State and Public School Life and Health Insurance Board Clinical and Fiscal Drug Utilization and Evaluation Committee

Minutes

October 5, 2009

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Monday, October 5, 2009 at 1:00p.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

Members present:	**Members absent:**
Dr. William Golden	Mark McGrew
Dr. Joe Stallings	Robert Watson
Kat Neill	Dr. James Bethea
Larry Dickerson	
Hank Simmons	
Matthew Hadley	

Jason Lee, Executive Director, Employee Benefits Division of DFA.

Others Present
Barry Fielder, NMHC; Jill Johnson, Clay Patrick, UAMS College of Pharmacy/EBRx; George Platt, Leigh Ann Chrouch, Sherri Saxby, Stella Greene, Shannon Roberts, Donna Cook, Sherry Bryant, Cathy Harris, EBD; Bryan Meldrum, Novasys; Barbara Melugin, Health Advantage; Shonda Rocke, Informed Rx; Ronda Walthall, Wayne Whitley, AHTD; Dwight Davis

Call to Order
Meeting was called to order by Dr. Golden.

Approval of Minutes
The motion was made by Dr Golden to approve the July 6, 2009 minutes. Minutes were approved by consensus.

Old Business *by Barry Fielder & Jill Johnson*

a. Tabled New Drugs from July meeting

Coartem Tab is indicated for the treatment of malaria. Typical therapy involves 6 doses total w/4 tabs/dose

Johnson said Coartem Tab it is not indicated as a preventive prescription and then provided the committee with information from the Center for Disease Control and Preventions (CDC) website.

Johnson recommended Coartem Tab be placed on T3 with a prior authorization (PA) criteria diagnosis of uncomplicated malaria.

The committee agreed by consensus.

Asacol HD is mesalamine delayed release tablets (800mg) indicated to be used for mildly to moderately active ulcerative collitis and for maintenance of remission of ulcerative colitis.

Johnson said the previous recommendation for Asacol HD was to exclude and the committee instructed her to consult with GI docs and get their opinions. Johnson said she contacted Dr. McKnight at UAMS. Johnson said she also found a systematic review from the Cochran Database comparing sulfasalazine to mesalamine. The Cochran review indicated sulfasalazine is superior in effectiveness with no difference in side effects.

Johnson said Dr. McKnight informed her that if you avoid giving the sulfasalazine to sulfa allergic patients you still going to have 20% of the patients who would be intolerant in some way, so typically they use mesalamine. McKnight also said the different in cost is substantial as well - $12 vs. $635 a month.

Recommendation: Exclude - One Asacol HD 800 mg tablet has not been shown to be bioequivalent to two Asacol 400 mg tablets. In a single dose, cross-over pharmacokinetic study in 20 healthy volunteers, the mean mesalamine Maximum plasma concentrations (Cmax) was 36% lower and the mean mesalamine. Area under the plasma drug concentration (AUC) was 25% lower with administration of one Asacol HD 800 mg tablet relative to two Asacol 400 mg tablets.

Johnson said the recommendation only applies to Asacol HD and they probably should not put further restrictions on Mesalamine.

The committee agreed by consensus.

Samsca Tab is indicated in the treatment of clinically significant hypervolemic and euvolemic hyponatremia that is symptomatic. Therapy should be initiated and reinitiated in a hospital to evaluate the therapeutic response. Initial starting dose is 15mg once daily with a maximum dose of 60mg daily.

FDA approved for Hyponatremia. Hyponatremia is a metabolic condition in which there is not enough sodium in the body fluids outside the cells.

Johnson said Samsca Tab plays a role with sclerosis and in heart failure but when they reviewed the trials for heart failure it did not reduce anything but it did improve the number for sodium cerium levels.

A discussion ensued.

Dr. Stallings said it's really good help for a very small percentage of hypervolemic patients but there is the potential to hurt people if prescribed for hyponatremia. Stallings said it could be helpful for the patient that really needs it. Stallings suggested prior approval (PA) with some type of diagnosis to substantiate the use of the drug for safety.

Simmons said it's a very questionable alternative for what should be an appropriate diagnosis work up. Simmons said he could not imagine putting someone on the drug with hyponatremia if they have not been properly evaluated.

Hadley commented on the Black box warning.

Recommendation: Neill made the recommendation to exclude with review in 6 months. Neill said at that point they will know how many people actually want it and also be able to determine if it is better to PA the drug.

