AGENDA

State and Public School Life and Health Insurance Board

Drug Utilization and Evaluation Committee

EBD Board Room - 501 Building - 5th Floor

October 4, 2011 1:00 p.m.

1. **Call to Order** ..... *Matthew Hadley, Chair*
2. **Approval of Minutes** ..... *Matthew Hadley, Chair*
3. **First Review Medications** ..... *Jill Johnson, UAMS*
4. **Second Review Medications** ..... *Jill Johnson, UAMS*
    a. **Vyvanse – Non-Covered Medication – Re-review for coverage**
    b. **Celexa – Covered Medication – FDA indication change**
5. **Statin Medication Chart for Reference Pricing**..... *Jill Johnson, UAMS*
6. **Director's Report**.....*Jason Lee, Executive Director*

Next Meeting:
2012 Schedule to be Determined

State and Public School Life and Health Insurance Board Clinical and Fiscal Drug Utilization and Evaluation Committee
Minutes
October 4, 2011

The State and Public Life and Health Insurance Board, Drug Utilization and Evaluation Committee (DUEC) met on Monday, October 4, 2011 at 1:00 p.m., in the EBD Board Room, 501 Woodlane, Little Rock, AR.

Members present:	**Members absent:**
Matthew Hadley	Kelly Chaney
Dr. William Golden	Dr. Joe Stallings
Kat Neill	Mark McGrew
Larry Dickerson/proxy	Scott Pace
Dr. Hank Simmons	

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

OTHERS PRESENT
Jill Johnson, UAMS College of Pharmacy/EBRx; Connie Bennett, Informed Rx; Rhonda Walthall, AHTD; Michelle Hazelett, Lori Eden, Amy Tustison, Sherri Saxby, Latryce Taylor, Cathy Harris, EBD; Bridget Johnson, Pfizer, Dwight Davis, Alan Hickman, UAMS; Bryan Meldrum, Novasys; Frances Baumen, Novo Nordisk; Warren Tyes, Merck; Mark DeClark, Lilly; Janie Huff, Takeda; BJ Himes, QualChoice

CALL TO ORDER
Meeting was called to order by Matthew Hadley, Chairman.

APPROVAL OF MINUTES
The motion was made by Dr Golden to approve the April 4, 2011 minutes. Minutes approved as amended.

FIRST REVIEW MEDICATIONS *by Jill Johnson*

Drug Name	Tier Status
Creon 3000 units	**T3**

Digestive enzyme. New infant specific dose (3000U)

Lastacaft **T3**
Ocular pruritus. Dose is 1 drop per day.

Tradjenta 5mg **T3 with DM Step Therapy**
Type 2 diabetes (DPP-4 inhibitor class)

Xarelto **T3 with QL 35 tabs/year. PA anything over that limit**
Prevention of thrombosis after hip/knee replacement. (oral dosage form)

Zirgan Ophthalmic gel **T3**
Acute herpes simplex keratitis

Complera 200mg tab **T3/W/ PA**
Antiretroviral combination for HIV infection - combo therapy targets different points in the life cycle of HIV

Dificid 200mg tabs **T3/w /PA, QL**
Tx of clostridium difficile - associated diarrhea in adults 18 and older.Sustained clinical response w/Dificid was greater at 25 days and at trial end for Dificid vs Vancocin70% vs 57% in trial 1 and 72% vs 57% in trial 2

Endurant **T3/w /PA**
HIV - in combo w/other antiretrovirals for the tx of HIV-1 infection in antiretroviarlas treatment naïve adult patients

Lupron Depot 45mg inj (6 mo formula) **Exclude**
Advanced prostrate cancer

Nulojix **T3 /w/PA**
First selective T-cell costimulation blocker for the prophylaxis in kidney transplants, in combo w/basiliximad induction, mycophenolate mofetil and corticosteroids

Phoslyra Solution **T3 /w/PA**
New 667mg oral solution formulation for reducing serum phosphorus in end stage renal disease

Drug Name	Tier Status

Staxyn 10mg tabs **T3 /w/PA, QL**
Erectile dysfunction. Orally disintergratin form of Levitra but cost less. $14/tab vs $19/tab for Levitra

Incivek 375mg **Exclude**
Chronic Hep C genotype 1 in combination w/ peginterferon alfa and ribavirin in adults 18 and older with compensated liver disease

Victrelis 200mg caps **T3/w/PA**
Chronic Hep C genotype 1 in combination w/ peginterferon alfa and ribavirin in adults 18 and older with compensated liver disease

NOTE: lost quorum for the following drug discussions

Zytiga 250mg tab **Exclude**
Oral treatment of prostrate cancer in combo with prednisone in patients who have received prior chemotherapy containing docetaxel

Zelboraf 240mg tabs **T3 /w/PA, QL**
*Charge ½ of T3 copay for each 14 day supply.
Oral treatment of malignant melanoma

Adcetris 50mg INJ **Exclude**
Hodgkin's and non Hodgkin's lymphoma

Arcapta **Exclude**
Treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Once daily dosing

Brilinta 90mg **T3**
Antiplatelet therapy. More effective than Plavix for acute coronary syndrome

Cenfol **Exclude**
Volic acid combination

Codar AR **Exclude**
Narcotic antitussive-antihistamine

Codar D **Exclude**
Narcotic antitussivedecongestant

Codar GF **Exclude**
Narcotic antitussive/expectorant

Drug Name	Tier Status

Daliresp 500mcg **Exclude**
First in class PDE4 inhibitor for the prevention of COPD exacerbations in patients w/ COPD associated with chronic bronchitis and a history of exacerbations.

