State and Public School Life and Health Insurance Board Clinical and Fiscal Drug Utilization and Evaluation Committee
Minutes
October 4, 2010

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Monday, October 4, 2010 at 1:00 p.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

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

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

OTHERS PRESENT
Jill Johnson, Clay Patrick, UAMS College of Pharmacy/EBRx; Leigh Ann Chrouch, Doug Shackelford, Michelle Hazelett, Lori Eden, Amy Tustison, Latryce Taylor, Sherry Saxby, Sherry Bryant; Cathy Harris, EBD; Pam Lawrence, AHH; Barbara Melugin, Health Advantage; Dwight Davis; Pfizer, Wayne Whitley, Ronda Walthall, Colleen Adkins, UAMS; Julie Ryba; Informed Rx

CALL TO ORDER
Meeting was called to order by Dr. Golden.

APPROVAL OF MINUTES
The motion was made by Dr Golden to approve the August 2, 2010 minutes. Minutes were approved by consensus.

SECOND REVIEW MEDICATIONS *by Jill Johnson*

a. **Saphris** (asenapine) Sublingual tablets are indicated for the acute treatment of adult patients with schizophrenia and as monotherapy for acute mania or mixed episodes associated with bipolar 1 disorder.

The committee decided by consensus to uphold the previous decision to exclude based on the current information.

b. **Avandia** (rosiglitazone) is an oral diabetes medicine that helps control blood sugar levels.

The committee decided by consensus to continue with the current policy in place– tier 3 status.

c. **Victoza** is a non-insulin once-daily medication that may help improve blood sugar levels in adults with type 2 diabetes.

Plan member Rob Gent addressed the committee to talk about the drug Victoza.

The committee decided by consensus to cover Victoza w/prior authorization (PA) – tier 3 status.

The committee will review step therapy for type 2 diabetes management in the next meeting.

FIRST REVIEW MEDICATIONS *by Jill Johnson*

Drug Name **Tier Status**

DULERA AER 100-5MCG, 200-5mcg **T3/PA**
An additional combination ICS/LABA product approved for the treatment of asthma in patients 12 years of age and older

IPRIVASK INJ 15MG **T3/PA, QL 12d/30d**
Is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients undergoing elective hip replacement surgery

ZUPLENZ MIS 4MG, 8mg **Exclude**
Prevention of Postoperative, Chemotherapy- and Radiotherapy-Induced Nausea & Vomiting

TRIBENZOR TAB **Exclude**
Is a combination product for the treatment of hypertension.
Amlodipine; hydrochlorothiazide, HCTZ; olmesartan is not indicated for the initial treatment of hypertension

BIOTHRAX INJ **Exclude**
Is used to help prevent anthrax in people exposed to the bacteria through the skin or lungs

JEVTANA INJ 60/1.5ML **N/A medical**
Antineoplastics in Combination with Prednisone for the Treatment of Patients with Hormone-Refractory Metastatic Prostate Cancer Previously Treated with a Docetaxel-Containing Treatment Regimen

DESONIL PLUS KIT CREAM **Exclude**
Topical corticosteroid used in the treatment of skin irritation including inflammation, redness, and itching

DESONIL PLUS KIT OINTMENT **Exclude**
Topical corticosteroid used in the treatment of skin irritation including inflammation, redness, and itching

XERESE CRE 5-1% **Exclude**
Acyclovir; hydrocortisone is a topical agent for the treatment of herpes labialis (cold sores)

SILENOR TAB 3MG, 6mg **Exclude**
Is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance

XEOMIN INJ 100UNIT, XEOMIN INJ 50 UNIT **Tier 3/PA**
Treatment of adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients and blepharospasm in adults previously treated with BOTOX (onabotulinumtoxinA)

Drug Name	Tier Status
RELHIST CHW	**Exclude**
NOVAFERRUM SOL	**Tier 3**

A combination product containing Ascorbic Acid, Folate, Polysaccharide iron complex, and Vitamin B 12)