The committee agreed by consensus.

b. Brands with Generics Available

Dr. Golden informed the committee he explained to the Board the notion that there are some brands of drugs that are so interesting price that the plan would end up being significantly injured financially for little gain if they continued the drug on tier 3. Golden said the Board does not want to make this into an official policy, but that the DUEC used their best judgment for these drugs on select instances where the cost is such that it would be within reason for the committee to recommend excluding the brand drug when there is a generic available at a substantially competitive advantage.

Fielder provided the committee with information for select brand products and their generic equivalents based on August 2009 claims data. Pricing provided is for equivalent quantities of brand and generic products. Currently, the benefit design is such that brands with generic equivalents available are placed in Tier 3 and collect a $60 co-payment while their generic equivalents collect the $10 generic co-payment.

A discussion ensued. How will the committee pick the drug products? At what point is the cost savings significant enough to say that it is time to do this?

The committee agreed by consensus that the brand drug will need to be over $100 dollars and the ratio above 2.5. Dr. Golden requested Fielder provide the list at the next DUEC meeting.

Neill requested Fielder provide additional reports with the ratio 2.0 and 2.5 so they can see the impact.

Dr. Golden suggested Fielder send the committee members the information via- email for review.

c. Uloric Coverage Review
Uloric (febuxostat), a new drug used to treat gout, is currently excluded from coverage based on the recommendation of the DUEC and Board approval. Since the drug has entered the market, EBRx has received a small number of requests from physicians wishing to use the drug. Based on the information provided in the specific appeals requests and after careful consideration among the physicians and pharmacists at EBRx, they are asking the DUEC to reconsider the coverage status of this product.

Recommendation: The recommendation from EBRx is to change Uloric's status from excluded to covered with PA required. The criterion for coverage would be documented hypersensitivity to allopurinol. All other requests for coverage would be denied. The anticipation is that allowance of coverage would be rare, but accommodating for this circumstance would be a sound approach from both patient and plan perspectives. This suggestion is based on direct feedback from Drs. Hank Simmons, Mark Helm, and Jill Johnson.

A discussion ensued.

The committee agreed by consensus to change Uloric's status from excluded and cover with PA.

Intranasal Steroids *by Barry Fielder & Jill Johnson*

There are currently two generic intranasal steroid products available, fluticasone propionate and flunisolide. They currently account for 58.83% and 1.41% of the prescriptions in this category respectively. The committee reviewed the utilization data.

Two brand products, Nasonex (mometasone) and Rhinocort AQ (budesonide), are in tier 2 today while Nasacort AQ (triamcinolone), Omnaris (ciclesonide), Beconase AQ (beclomethasone), and Flonase (fluticasone propionate) are in tier 3. Veramyst (fluticasone furoate) is currently not covered by the plan.

Recommendation: Considerable cost savings could be realized by moving all brands to tier 3 and leaving the generics available in tier 1. Moving Nasonex and Rhinocort AQ to tier 3, assuming a 50% conversion from brand to generic and 50%

remaining on the brand product, would result in approximate annual savings of $160,000.

Neill asked if there would be justification for reference pricing.

Lee asked the committee to consider reference price for the beginning of the plan year going forward. Lee said there is a significant high costs for members who choose to stay on this product, so giving them lots of notice is appropriate for the membership. Lee said only giving 90 days notice does not allow members to adjust their pre-taxed cafeteria plan and family budget.

Dr. Golden referenced the utilization data for intranasal steroid products and then suggested to Fielder that it might be helpful if he provided them with the plan cost plus member cost.

The committee agreed by consensus to moving all brands to tier 3 and leaving the generics available in tier 1 with consideration for reference pricing for the 2011 plan year.

Triptan *by Barry Fielder & Jill Johnson*

Currently, generic sumatriptan (all dosage forms), Maxalt, Maxalt MLT, Relpax, and Amerge are on formulary for the plan. Frova, Zomig (all dosage forms), and Axert are in tier 3. All products currently have quantity limits in place as well. The committee reviewed the formulary options based on a plan design of preferred drug step therapy with no grandfathering of current users. Upon implementation of one of these options, nonformulary products would reject at the point of sale with messaging indicating what products were available. A prior authorization outlet would be available for these members that would allow their physician to call EBRx with rationale for why they needed a non-formulary product rather than one of the preferred products.

All formulary options would include moving Amerge to Tier 3 and member impact/savings estimates include this assumption.