Endal CD Syrup **Exclude**
Narcotic cough-decongestant antihistamine

Flo-pred Suspension **Exclude**
Corticosteroids

Generess FE chewable **Exclude**
oral contraceptive

Gralise **Exclude**
Postherpetic neuralgia(PHN)

Horizant 600 **Exclude**
Anticonvulsant/neuropathic pain

Lamictal XR 300mg tab **Exclude**
Anticonvulsant, bipolar disorder

Lunglaid Emulsion **Exclude**
Respiratory medical food

Makena injection **Exclude**
Reduces the risk of preterm birth

Naproderm Cream **Exclude**
Topical analgesic (NSAIS)

OB Complete Cap 400 **Exclude**
Prenatal vitamin

Procort **Exclude**
Anorectal inflammation

Spirix Nasal Spray **Exclude**
Mild to moderate pain in nasal spray form

Sumadan Wash **Exclude**
Acne Product

Drug Name	Tier Status
Sylatron Kit Melanoma	**Exclude**
Topicort LP oint 0.05% Topical corticosteroid	**Exclude**
Tricode AR Narcotic antitussive/decongestant/antihistamine	**Exclude**
Tricode GF Narcotic antitussive/expectorant/decongestant	**Exclude**
Vandetanib 100 and 300mg tabs (Caprels) Oral tx of symptomatic or progressive medullar thyroid cancer in patients with unresectable locally advanced or metastatic disease	**Exclude**
Viibryd Major deprssive disoder	**Exclude**
Viramune XR 400mg tab HIV-1 infections in adults	**Exclude the XR form**
Vitafol-one caps Prenatal vitamin	**Exclude**
Ztuss Narcotic antitussive/expectorant/decongestant	**Exclude**
Solesta injection Tx of fecal incontinence who have failed conservative therapy. 4 injections per procedure administered by trained physician as an outpatient w/o anesthesia.	**N/A Medical**
Calcium folinate Due to a shortage of leucovorin calcium injection, the FDA has approved temporary importation and distribution of this European product, from TEVA UK	**N/A Medical**
Wilate Tx of spontaneous and traumic induced bleeding episodes in patients with severe VWD or moderate VWD in whom the use of desmopressin is known/suspected to be ineffective or contraindicated. Not for the prevention of excessive bleeding during/after surgery in patient's w/VWD. Not indicated for Hemophilia A	**N/A Medical**

Drug Name	Tier Status
Xyntha Injection	**N/A Medical**

Congent factor VIII disorder/hemophilia a carrier/asympt hemophjlia A carrier/sympt hemophil a carrier. Not indicated for VWD

Yervoy	**N/A Medical**

Unresectable or metastatic melanoma

New drugs were approved by consensus.

SECOND REVIEW MEDICATIONS*, Jill Johnson*

a. Vyvanse (currently excluded from coverage) is a central nervous system stimulant.

Vyvanse is used to treat attention deficit hyperactivity disorder (ADHD) in adults and in children who are at least 6 years old. It is used as a part of a total treatment program that may include psychological, educational, and social therapy.

The DUEC reviewed Adderall XR and generic Adderall XR and considered generic Adderall XR cost will decrease further due to competition in the market and QL would prevent exceeding the maximum recommended daily dose.

Recommendation: Cover Vyvanse at Tier 3 with quantity limit same as other ADHD medications - No Therapeutic duplication *(use of multiple agents from the same chemical family or therapeutic class).*

b. Citalopram (Celexa®)

Celexa (citalopram hydrobromide) is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs).recommendations for healthcare professionals and patients

ISSUE: FDA notified healthcare professionals and patients that the antidepressant Celexa (citalopram hydrobromide) should no longer be used at doses greater than 40 mg per day because it can cause abnormal changes in the electrical activity of the heart. Changes in the electrical activity of the heart (prolongation of the QT interval of the electrocardiogram [ECG]) can lead to an abnormal heart rhythm (including Torsade de Pointes), which can be fatal. Patients at particular risk for developing prolongation of the QT

interval include those with underlying heart conditions and those who are predisposed to low levels of potassium and magnesium in the blood.

Citalopram causes dose-dependent QT interval prolongation. Citalopram should no longer be prescribed at doses greater than 40 mg per day. Citalopram should not be used in patients with congenital long QT syndrome. Patients with congestive heart failure, bradyarrhythmias, or predisposition to hypokalemia or hypomagnesemia because of concomitant illness or drugs, are at higher risk of developing Torsade de Pointes. See the FDA Drug Safety Communication for additional recommendations for healthcare professionals and patients

RECOMMENDATION: Place QL on Citalopram on all strengths for dose optimization. (40mg tabs max 31/31 days, 20mg tabs 31/31 days, 10mg tabs 31/31 days. Patients should move to the next higher strength rather than take multiple tabs to achieve the dose.

The committee decided by consensus to approve recommendations for Vyvanse and Citalopram (Celexa®).

STATIN MEDICATION CHART FOR REFERENCE PRICING *by Jill Johnson*

Recommendation: Move Lipitor 40mg and Crestor 10mg to Tier 2 copay with an approved prior authorization (same as Lipitor 80mg and Crestor 20mg and 40mg).

Lipitor 10mg and 20mg and Crestor 5mg will remain covered under the reference pricing arrangement.

The committee decided by consensus to approve.

Meeting adjourned.