CLOBETAPLUS KIT CREAM **Exclude**
Clobetasol is used to relieve the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses and psoriasis

CLOBETAPLUS KIT OINTMENT **Exclude**
Clobetasol is used to relieve the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses and psoriasis

MELOXICAM KIT COMFORT **Exclude**
Is used to relieve pain, tenderness, swelling, and stiffness caused by osteoarthritis (arthritis caused by a breakdown of the lining of the joints) and rheumatoid arthritis (arthritis caused by swelling of the lining of the joints)

TEKAMLO TAB 150-10MG, 150-5mg **T3/step therapy**
Aliskiren; amlodipine (Tekamlo) is a combination product for the treatment of hypertension

TEKAMLO TAB 300-10MG **T3/step therapy**
Aliskiren; amlodipine (Tekamlo) is a combination product for the treatment of hypertension

FORMULARY MANAGEMENT RULES *by Jason Lee*

The committee reviewed 6 defined formulary management rules from the Benefits Strategic Planning Workgroup (BSPW). The DUEC made some edits to the document. The information will be forwarded to the Benefits Subcommittee for further analysis.

AGENDA

State and Public School Life and Health Insurance Board

DUEC Sub-Committee

EBD Board Room
501 Building, 5th Floor
October 4, 2010 1:00 p.m.

1. **Call to Order** .....Dr. William Golden, Chairman
2. **Approval of Minutes** .....Dr. William Golden, Chairman
3. **Second Review Medications**..... Jill Johnson, UAM
    - **a.** Victoza
    - **b.** Saphris
    - **c.** Avandia
4. **First Review Medications** ..... Jill Johnson, UAM
5. **Formulary Management Rules** .....Jason Lee, Executive Director
6. **Director's Report**.....Jason Lee, Executive Director

Next Meeting: 2011 Schedule to be Released

DUEC

October 4, 2010

Jill Johnson, Pharm.D.

Saphris

2 trials:

- **In one trial comparing asenapine vs risperidone vs placebo, valid conclusions may not be drawn because only 30-46% of patients completed the trial. Of those evaluable pts, there was a 1.6kg weight gain with risperidone and 0.47kg weight gain with asenapine. Even their authors did not profess a clinical difference with asenapine vs risperidone except this difference in weight gain.** Efficacy and tolerability of asenapine in acute schizophrenia: a placebo- and risperidone-controlled trial. **J Clin Psychiatry. 2007 Oct;68(10):1492-500.**

- In this trial, asenapine was noninferior to olanzapine for treatment of bipolar with almost exact response rates on one rating scale. Asenapine versus olanzapine in acute mania: a double-blind extension study. **Bipolar Disord. 2009 Dec;11(8):815-26. Epub 2009 Oct 14.**

Neither of these trials warrant preferring asenapine over another agent. We still need clinical trials to show it is better and so far there aren't any in PubMed.

Avandia

FDA NEWS RELEASE

For Immediate Release: Sept. 23, 2010

Media Inquiries: Karen Riley, 301-796-4674; karen.riley@fda.hhs.gov

Consumer Inquiries: 888-INFO-FDA

FDA significantly restricts access to the diabetes drug Avandia

Makes regulatory decisions on RECORD and TIDE trials

The U.S. Food and Drug Administration today announced that it will significantly restrict the use of the diabetes drug Avandia (rosiglitazone) to patients with Type 2 diabetes who cannot control their diabetes on other medications. These new restrictions are in response to data that suggest an elevated risk of cardiovascular events, such as heart attack and stroke, in patients treated with Avandia.

"The FDA is taking this action today to protect patients, after a careful effort to weigh benefits and risks," said FDA Commissioner Margaret A. Hamburg, M.D. "We are seeking to strike the right balance to support clinical care."