Based on July 1, 2009 – September 27, 2009 claims data

1. Generic sumatriptan and Relpax on formulary
   Estimated Annual Savings $336,000

2. Generic sumatriptan only on formulary; all brands in tier 3
   Estimated Annual Savings $200,000

3. Generic sumatriptan, Relpax, and Maxalt/Maxalt MLT on formulary
   Estimated Annual Savings $179,000

4. Generic sumatriptan and Maxalt/Maxalt MLT on formluary
   Estimated Annual Savings $156,000

A discussion ensued.

Motion: The committee agreed by consensus to move Amerge to tier 3 with no prior authorization. The Committee will review in one year.

Testosterone Replacement Products Report *by Barry Fielder & Jill Johnson*

Dr. Golden explained he has seen a lot of advertising about low Testosterone syndrome. Golden said according to the reading he has done, the symptoms were non-specific, the testing not all that great, the toxicity of the drug is mixed-bagged and the impact on the symptoms are even murkier. Dr. Golden said the drug is going to become heavily marketed and they should put some sort of criteria in place for coverage. Dr. Golden said it can be a very expensive and an unclear benefit to the members. Dr. Golden said he has referenced information from pub med to see if there was any recent discussion about the Androgen deficiency syndrome or Low T syndrome.

Fielder provided utilization data for this class of drugs. EBRx pulled together a random sampling of 25 members currently receiving Androgel, Testim, or Androderm and their 24 month history of diagnoses from the medical claims data from Integrail.

Of the 25 members reviewed, 14 showed a diagnosis of testicular hypofunction, which would be consistent with the FDA approved indication for these products. The other 11 members did not show this diagnosis in the past 24 months. Three of these members had a diagnosis of impotence and there was one female patient in this group with a diagnosis of breast cancer. Annual plan expenditures for the category will be close to $700,000 based on the 3 months of data.

Motion: The committee agreed by consensus to cover Testosterone replacement product with a PA with documentation of a deficient state (probably less than 250) and let previous members continue on it but if they miss some of their therapy (3 months/90 days) and want to restart they will need a level .

New Drugs *by Jill Johnson*

Drug	Tier
Nucynta	**Exclude**

Is a single molecule with a different approach to pain relief of moderate to severe acute pain in patients 18 years of age or older

Edluar Sublingual	**Exclude**

A sublingual formulation of zolpidem tartrate for the short-term treatment of insomnia characterized by difficulties initiating sleep

Acuvail sol	**Exclude**

Approved for the treatment of Pain and Inflammation Following Cataract Surgery

Aloquin gel **Tabled/review next meeting**
(1.25% Iodoquinol and 1% Aloe Polysaccharides) Iodoquinol is an antifungal and antibacterial agent.

Effient tabs **T2/revisit in 6 months**
Is an antiplatelet agent indicated to reduce the rate of thrombotic cardiovascular events (including stent thrombosis) in patients with ACS who are to be managed with percutaneous coronary intervention

Multaq **T3**
Is an antiarrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors

Triaz cloths 3% **Exclude**
Topical preparations containing benzoyl peroxide for use in the treatment of acne.

Onglyza tabs **T3 w/step therapy- revisit**
Is a dipeptidyl peptidase-4 [DPP4] inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Zipsor cap **Exclude**
Is indicated for the relief of Mild to Moderate Acute Pain

Fibricor tabs **Exclude**
Is an oral antilipemic agent and is the active metabolite of fenofibrate. It is indicated for severe hypertriglyceridemia, primary hyperlipidemia, or mixed dyslipidemia.

Drug **Tier**

Renvela pak **T2**
Approval of 0.8 gram & 2.4 gram powder packets for the control of serum phosphorus in patients with chronic kidney disease on dialysis

Saphris **Exclude**
Is an atypical antipsychotic indicated for the acute treatment of: (1) schizophrenia in adults and (2) manic or mixed episodes associated with bipolar I disorder with or without psychotic features in adults.

Tyvaso Sol. **T3 w/PA**
Is indicated to increase walking distance in patients with NYHA Class III symptoms associated with WHO Group 1 Pulmonary Arterial Hypertension.

Sabril **Exclude**

Sabril is indicated as monotherapy for pediatric patients 1 month to 2 years of age with infantile spasms (IS) for whom the potential benefits outweigh the potential risk of vision loss. Sabril is also indicated as adjunctive therapy for adult patients with refractory complex partial seizures (CPS) who have inadequately responded to several alternative treatments and for whom the potential benefits outweigh the risk of vision loss

Meeting adjourned.