DUEC New Drugs April-Aug 2011

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
T3							
51200024 0067**	**Creon 3000 units**	**n/a**	**n/a**	Digestive enzyme. New infant specific dose (3000U)	**T3.** Look at EBD Report. PBM should negotiate lowest net cost pancreatic enzyme replacement among Creon, Zenpep, and Pancreaze.		
86802004 0020**	**Lastacaft**	**alcaftadine**	**Ketorolac- One drop qid. Patanol- One drop bid**	Ocular pruritus . Dose is 1 drop per day.	**T3 .** OTC is available and without data to show any are more effective or safer than another, it is not possible to determine which is better. AWP pricing: • alcaftadine $105.60/3 ML • azelastine $104.04/6 ML • emedastine$ 81.75/5ML • epinastine $106.99/5 ML • ketotifen $ 6.75 – 12.00/5 ML (SEVERAL BRANDS OTC) • olopatadine$125.75/5ML (1gtt BID)		
T3 ST or QL							
27550050 0003**	**Tradjenta 5mg**	**linagliptin**	**Januvia, Onglyza**	Type 2 diabetes (DPP-4 inhibitor class)	**<u>T3 with DM Step Therapy.</u>** 1. Deny if any insulin claim in the past 30 days. 2. No monotherapy access for sitagliptin or saxagliptin or linagliptin. Combination products require generic monotherapy prior to access.(i.e. Must fail metformin monotherapy as well as other generic combo therapies prior to getting this nonvalidated therapy.) 3. PA all prescriptions, criteria: ▪ require a current metformin fill for 90 of the past 120 days at the maximum or near-maximum dose, failure to reach goal A1C, AND then ▪ Require the use of concomitant sulfonylurea, unless contraindicated, &/or pioglitazone in patients who have not reached HbA1C goal with metformin monotherapy, unless pioglitazone is contraindicated due to HF, edema, or fracture risk. ▪ Prior to access to Kombiglyze XR (saxagliptin + metformin), metforminb + sulfonylurea + pioglitazone and without saxagliptin must fail to achieve goal HbA1C. 4. No therapeutic duplication with sita- or saxa- or lina-gliptin. (Deny the drug if the other is filled in the previous 30 days.) aMetformin must be titrated slowly upward. Metformin 500mg twice daily is the initial dose. Patients should increase to at least 850 mg twice daily before determining failure. bMetformin must have an adherence rate of 4 of the past 5 months prior to gaining access to sitagliptin or saxagliptin or linagliptin.		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
83370060 0003**	**Xarelto**	**Rivaroxaban 10mg**	**Enoxaparin, Lovenox (injectables)**	Prevention of thrombosis after hip/knee replacement. (oral dosage form)	**T3, QL of 35 tabs/year for VTE Proph in Hip or Knee replacement. Non-inferior to warfarin in AF and VTE Treatment.**		
86103007 0040**	**Zirgan Ophthalmic gel**	**ganccicIovir**	**Viroptic Drops, Trifluridine Drops**	Acute herpes simplex keratitis	**T3**. Not superior to acyclovir 3% ointment. Hoh HB, et al. Randomised trial of ganciclovir and acyclovir in the treatment of herpes simplex dendritic keratitis: a multicentre study. Br J Ophthalmol. 1996 Feb; 80(2):140-3.		