Rosiglitazone also is available in combination with other diabetes medications, metformin under the brand name Avandamet or glimepiride under the brand name Avandaryl.

Avandia, manufactured by GlaxoSmithKline (GSK), is in a class of drugs known as thiazolidinediones, or TZDs. It is intended to be used in conjunction with diet and exercise to improve glucose (blood sugar) control in patients with Type 2 diabetes mellitus.

The FDA will require that GSK develop a restricted access program for Avandia under a risk evaluation and mitigation strategy, or REMS. Under the REMS, Avandia will be available to new patients only if they are unable to achieve glucose control on other medications and are unable to take Actos (pioglitazone), the only other drug in this class. Current users of Avandia who are benefiting from the drug will be able to continue using the medication if they choose to do so.

Doctors will have to attest to and document their patients' eligibility; patients will have to review statements describing the cardiovascular safety concerns associated with this drug and acknowledge they understand the risks. The agency anticipates that the REMS will limit use of Avandia significantly.

“Allowing Avandia to remain on the market, but under restrictions, is an appropriate response, given the significant safety concerns and the scientific uncertainty still remaining about this drug,” said Janet Woodcock, M.D., director of the FDA’s Center for Drug Evaluation and Research.

Also today, the FDA ordered GSK to convene an independent group of scientists to review key aspects of the company’s clinical trial known as RECORD, which studied the cardiovascular safety of Avandia compared to standard diabetes drugs. During the course of the FDA’s review of the RECORD study, important questions arose about potential bias in the identification of cardiovascular events. The FDA is requiring this independent review to provide additional clarity about the findings.

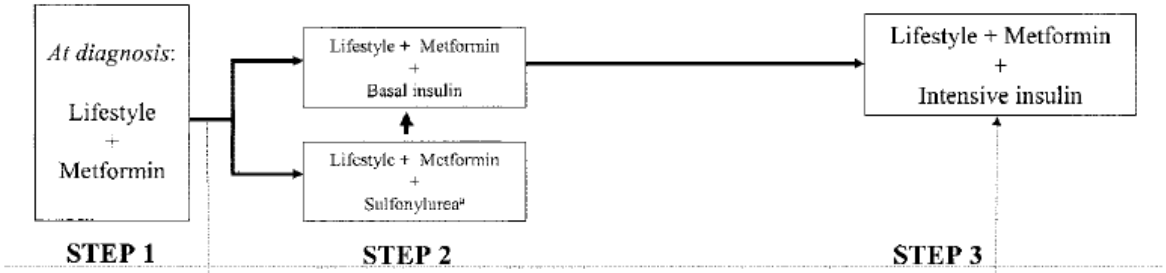
In addition, the agency halted the GSK’s clinical trial known as TIDE and rescinded all of the regulatory deadlines for completion of the trial. The TIDE trial compares Avandia to Actos and to standard diabetes drugs.

The FDA may take additional actions after the independent re-analysis of RECORD is completed.

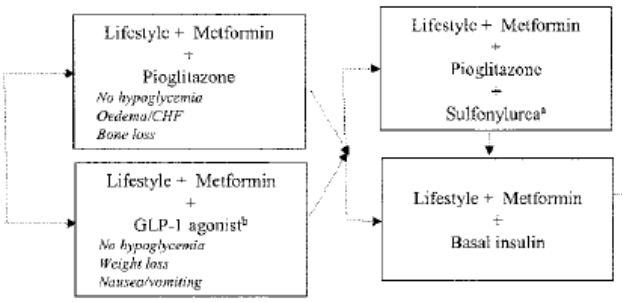
Victoza

- **Not known if Victoza reduces micro- or macrovascular complications. No published trials.**
- C:\Documents and Settings\johnsonjillt1\My Documents\Johnson\1Jill\My Dropbox\PDF's\DiabetesT2 Hyperglycemia management stmnt'.pdf

