher than this are associated with increased adverse effects.

Dr. Burke asked Dr. Bell if the plan was to alert providers to an upcoming PA by sending out a letter and then to revisit this topic at the next DUR meeting. Dr. Bell said we could do that or we could work on the criteria now and make an effective date of June 1 or bring it back to the next DUR meeting.

Dr. Burke asked the board if they want to recommend drafting a letter to prescribers. He stated that it shouldn't be hard to track down the providers. He suggested the letters should not only be educational, but they should mention that a PA will be required in the future.

Dr. Burke asked for a motion to send the letters with education on dosing and mention the upcoming PA requirement.

**Xenazine®**

Ms. Todd stated that Xenazine® is a monoamine depletor and is an orphan drug. It has been approved for chorea associated with Huntington's Disease. The package insert has many warnings and concerns. For safety reasons the criteria has been written to ensure that the patients that truly need it can get it. Ms. Todd presented the draft prior authorization criteria:

Must meet all of the following for doses of less than or equal to 50mg per day:

- Diagnosis of chorea associated with Huntington's disease
- Patient must be 18 years of age or older
- Patient must not have impaired hepatic function
- Prescribed by a neurologist
- Must NOT be taking a monoamine oxidase inhibitor (MAOI)
- Must NOT be taking reserpine (at least 20 days should elapse after stopping reserpine before starting Xenazine®)

- I. Xenazine®
  - i. Public Comment
  - ii. Board Discussion/Action

Dr. Schewe moved to accept the Xenazine® PA criteria with the spelling correction.

Dr. Unruh seconded and it carried with a unanimous vote.

Must meet all of the following for doses greater than 50mg per day:

- Must meet all of the above stated criteria for less than 50mg per day.
- Patient must be genotyped for CYP2D6 and must be extensive or intermediate metabolizers.

Length of Prior Authorization: 1 year

NOTE: WARNING AND PRECAUTION:

Xenazine<sup>®</sup> can increase the risk of depression and suicidal thought and behavior (suicidality) in patients with Huntington's disease. (See black box warning)

Caution should be used when adding a strong CYP2D6 inhibitor (such as fluoxetine, paroxetine, quinidine) to a patient already receiving a stable dose of tetrabenazine.

Ms. Todd explained the top set of criteria will be required for all patients to meet. For patients receiving more than 50mg per day, genotyping is required in addition to the first set of criteria.

Dr. Burke asked what it means to be an orphan drug. Dr. Bell stated that orphan drugs are approved to treat diseases that affect less than 200,000 in the whole United States. It encourages pharmaceutical companies to develop drugs to treat rare diseases, where the market base upon which to recoup cost of drug development is very small.

Dr. Burke emphasized that there are significant safety issues with Xenazine. There are also some dosing issues. It is heavily dependent on CYP2D6 and for high doses, genotyping is necessary to ensure the patient is not a slow metabolizer. There is also a risk of off-label use that is relatively significant.

Dr. Burke referred to the U.S. Pharmacist newsletter in the meeting materials. According to the newsletter, tetrabenazine has been examined for at least 30 years. There are several poor quality, small studies where a few people with dystonic reactions, central tremors, or tardive dyskinesia have had some improvement, however Dr. Burke states he has experience in treating those conditions and tetrabenazine is not on the list of relevant treatment options. Because of the safety issues and risk of off-label use the PA is appropriate. The PA criteria that was put together follows the

	<p>package insert very closely and limits the use to patients who have Huntington’s Chorea.</p> <p>No public comment.</p> <p>Ms. Todd stated that there is no hard fact that they shouldn’t take more than 100mg per day, but there are several places that state it is the maximum recommended daily dose. We can’t limit the dosage on the PA, but we can dose limit it in the system if that is something the Board would like to consider. Dr. Burke stated that it is more of an issue of accessing it versus whether people are going to be pushing it above the maximum dose. Ms. Quintanilla said that we can put it on Super PA for auditing purposes.</p> <p>Mr. Sutherland asked if genotyping is a covered service. Dr. Smith said that we cover genotyping for other conditions, but she doesn’t know if it would be covered for this. Dr. Schewe said that since it would be a requirement it would hard to say that it wouldn’t be covered.</p> <p>Dr. Kollhoff asked how many beneficiaries are diagnosed with Huntington’s Chorea. Dr. Bell said that we’ve only heard from one that is interested in taking this drug.</p> <p>Dr. Burke referred to the requirement of a neurologist being the prescriber. He said that the board anticipates that specialist prescribers will be particularly familiar with the risk: benefits of the unique drugs they are prescribing.</p> <p>Dr. Burke asked for a motion to accept the PA.</p>	
VI. Adjournment	Dr. Burke announced the meeting was adjourned.	<p>Dr. Schewe made a motion to adjourn the meeting.</p> <p>Dr. Kollhoff seconded and it was carried by a unanimous vote.</p>