T3PA

12109903 4003**	**Complera 200mg tab**	**emtricetobine/rilpivirine/tenofovir**	**Atripla**	Antiretroviral combination for HIV infection - combo therapy targets different points in the life cycle of HIV	**T3 PA** . The following points should be considered when initiating therapy with rilpivirine: more rilpivirine treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared with subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy; the observed virologic failure rate in rilpivirine treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared with efavirenz; more subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared with efavirenz. Rilpivirine's advantage is fewer adverse effects compared to efavirenz. PA criteria: 1. Dx of HIV 1 and patient is HIV-treatment-naive, 2. Pt is without baseline NNRTI-limiting mutations and does the pt have full susceptibility to the background NRTIs, 3. Id the patient female and able to bear children,OR 4, Does the patient have underlying psychiatric issues that would prevent efavirenz from being started? To gain access to the drug, patient must have 1 AND 2 AND EITHER 3 OR 4.		
03530025 00003**	**Dificid 200mg tabs**	**fidaxomicin**	**Vancocin 500-2000mg / day**	Tx of clostridium difficile - associated diarrhea in adults 18 and older.Sustained clinical response w/Dificid was greater at 25 days and at trial end for Dificid vs Vancocin70% vs 57% in trial 1 and 72% vs 57% in trial 2	**T3 PA**: 1. Dx of Clostridium difficile infection producing diarrhea, 2. Failure of metronidazole and oral vancomycin as per the current IDSA Cdif infection guidelines. QL of 20 units per fill.		
12109080 1003**	**Endurant**	**rilpivirine**	**Intelence, Rescriptor, Sustiva, Viramune**	HIV - in combo w/other antiretrovirals for the tx of HIV-1 infection in antiretroviarlas treatment naïve adult patients	**T3 PA** . The following points should be considered when initiating therapy with rilpivirine: more rilpivirine treated subjects with HIV-1 RNA greater than 100,000 copies/mL at the start of therapy experienced virologic failure compared with subjects with HIV-1 RNA less than 100,000 copies/mL at the start of therapy; the observed virologic failure rate in rilpivirine treated subjects conferred a higher rate of overall treatment resistance and cross-resistance to the NNRTI class compared with efavirenz; more subjects treated with rilpivirine developed lamivudine/emtricitabine associated resistance compared with efavirenz. Rilpivirine's advantage is fewer adverse effects compared to efavirenz.		
21405010 2564**	**Lupron Depot 45mg injection (6 month formulation**	**leuprolide**	**other Lupron formulations**	Advanced prostrate cancer	**T3PA**: 1. Dx of prostate Ca.		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
99408020 0021 **	**Nulojix**	**belatacept**	**none**	First selective T-cell costimulation blocker for the prophylaxis in kidney transplants, in combo w/basiliximad induction, mycophenolate mofetil, and corticosteroids	**T3 PA.** Criteria Is the patient s/p kidney transplant, currently taking mycophenolate mofetil and corticosteroids, and known to be seropositive for Epstein-Barr Virus?		
52800020 1020 **	**Phoslyra Solution**	**calcium acetate oral solution**	**Phoslo / calcium acetate caps**	New 667mg oral solution formulation for reducing serum phosphorus in end stage renal disease	**T3PA**. Criteria: 1. Unable to swallow tablets or capsules. Deny if other tablets/capsules are on the current profile.		
40304090 14072**	**Staxyn 10mg tabs**	**vardenafil orallu disintegrating tab**	**Viagra, Cialis, Levitra**	Erectile dysfunction. Orally disintergratin form of Levitra but cost less. $14/tab vs $19/tab for Levitra	**T3 w/ QL and PA** (same criteria as other ED drugs). Watch for generic soon.		
12353085 0003 **	**Incivek 375mg**	**telaprevir tabs**	**Victrelis**	Chronic Hep C genotype 1 in combination w/ peginterferon alfa and ribavirin in adults 18 and older with compensated liver disease	**T3PA**. In your packet.		
12353015 0001 **	**Victrelis 200mg caps**	**boceprevir 200mg**	**Incivek**	Chronic Hep C genotype 1 in combination w/ peginterferon alfa and ribavirin in adults 18 and older with compensated liver disease	**T3 PA**. **Criteria for tx-naive**: 1. Dx of chronic HCV, genotype 1, with a quantitative plasma HCV RNA of at least 10,000 IU/mL, 2. is the patient without decompensated cirrhosis, coinfection with HBV or HIV, or active cancer, or pregnancy, 3. will concomitantly recieve peginterferon and ribavirin therapy with boceprevir. If approved, the PA would provide 20 weeks of boceprevir. If after 20 weeks of boceprevir (week 24 of total therapy including the first 4 w of lone peginterf/ribavirin) **Criteria for previously treated**: 1. Dx of chronic HCV, genotype 1, 2. Pt must have received at least 12 w of peginterferon and ribavirin and failed to have at least a 2 log10 decrease in the HCV RNA level, AND 3. absence of decompensated cirrhosis, coinfection with hepatitis B virus infection or HIV, or active cancer, or pregnancy		
21406010 2003 **	**Zytiga 250mg tab**	**abiraterone**	**Jevtana, Provenge**	Oral treatment of prostrate cancer in combo with prednisone in patiens who have received prior chemotherap containing docetaxel	**T3PA**. Drug has limited medical benefit. QL of 120/30d. No 90 day fills. Criteria are 1. Dx of metastatic prostate cancer, 2. has the pt received prior chemotherapy containing docetaxel. N Engl J Med 2011; 364:1995-2005. 1000mg (250mg tablets) daily. Extended overall survival by 3.9m (14.8 vs 10.9m). No difference in withdrawal due to AE's. Noteworthy: all authors were heavily invested and conflicted, many being employees of the manufacturer. Trial was (abir + pred) vs (plac + pred). The plac group took their meds a median of only 4 months while the abir group took abir a median of 8 months		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
21532080003**	**Zelboraf 240mg tabs**	**vemurafenib**	**none**	Oral treatment of malignant melanoma	**This drug has limited medical benefit.** In patients with 1. Dx of unresectable or metastatic, previously untreated stage IIIC or stage IV melanoma that tested positive for the BRAF V600E mutation on real-time polymerase-chain-reaction assay. (Not the wildtype BRAF) At 6 months, overall survival was 84% (95% CI, 78 to 89) in the vemurafenib group and 64% (95% CI, 56 to 73) in the dacarbazine group. N Engl J Med 2011;364:2507-16. T3PA		