Tier 1: Well-validated core therapies



Tier 2: Less well-validated therapies



LETTER PRESCRIBER'S LETTER

–This Detail-Document accompanies the related article published in–

PHARMACIST'S LETTER / PRESCRIBER'S LETTER

May 2010 ~ Volume 26 ~ Number 260504

Stepwise Approach to Selecting Treatments for Type 2 Diabetes

(American Diabetes Association Consensus Statement)

Diagnosis of type 2 diabetes[1,a]

↓

Counsel patients regarding lifestyle modification (weight loss, exercise) (expected decrease in A1C 1-2%) [well-validated*]

and

Initiate metformin [*Glucophage*, others] 500 mg once or twice daily, titrate to 850 mg to 1000 mg twice daily (expected decrease in A1C 1-2%) [well-validated*]

↓ **A1C 7% or greater three months later**

Add sulfonylurea, not glyburide or chlorpropamide (expected decrease in A1C 1-2%) [well validated*]

or

Add basal insulin (bedtime intermediate-acting insulin or bedtime or morning long-acting insulin) (expected decrease in A1C 1.5%) [well-validated*]

or

Add pioglitazone [*Actos*], NOT rosiglitazone [*Avandia*] (expected decrease in A1C 0.5-1.4%) [less well-validated]

or

Add exenatide [*Byetta*] (expected decrease in A1C 0.5-1%) [Insufficient clinical use to be confident regarding safety, less-well-validated]

A1C 7% or greater three months later ↓

In those receiving metformin and basal insulin or sulfonylurea, change to metformin plus intensive or basal insulin, respectively [well-validated*]

or

In those receiving metformin plus pioglitazone, add sulfonylurea or change to metformin plus basal insulin [less well-validated]

or

In those receiving metformin plus exenatide, change to metformin plus pioglitazone and sulfonylurea or metformin plus basal insulin [less well-validated]

↓ **A1C 7% or greater three months later**

In patients not yet receiving metformin plus insulin, change to metformin plus basal insulin [well-validated*]

or

In those receiving metformin plus basal insulin, intensify insulin and continue to adjust [well-validated*]

***Well-validated therapies** are those which are the best established, most effective, and cost effective therapies. These therapies are the preferred route of therapy for most patients with type 2 diabetes.

- When insulin is added, insulin secretagogues such as the sulfonylureas or the glinides (repaglinide, nateglinide) should be discontinued.
- Consider insulin as initial therapy (with lifestyle modification) in patients with fasting glucose greater than 250 mg/dL or A1C greater than 10% or those with ketonuria or symptoms of hyperglycemia.
- The algorithm does not include pramlintide [*Symlin*], alpha-glucosidase inhibitors [*Precose, Glyset*], glinides [*Prandin, Starlix*], or sitagliptin [*Januvia*] because of their lower or equivalent overall glucose-lowering effectiveness compared with other agents and/or limited clinical data or relative expense. However, these agents may be appropriate for certain patients. It does not include liraglutide (*Victoza*) or saxagliptin (*Onglyza*) which were not available at the time of writing this consensus statement.

DUEC New Drugs July-Sept 2010

Drug	Generic Name	Other Drugs in Same Class (AWP Pricing)			AWP per unit	Estimated AWP/month
DULERA AER 100-5MCG, 200-5mcg	MOMETASONE FUROATE-FORMOTEROL FUMARATE AEROSOL 100-5 MCG/ACT, 200-5mcg/act	Symbicort 80 mcg /4.5 mcg = $19.52/gram, 160 mcg /4.5 mcg = $22.31/gram, Advair Diskus 100 mcg /50 mcg = $3.22/dose, 250 mcg /50 mcg =$4.00/dose, 500 mcg /50 mcg =$5.26/dose. Advair HFA 45 mcg/21 mcg =$16.09/gram, 115 mcg/21 mcg = $19.99/gram, 230 mcg/21 mcg =$26.29/gram	30 day supply SYMBICORT (80 mcg/4.5 mcg = $199.07; 160 mcg/4.5 mcg = $227.53); ADVAIR Diskus (100 mcg /50 mcg = $193.07; 250 mcg /50 mcg = $239.88; 500 mcg /50 mcg $315.52) and ADVAIR HFA (45 mcg/21 mcg = $193.07; 115 mcg/21 mcg = $239.88; 230 mcg/21 mcg = $315.52; 115 mcg/21 mcg = $ 226.68)		100 mcg/5 mcg , 200 mcg/5 mcg = $17.36/gram	30-day supply of DULERA (100 mcg/5 mcg and 200 mcg/5 mcg = $225.72),
IPRIVASK INJ 15MG	DESIRUDIN FOR INJ 15 MG	FRAGMIN (dalteparin) Eisai 5000 IU SC once daily LOVENOX (enoxaparin) Sanofi Aventis 30 mg SC every 12 hours or 40 mg SC once daily, ARIXTRA (fondaparinux) GlaxoSmithKline 2.5 mg SC once daily Heparin sodium) Various 5000 IU SC every 8 to 12 hours	10 day supply for hip replacemnt: Fragmin $366.91 Lovenox $360.83 to $541.28 Arixtra $578.33 Heparin $61.68 to $92.52		$180 for 10 single use 15mg vials (5 days) $360 for 10-day supply	$1080/month
ZUPLENZ MIS 4MG, 8mg	ONDANSETRON ORAL SOLUBLE FILM 4 MG, 8mg	Zofran 4mg ODT=$28.79, 8mg=$42.18, Ondansetron ODT 4mg=Average generic 17.83, 8mg average generic 29.70 Anzemet			4mgand 8mg= $11.34	

Drug	Generic Name	Other Drugs in Same Class (AWP Pricing)			AWP per unit	Estimated AWP/month
TRIBENZOR TAB	OLMESARTAN-AMLODIPINE-HYDROCHLOROTHIAZIDE TAB 20-5-12.5 MG, 40-5-12.5 MG, 40-5-25 MG, 40-10-12.5 MG, 40-10-25 MG	ARB/CCB/HCTZ Exforge HCT (Amlodipine Besylate , Valsartan Hydrochlorothiazide) Azor (olmesartan, amlodipine)	Exforge HCT 5/160/12.5mg, 5/160/25mg=$3.30, 10/160/12.5mg, 10/160/25mg=$3.74, 10/320/25mg=$4.75 Azor 5/20, 5/40=$3.39, 10/20 and 10/40mg=$4.29		20-5-12.5 MG,=$3.39 40-5-12.5 MG, 40-5-25 MG, 40-10-12.5 MG, 40-10-25 MG= $4.29	$101.70, $128.70
BIOTHRAX INJ	ANTHRAX VACCINE ADSORBED INJ	none			5ml vial=$237.6	
JEVTANA INJ 60/1.5ML	CABAZITAXEL INJ 60 MG/1.5ML (FOR IV INFUSION)	none			Cost AWP $6400.00 / doseIV infusion Single use vial containing 60 mg/1.5 mL, supplied with diluent (5.7 mL) for JEVTANA	* Cost = $6,400 every 3 weeks (max of 10 cycles)
DESONIL PLUS KIT CREAM	*DESONIDE CREAM 0.05% W/ WOUND DRESSING CREAM KIT**	Desonide cream 0.05% cream= $ 33.60/60gm (MAC is $20.40)			$292.50 per 130gm	
DESONIL PLUS KIT OINTMENT	*DESONIDE OINT 0.05% W/ WOUND DRESSING CREAM KIT**	Desonide cream 0.05% cream= $ 33.60/60gm (MAC is $20.40)			$292.50 per 130gm	
XERESE CRE 5-1%	ACYCLOVIR-HYDROCORTISONE CREAM 5-1%	Zovirax Cream 5% 5gm tube+ $158.70			5gm tube=$174.00	
SILENOR TAB 3MG, 6mg	DOXEPIN HCL (SLEEP) TAB 3 MG , 6mg	Rozerem 8mg $5.17, Ambien Cr $6.80, Edluar $5.25, Lunesta $6.70, zolpidem AWP $3.65, 44.62, zaleplon $3.65			3mg, 6mg =$6.06	$181.80