Exclude

21355020202100**	**Adcetris 50mg inj**	**blentuximad for IV infusion**	**none**	Hodgkin's and non Hodgkin's lymphoma	**Exclude for now.** Only 1 phase 1 trial in peer-reviewed literature. FDA-approval is 1. Dx of Hodgkin's Lymphoma after failure of at least 2 prior chemotherapy regimens in patients ineligible for transplant or after stem cell transplant failure. 2. Dx of treatment of systemic anaplastic large cell lymphoma after failure of at least 1 prior chemotherapy.		
44201042200100**	**Arcapta**	**indacaterol inhal powder**	**Serevent, Foradil, Performist**	Treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. Once daily dosing	**T3. Step therapy for LABAs was adopted 1/19/10 with 2 changes from previous ST. ST: Allow LABA if inhaled steroid is on the profile 3 of the past 4 months OR if the patient currently qualifies as Moderate-Persistent Asthma (with questionnaire at EBRx Call Center which is the case with Advair) If filling salmeterol or formoterol alone will need criteria requiring concurrent use of ICS. PAs for LABAs are good for only 4 months. Indacaterol was compared to salmeterol and to formoterol. (Formoterol12 vs Inda 300-600mcg)Thorax. 2010 Jun;65(6):473-9. (Salmeterol Resp Med. 2011;105:719-726.** **Exclude at this time. No data vs other LABAs at equipotent dosing.**		
85158470003	**Brilinta 90mg**	**ticagrelor**	**Plavix, Effient**	Antiplatelet therapy. More effective than Plavix for acute coronary syndrome	**Exclude,** Did NOT have a significant advantage over clopidogrel in the North American group. No subgroup analysis available. Some think it may involve higher ASA doses used in North Am.		
82991503200	**Cenfol**	**folic acid/Vit B6/Vit B12**		Volic acid combination	**Exclude.** No info on this specifically in Facts & Comparisons. Not indexed in Lexicomp. Multiple OTC-containing B vitamins are available.		
43995202320900**	**Codar AR**	**Chlorpheniramine w/Cod liqiud**	**Multiple**	Narcotic antitussive-antihistamine	**Exclude**		
43995102300	**Codar D**	**Pseudoephedrine w/Cod**	**Multiple products**	Narcotic antitussive-decongestant	**Exclude**		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
43997002 2809**	**Codar GF**	**Guaifenesin-Codeine**	**Multiple options of Narcotic antitussive - expectorant**	Narcotic antitussive/expectorant	**Exclude.** Not sure why we would cover this given the $3/120mL option. Not indexed in Lexicomp. Not listed in Facts & Comparisons although multiple generics C-V's were listed with codeine 5-10mg, then C-IIIs up to 20mg codeine.		
44450065 0003**	**Daliresp 500mcg**	**roflumilast**	**NA**	First in class PDE4 inhibitor for the prevention of COPD exacerbations in patients w/ COPD associated with chronic bronchitis and a history of exacerbations.	**Exclude.** Daliresp has not been compared to ICS. In the trial that COPD patients were allowed to continue the same dose ICS they took pretrial, there was no difference in moderate or severe COPD exacerbations. In the very severe COPD subgroup (GOLD stage IV), the rate of COPD exacerbations was 1.01 in the roflumilast group and 1.59 in the placebo group per patient per year, p=0.024. "Exacerbations" was symptomatic deteriorations treated with systemic corticosteroids and/or antibiotics. Severe exacerbations were hospitalizations. Patients in the trial were prohibited from increasing their use of ICS.		
43995303 1412**	**Endal CD Syrup**	**Phenylep-diphenhydramine-Codeine**	**multiple options**	Narcotic cough-decongestant-antihistamine	**Exclude.** Not sure of the cost comparison vs others in the class.		
22100040 1018**	**Flo-pred Suspension**	**Prednisolone acetate oral suspension**	**Prelone**	Corticosteroids	**Exclude.** Use generic. The difference is Flo-Pred is the only oral suspension. The others are solutions or syrups.		
25990036 005**	**Generess FE chewable**	**norethindrone/ ethiyl estradiol w/FE**	**Microgestin FE, TiliaFe**	oral contraceptive	**Exclude.** Norethindrone 0.8 mg/ethinyl estradiol 0.025mg-monophasic 24 days; 4 days of ferrous fumarate 75mg. No other exact alternative. Several close alternatives.		
62540030 0003**	**Gralise**	**gabapentin (PHN)**	**gabapentin immediate release**	Postherpetic neuralgia(PHN)	**Exclude, generic available.**		
62560002 07**	**Horizant 600**	**gabapentin sustained release tab**	**gabapentin immediate release**	anticonvulsant/neuropathic pain	**Exclude.** For Restless Legs Syndrome. Regular gabapentin has been shown effective in RLS. No comparisons yet b/w gabapentin and gaba enacarbil. Happe S, Klosch G, et al. Treatment of idiopathic RLS with gabapentin. Neurology. 2001;57:1717-1719. Bogan RK, et al. Lonterm maintenance treatment of RLS with gabapentin enacarbil: a RCT. May Clin Proc. 2010;85(6):512-21. Garcia-Borreguero D, et al. Treatment of RLS with gabapentin. Neurology. 2002;59:1573-79.		
72600000 05**	**Lamictal XR 300mg tab**	**lamotrigine sustaied release**	**lamotrigie immediate release**	anticonvulsant, bipolar disorder	**Exclude.**		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
81259990 0016**	**Lunglaid Emulsion**	**Dietary management product**		Respiratory medical food	**Exclude.**		
26000010 1017**	**Makena injection**	**hydroxyprogesterone caproate 250mg/ml**	**Hydroxyprogesterone caproate 250mg/ml compounded by specialty pharmacies**	Reduces the risk of preterm birth	**Exclude**. Has been compounded by pharmacists to date. FDA issued a statement 3/30/11 stating the FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesteroine caproate unless the compounded products are unsafe, of substandard quality, or are not being compounded appropriately.		
90210065 00370**	**Naproderm Cream**	**naproxen cream**	**Voltaren**	topical analgesic (NSAIS)	**Exclude. No info in pub med.**		
78512070 0013**	**OB Complete Cap 400**	**Prenatal + DHA**	**Prenatal + DHA**	Prenatal vitamin	**Exclude.**		
89991002 3137	**Procort**	**HC/pramoxine**	**Analpram HC, Pramcort**	Anorectal inflammation	**Exclude.** Hydroc 1.85%/Pramoxine 1.15%. Generic Hydrocort 2.5%/Pram 1% is $49.99/30g tube at drugstore.com		
66100037 1020	**Spirix Nasal Spray**	**ketorolac nasal spray**	**ketorolac tablets**	mild to moderate pain in nasal spray form	**Exclude.** This drug has a 5 day limit. It has not been compared to any other analgesic that is available in this country.		
90059903 2009**	**Sumadan Wash**	**Sulfacetamide w/sulfur wash**	**Sulfacetamide w/sulfur wash**	Acne Product	**Exclude.**(sodium sulfacetamide 9% & sulfur 4.5% cream). Generics available.		
21700075 2064**	**Sylatron Kit**	**peginterferon alfa-2b for injection**	**none**	Melanoma	**Exclude.** Specialty. No effect on overall survival. Provides a worse QOL than observation. Specifically, fatigue, appetite loss, dyspnea, Has, sore muscles, and fever were worse with treatment. J Clin Oncol. 2009;27:2916-23. Did provide a superior recurrence-free survival of 45.6% vs 38.9%, a HR of 0.82 at 3.8y, p=0.01. However at 4 years, only 22.5% remained in the treatment group. 99% in the tx group reported adverse effects. Eggermont AMM, et al. Adjuvant therapy with pegylated interferon alfa-2b versus observation alone in resected stage III melanoma: fi nal results of EORTC 18991, a randomised phase		
90550040 0042	**Topicort LP oint 0.05%**	**desoximetasone oint**	**betamethasone, mometasone**	topical corticosteroid	**Exclude.**		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
43995303 2009**	**Tricode AR**	**Pseudoephedrine/ chlorphen w/Cod**	**Multiple products**	Narcotic antitussive/decongestant/antihistamine	**Exclude.** Active ingredients (in each 5 mL teaspoonful) Chlorpheniramine Maleate 2 mg Codeine Phosphate* 8 mg *WARNING: May be habit forming Pseudoephedrine Hydrochloride 30 mg		
43997303 3009**	**Tricode GF**	**pseudoephedrine w/Cod-GG**	**Multiple products**	Narcotic antitussive/expectorant/decongestant	**Exclude.**		
21534085 0003**	**Vandetanib 100 and 300mg tabs (Caprels)**	**vandetanib**	**no other oral therapies**	Oral tx of symptomatic or progressive medullar thyroid cancer in patients with unresectable locally advanced or metastatic disease	**This drug is intended to treat metastatic or unresectable locally advanced medullary thyroid cancer. EXCLUDE. This drug provides limited medical benefit.**		
58120088 1003**	**Viibryd**	**vilazone**	**citalopram fluoxetine, Lexapro, paroxetine, sertraline**	Major deprssive disoder	**Exclude.** Reevaluate in 6 months. There is only 1 clinical trial in Pub Med and it is vs placebo.		
12109050 0075**	**Viramune XR 400mg tab**	**nevirapine SR**	**Rescriptor, Sustiva, Viramune, Intelence**	HIV-1 infections in adults	**Exclude the XR form.** Immediate release is given twice daily while the XR is once daily; generic immediate release is expected May 2012. Nevirapine is included in the current HIV guidelines as alternate. See Current Guidelines.		
78516032 0001**	**Vitafol-one caps**	**Prenatal + DHA**	**Prenatal + DHA**	Prenatal vitamin	**Exclude.**		
43997303 3009**	**Ztuss**	**Pseudoephrine /Cod/GG**	**Multiple products**	Narcotic antitussive/expectorant/decongestant	**Exclude**		