Drug	Generic Name	Other Drugs in Same Class (AWP Pricing)			AWP per unit	Estimated AWP/month
XEOMIN INJ 100UNIT, XEOMIN INJ 50 UNIT	INCOBOTULINUMTOXINA FOR INJ 100 UNIT 50 UNIT	BOTOX –DYSPORT, Myobloc injection	Botox 100unit=$630, 200unit=$1260, Dysport 500unit=$852, Myobloc 2500unit=$599,5000unit=$1198 for 2ml	for cervical dystonia Botox $1486 for 236 units Dysport $852, Myobloc $599-$1198 every 12 weeks For Blepharospasm, Botox and Xeomin are the same.		$756 for 120units every 12 weeks
RELHIST CHW	BROMPHEN TAN-PHENYLEPH TAN CHEW TAB 6-15 MG	Vazotab-- BROMPHENIRAMINE MAL-PHENYLEPHRINE HCL TANN CHEW TAB 6-15 MG $2.73	BROMPHEN TAN-PHENYLEPH TAN CHEW TAB 2.2-1.58 MG $ 1.58		$2.14/tablet	
NOVAFERRUM SOL	POLYSACCH FE COMPLEX-C-FA-B12 SOLN 100-60-1-0.015 MG/5ML	many iron B12 complexes available generically			$30.00 per 4oz, 0.26/ml or $1.25 per dose	
CLOBETAPLUS KIT CREAM	CLOBETASOL PROPIONATE CREAM 0.05% & COAL TAR SOLN 2.3% KIT	Clobetasol propionate cream 0.5% 60 gm=$63.60, average generic cost $59.40 CLOBETASOL PROPIONATE EMOLLIENT BASE CREAM 0.05%=$69.00 for 60gm			293.75=60gm	
CLOBETAPLUS KIT OINTMENT	CLOBETASOL PROPIONATE OINT 0.05% & COAL TAR SOLN 2.3% KIT	Clobetasol propionate cream 0.5% 60 gm=$63.60, average generic cost $59.40 CLOBETASOL PROPIONATE EMOLLIENT BASE CREAM 0.05%=$69.00 for 60gm			293.75=60gm	
MELOXICAM KIT COMFORT	*MELOXICAM TAB 15 MG & LINIMENT TOPICAL GEL KIT**				114.75	
TEKAMLO TAB 150-10MG, 150-5mg	ALISKIREN-AMLODIPINE TAB 150-10 MG, 150-5mg	Tekturna $2.97			2.976	$89.10

Drug	Generic Name	Other Drugs in Same Class (AWP Pricing)			AWP per unit	Estimated AWP/month
TEKAMLO TAB 300-10MG	ALISKIREN-AMLODIPINE TAB 300-10 MG, 300-5mg	Tekturna $3.75			3.756	$112.68

Indications	Notes	Consultant's Notes	DUEC Vote	Insurance Vote
DULERA is an additional combination ICS/LABA product approved for the treatment of asthma is patients 12 years of age and older.	Approval of a combination product containing a corticosteroid (mometasone furoate; ASMANEX) and a long-acting beta2-adrenergic agonist (formoterol fumarate; FORADIL). DULERA is available in two strengths: 100 mcg/5 mcg• and 200mcg/5mcg • DULERA has limitations when compared to its counterparts, ADVAIR and SYMBICORT, because ADVAIR and SYMBICORT are approved for the treatment of asthma and COPD. Additionally, ADVAIR can be used in pediatric patients starting at 4 years of age.• There are currently no head-to-head clinical trials comparing the efficacy or safety of DULERA to SYMBICORT. • In a 1 year Phase III, randomized, open label, parallel assignment, safety/efficacy study comparing DULERA to the active ingredients of ADVAIR Diskus/HFA (Fluticasone Propionate/Salmeterol) , it was concluded that the adverse event profile was similar between the treatment groups. Furthermore, DULERA (Mometasone Furoate/Formoterol fumarate 200 mcg/10 mcg) was shown to be non-inferior to Fluticasone Propionate/Salmeterol 250 mcg/10 mcg. DULERA may be considered for addition to the formulary. The formulary status for DULERA may rely on pricing factors	T3; same criteria as Advair and Symbicort		
IPRIVASK (desirudin for injection) is indicated for the prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism (PE), in patients undergoing elective hip replacement surgery.	IPRIVASK will likely compete with heparin, the low molecular weight heparins (LMWH) [e.g., FRAGMIN and LOVENOX], and the indirect factor Xa inhibitor, fondaparinux [ARIXTRA]. However, these competing products have more FDA-approved indications and have been on the market in the US for some time. Additionally, the LMWH and factor Xa inhibitor products do not require reconstitution prior to administration as IPRIVASK does.	T3PA, PA criteria: 1. dx of current hip replacement surgery, 2. past history of HIT?, QL 12d/30d; relook in 6m. PA good for 1 year.		
Prevention of Postoperative, Chemotherapy- and Radiotherapy-Induced Nausea & Vomiting	Approval of an oral soluble film formulation of ondansetron for the prevention of postoperative, highly and moderately emetogenic cancer chemotherapy-induced, and radiotherapy-induced nausea and vomiting. FDA approval was granted based on bioequivalence of ZUPLENZ 8 mg to ZOFRAN ODT (orally dissolving tablet) 8 mg; a single dose of ZUPLENZ, taken with or without water and under fed and fasting conditions, is comparable to ZOFRAN ODT. ZUPLENZ uses proprietary PharmFilm oral soluble film technology from MonoSol Rx to rapidly dissolve on the tongue without the need for water. Recommendation: Do not add. Generic Onansetron is Mac'd at much lower cost	Exclude		

Indications	Notes	Consultant's Notes	DUEC Vote	Insurance Vote
Amlodipine; hydrochlorothiazide, HCTZ; olmesartan (Tribenzor) is a combination product for the treatment of hypertension. Amlodipine; hydrochlorothiazide, HCTZ; olmesartan is not indicated for the initial treatment of hypertension	A new three-in-one combination product taken once-daily for the treatment of hypertension in patients who are not adequately controlled on any two of the following antihypertensive drug classes: angiotensin receptor blockers, calcium channel blockers and diuretics. TRIBENZOR is not indicated for initial therapy. TRIBENZOR may be substituted for its individually titrated components for patients on olmesartan medoxomil, amlodipine, and hydrochlorothiazide. Available in the following strengths as tablets: 20/5/12.5 mg, 40/5/12.5 mg, 40/5/25 mg, 40/10/12.5 mg, and 40/10/25 mg. Recommendation : Add to tier 3 with Azor and Exforge HCT	T3 with ARB ST		
	Recommendation : exclude, vaccines not covered	N/A		
Antineoplastics in Combination with Prednisone for theTreatment of Patients with Hormone-Refractory Metastatic Prostate Cancer Previously Treated with a Docetaxel-Containing Treatment Regimen	25 mg/m2 administered every three weeks as a one-hour intravenous (IV) infusion in combination with oral prednisone 10 mg administered daily throughout JEVTANA treatment; Premedication is recommended prior to treatment * Recommendation: Cover through specialty or medical benefit.	PA Specialty		
	Recommendation: exclude, generic desonide available at much less cost	Exclude Kits		
	Recommendation: exclude, generic desonide available at much less cost	Exclude kits		
Acyclovir; hydrocortisone is a topical agent for the treatment of herpes labialis (cold sores)		Need cost of hydrocortisone cream 1%--it is OTC, so could exclude the combo.		
Silenor (doxepin hydrochloride) is indicated for the treatment of insomnia characterized by difficulty with sleep maintenance.	Advantages of SILENOR are: (1) it is the only prescription sleep aid approved for sleep maintenance into the seventh and eighth hour of rest that is not a scheduled controlled substance, meaning it does not carry a risk of abuse, and (2) it has not been shown to cause side effects after waking. Reccomendation: add to reference based pricing for sedative hypnotics	RP with the SED-HYPs		