N/A Medical (see individual drugs)

99379902 4040**	**Solesta injection**		**none**	Tx of fecal incontinence who have failed conservative therapy. 4 injections per procedure administered by trained physician as an outpatient w/o anesthesia.	**N/A Medical**		

GPI	Drug	Generic Name	Other Drugs in Same Class	Indications	Consultant's Notes	DUEC Vote	Insurance Vote
21755040102004**	**Calcium folinate**	**leucovorin calcium**	**n/a**	Due to a shortage of leucovorin calcium injection, the FDA has approved temporary importation and distribution of this European product, from TEVA UK	**N/A IV infusion**		
85100015102100**	**Wilate**	**Antihemophilic factor/VWD**	**Humate**	Tx of spontaneous and traumic induced bleeding episodes in patients with severe VWD or moderate VWD in whom the use of desmopressin is known/suspected to be ineffective or contraindicated. Not for the prevention of excessive bleeding during/after surgery in patients w/VWD. Not indicated for Hemophilia A	**N/A Inpatient only.**		
85100010264400**	**Xyntha Injection**	**Antihemophilic Factor VIII, plasma/albumin free**		Congent factor VIII disorder/hemophilia a carrier/asympt hemophjlia A carrier/sympt hemophil a carrier. Not indicated for VWD	**N/A Medical.** Or if covered by Rx benefit, reject at the POS, T3PA for 1. Dx of Hemophilia A, others?. Dose for major to life-threatening hemorrhage: Initial dose 40-50 IU/kg then 20-25 IU/kg q8-24h until threat is resolved. 70kg person…3500 IU now and 1750 IU q8h is 35 vials or 8750 in the first 24h. $14,525 first		
21353032002000**	**Yervoy**	**ipilimumab**	**dacarbazine, Proleukin**	Unresectable or metastatic melanoma	**N/A Medical, IV** . If covered by pharmacy benefit, T3PA: 1. Dx of metastatic malignant melanoma.		

Vyvanse vs Adderall XR

August 1-August 31, 2011

Vyvanse (currently excluded from coverage) vs Adderall XR and generic Adderall XR

August 1-August 31, 2011

	Strength*	Utilizers	#Rxs	AWP/ capsule		Strength	Utilizers	#Rxs	AWP/ capsule		Strength	Utilizers	#Rxs	AWP/ capsule
	20 mg	18	14	$5.80		5 mg ER	2	2	$7.50		5 mg ER	4	4	$6.13
	30 mg	49	30	$5.80		10mg ER	20	26	$7.36		10mg ER	36	57	$6.13
	40 mg	24	23	$5.80	Brand Adderall XR (Mixed amphetamine Salts) MAS	15 mg ER	11	10	$7.46	Generic Adderall XR (MAS)	15 mg ER	38	49	$6.13
Vyvanse (lisdexamphetamine)	50 mg	27	27	$5.80		20 mg ER	58	74	$7.60		20 mg ER	190	226	$6.13
	60 mg	13	12	$5.80		25 mg ER	11	10	$7.75		25 mg ER	39	43	$6.13
	70 mg	21	25	$5.80		30 mg ER	41	37	$7.84		30 mg ER	135	141	$6.13

*30 mg lisdexamphetamine is equivalent to 10 mg MAS (ER)

Considerations:

1. Generic Adderall XR cost will decrease further due to competition in the market.
2. QL would prevent exceeding the maximum recommended daily dose.

Citalopram (Celexa®)
10/4/11 DUEC

Considerations:

1. Hard edit at point of sale rejecting >40mg daily.

2. Dose optimize all strengths and place QL on all strengths. 40mg tabs max 31/31d, 20mg 31tabs/31d, 10mg 31 tabs/31d) Patients should move to the next higher strength rather than take multiple tabs to achieve the dose.

3. Per the PI: "Celexa (citalopram HBr) should be administered at an initial dose of 20 mg once daily, with an increase to a maximum dose of 40 mg/day. Dose increase should usually occur in increments of 20 mg at intervals of no less than one week. Doses above 40 mg/day are not recommended due to the risk of QT prolongation. Additionally, the only study pertinent to dose response for effectiveness did not demonstrate an advantage for the 60 mg/day dose over the 40 mg/day dose."

From Connie Bennett at Informed Rx:
I ran a report from Jun 1, 2011 thru today to check for any members that may be exceeding 40mg/day. **The report revealed ~120 members**. One solution would be to place quanity limits on Celexa.

Celexa (citalopram hydrobromide): Drug Safety Communication - Abnormal Heart Rhythms Associated With High Doses[Posted 08/24/2011]

AUDIENCE**: Psychiatry, Cardiology**

ISSUE: FDA notified healthcare professionals and patients that the antidepressant Celexa (citalopram hydrobromide) should no longer be used at doses greater than 40 mg per day because it can cause abnormal changes in the electrical activity of the heart. Changes in the electrical activity of the heart (prolongation of the QT interval of the electrocardiogram [ECG]) can lead to an abnormal heart rhythm (including Torsade de Pointes), which can be fatal. Patients at particular risk for developing prolongation of the QT interval include those with underlying heart conditions and those who are predisposed to low levels of potassium and magnesium in the blood.

Studies did not show a benefit in the treatment of depression at doses higher than 40 mg per day. Previously, the citalopram drug label stated that certain patients may require a dose of 60 mg per day. The citalopram drug label has been revised to include the new drug dosage and usage recommendations, as well as information about the potential for QT interval prolongation and Torsade de Pointes. See the FDA Drug Safety Communication Data Summary for additional information.

BACKGROUND: Celexa (citalopram hydrobromide) is in a class of antidepressants called selective serotonin reuptake inhibitors (SSRIs).

RECOMMENDATION: Citalopram causes dose-dependent QT interval prolongation. Citalopram should no longer be prescribed at doses greater than 40 mg per day. Citalopram should not be used in patients with congenital long QT syndrome. Patients with congestive heart failure, bradyarrhythmias, or predisposition to hypokalemia or hypomagnesemia because of concomitant illness or drugs, are at higher risk of developing Torsade de Pointes. See the FDA Drug Safety Communication for additional recommendations for healthcare professionals and patients.

Employee Benefits Division Prescription Drug Program
HMG Co-A Reductase Inhibitor (Statin) Evaluation
July 2011

1. Overview of Statin Reference Pricing Program

The table below summarizes the comparative potencies of the currently-available statin agents with respect to lowering of LDL-cholesterol.

Atorva (Lipitor)	Fluva (Lescol)	Pitava (Livalo)	Lova (Mevacor)	Prava (Pravachol)	Rosuva (Crestor)	Vytorin*	Simva	%↓ LDL-C
-----	40 mg	1 mg	20 mg	20 mg	-----	-----	10 mg	30%
10 mg	80 mg	2 mg	40 or 80 mg	40 mg	-----	-----	20 mg	38%
20 mg	-----	4 mg	80 mg	80 mg	5 mg	10/10 mg	40 mg	41%
40 mg	-----		-----	-----	10 mg	10/20 mg	80 mg	47%
80 mg	-----		-----	-----	20 mg	10/40 mg	-----	55%
	-----		-----	-----	40 mg	10/80 mg	-----	63%

Agents in the grey area (below 80mg simvastatin), with the exception of Vytorin, require prior authorization. These entities include Lipitor 80mg, Crestor 20mg and 40mg and are limited for individuals who require >50% reduction in LDL. All other agents are subject to reference pricing based on the price of the reference drug, simvastatin (shaded in yellow).

2. Summary of June 8, 2011 FDA Recommendations pertaining to simvastatin usage

a. Simvastatin 80mg should be used only in patients who have been taking this dose for 12 months or more without evidence of muscle injury (myopathy). Simvastatin 80mg should not be started in new patients, including patients already taking lower doses of the drug.

b. When used with simvastatin, the following medications can raise levels of simvastatin in the body and increase the risk of myopathy. Taking no more than the recommended dose of simvastatin with these medications will help keep simvastatin levels in the body at a safer level. A summary of these recommendations is included below and in the table on the following page.

   i. Contraindicated in combination with simvastatin: Gemfibrozil

   ii. Do not exceed 10mg simvastatin with: Amiodarone, Verapamil, or Diltiazem

iii. Do not exceed 20mg simvastatin with: Amlodipine, ranolazine

The table below provides a summary of the FDA's recommendation in greater detail.