Indications	Notes	Consultant's Notes	DUEC Vote	Insurance Vote
Treatment of adults with cervical dystonia, to decrease the severity of abnormal head position and neck pain in both botulinum toxin-naïve and previously treated patients and blepharospasm in adults previously treated with BOTOX (onabotulinumtoxinA)	Cervical dystonia: 120 units per treatment session. Blepharospasm: The recommended initial total dose should be the same dose as the patient's previous treatment of onabotulinumtoxinA (BOTOX). If the previous dose of BOTOX isnot known, the initial dose of should be between 1.25-2.5 units/injection site. Botox is Tier 3 with PA, Myobloc and Dysport are tier 2.	Select the cheapest botulinum toxin & maximize rebates. Relook in 1 y to determine if less immunogenicity in Xeomin. No trials, only a theoretical difference in antibody production.		
	Many combinations on the market in different strengths	Exclude, OTC alternatives.		
		T3		
Clobetasol is used to relieve the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses and psoriasis	Promoted as a new quick drying formualtion of coal tar that reduces the unpleasant aspects of coal tar therapy. Recommendation: do not add. Geneeric clobetasol available at much less cost. Coal tar is available separetly at a fraction of the cost	Exclude Kits		
Clobetasol is used to relieve the inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses and psoriasis	Promoted as a new quick drying formualtion of coal tar that reduces the unpleasant aspects of coal tar therapy. Recommendation: do not add. Geneeric clobetasol available at much less cost. Coal tar is available separetly at a fraction of the cost	Exclude Kits		
	Recommendation :do not add	Exclude kits		
Aliskiren; amlodipine (Tekamlo) is a combination product for the treatment of hypertension.	Recommendation: tier 3 with ST	T3 w/ ARB/Aliskiren ST		

Indications	Notes	Consultant's Notes	DUEC Vote	Insurance Vote
	Recommendation: tier 3 with ST	T3 w/ ARB/Aliskiren ST		

Formulary Management Rules – For Consideration – October 4, 2010

1. Formulary changes for existing covered medications that are not due to significant clinical, access or financial reasons will only be made at the beginning of a plan year.

2. New products not currently covered by the plan in some other form will not be added to the formulary until a clinical review is completed by the DUEC. The college of pharmacy will bring new products to the DUEC for review in the following conditions:
    a. When newly available on the market
    b. When requested by EBD, a member, a provider or the Board
    c. As part of a class review
    d. When medical literature shows a significant improvement in efficacy

3. Brand products on tier 2 will automatically move to tier 3 when a generic equivalent is released with the generic version added to tier 1; if a generic is removed from the market or has significant shortages in supply, the equivalent brand product on tier 3 will automatically move to tier 2.

4. Excluded drugs will be reviewed in the following conditions:
    a. When requested by EBD, a member, a provider or the Board
    b. As part of a class review
    c. When medical literature shows a significant improvement in efficacy

5. Financial appeals of formulary rules are not allowed; evidence of a medical reason to change a formulary rule will be considered by DUEC as part of a class review. This rule encompasses traditional tiered drugs, reference price drugs, and excluded drugs.

6. Applicable state and federal laws will be followed for the utilization of covered medications