Previous simvastatin label	New simvastatin label
Avoid simvastatin with: Itraconazole Ketoconazole Erythromycin Clarithromycin Telithromycin HIV protease inhibitors Nefazodone	Contraindicated with simvastatin: Itraconazole Ketoconazole Posaconazole (New) Erythromycin Clarithromycin Telithromycin HIV protease inhibitors Nefazodone Gemfibrozil Cyclosporine Danazol
Do not exceed 10 mg simvastatin daily with:	**Do not exceed 10 mg simvastatin daily with:**
Gemfibrozil Cyclosporine Danazol	Amiodarone Verapamil Diltiazem (Note: These drugs are contraindicated with Simcor as Simcor is only available with 20 mg or 40 mg of simvastatin.)
Do not exceed 20 mg simvastatin daily with:	**Do not exceed 20 mg simvastatin daily with:**
Amiodarone Verapamil	Amlodipine (New) Ranolazine (New)
Do not exceed 40 mg simvastatin daily with: Diltiazem	
Avoid large quantities of grapefruit juice (>1 quart daily)	Avoid large quantities of grapefruit juice (>1 quart daily

3. EBD Member Impact related to the FDA's recommendation

The table below summarizes the FDA's individual recommendations related to safe simvastatin usage along with EBD's members who could potentially be affected. The group in RED correspond patients using simvastatin 80mg for less than 12 months. The group in BLUE represents concomitant use of simvastatin and gemfibrozil. The group in YELLOW represents patients exceeding 10mg of simvastatin concomitantly with the specific drug. The group in ORANGE represents patients who are exceeding 20mg of simvastatin concomitantly with amlodipine.

FDA Recommendation	Patient Group(s)	Number of EBD utilizing members	% of Total
Simvastatin 80mg utilizing members for less than 12 months		814	7.1%
Concomitant use of simvastatin and gemfibrozil		336	2.9%
Simvastatin 20mg with amiodarone		140	1.2%
Simvastatin 20mg with verapamil		449	3.9%
Simvastatin 20mg with diltiazem		676	5.9%
Simvastatin 40mg with amlodipine		1,725	15.2%
Totals		**4,140**	**36.4**
Total Simvastatin Utilizers		11,385	

The table below cross-references the components of the FDA's recommendations with corresponding statin potency comparisons to identify potential product impact. The colors in the table below correspond to the patient groups identified above.

Atorva (Lipitor)	Fluva (Lescol)	Pitava (Livalo)	Lova (Mevacor)	Prava (Pravachol)	Rosuva (Crestor)	Vytorin*	Simva	%↓ LDL-C
-----	40 mg	1 mg	20 mg	20 mg	-----	-----	10 mg	30%
10 mg	80 mg	2 mg	40 or 80 mg	40 mg	-----	-----	20 mg	38%
20 mg	-----	4 mg	80 mg	80 mg	5 mg	10/10 mg	40 mg	41%
40 mg					10 mg	10/20 mg	80 mg	47%
80 mg	-----		-----	-----	20 mg	10/40 mg	-----	55%
	-----		-----	-----	40 mg	10/80 mg	-----	63%

4. Projected Economic Impact to EBD if Reference Pricing was suspended.

Based on the previous 4 months' of data (January 1, 2011 – April 30, 2011), EBD plan spend for the statin class amounted to $569,211. The Plan Paid amount represents the total prescription cost within the statin category less the contribution of plan beneficiaries. During this period, the

Average Member Paid amount per prescription was $17.64 and the average Plan Paid amount was $12.09. Additionally, simvastatin accounted for 64.1% of the plan's entire statin usage. The plan's Statin Utilization Summary is included in this report.

Applying the plan's traditional 3-tier co-payment model ($10.00 – generics, $30.00 – preferred brands, and $60.00 – non-preferred brands) to the statin class would yield a Plan Paid amount of $792,458. This assumes no shifts in market share among the statin products, although such an assumption is highly unlikely. Based on the current utilization, the savings realized by the plan as a result of reference pricing within this class is estimated at **$670,000** annually.

While it is not possible to predict the future market share shifts as a result of the FDA's new recommendations, modeling is provided here to gauge the impact of changing prescribing patterns. The table on **page 5** models projected market share shifts if prescribing patterns changed by varying degrees (30%, 50%, 70%, or 90%). The difference in Plan Paid/Rx between simvastatin and the weighted average of the Plan Paid/Rx for Crestor/Lipitor is multiplied by the percentage of prescriptions projected for conversion.

5. EBD's Statin Market Share (May 2011 vs. June 2011)

The table below provides a summary of market share (% of Rxs) for each of the statin products within EBD's utilization. As the recommendation from the FDA was released in early June, only slight movement in market share can be detected. Additionally, as of the first week of July 2011, the EBRx Call Center has not experienced significant call volume as a result of the issued recommendations.

	Market Share (% of Rxs)	
Product	**May 2011**	**June 2011**
Simvastatin	64.5%	63.8%
Crestor	4.9%	5.0%
Lipitor	4.8%	4.9%
Pravastatin	20.8%	20.9%
Lovastatin	5.0%	5.4%
Total	**100%**	**100%**

EBD Prescription Drug Program

Projected Market Share Shifts as a Result of FDA Recommendations on Simvastatin

June 2011

									Conversion Percentage			
abel Name	# of Mbrs	# of Rxs	Rxs/Utilizer	# of Affected Mbrs	# of Affected Rxs	Plan Pd/Rx Simva	Crestor	Lipitor	30%	50%	70%	90%
mvastatin)mg	4,012	10,281	2.56	1,265	3,242	$8.89		10mg/$84.31	$73,345	$122,242	$171,139	$220,036
mvastatin)mg	5,284	13,659	2.58	1,725	4,459	$5.79	5mg/$105.21	20mg/$130.24	$149,437	$249,062	$348,687	$448,311
mvastatin)mg	594	1,540	2.59									
mvastatin ng	19	42	2.21									
otals	**11,723**	**30,197**	**2.58**	**3,804**	**9,799**				**$292,445**	**$487,408**	**$682,371**	**$877,335**