



Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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**TO:** Maine Drug Utilization Review Board

**DATE:** October 15, 2015

**RE:** Maine DUR Board **Meeting** minutes from October 13, 2015

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD	X		
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mark Braun, M.D., FACP, Internist/Geriatician	X		
Mike Antonello, MD	X		
Mike Ouellette, R.Ph., GHS	X		
Jeffrey S. Barkin MD, DFAPA	X		
<b>Non –Voting</b>			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Roger Bondeson, Director of Operations, OMS			X

**Guests of the Board:** Ed Bosshart, PharmD, Kristine Morse, Carla Quinlivan

**CALL TO ORDER: 6PM**

**PUBLIC COMMENTS**

**Margaret Fisher** from Novo Nordisk presented Norditropin® FlexPro pen device. Norditropin® FlexPro delivers growth hormone somatropin. Many unique attributes make the Norditropin® FlexPro patient friendly to help improve medication adherence which could improve overall outcomes. Novo Nordisk markets the only growth hormone that uses histidine as a buffer instead of citrate salts or phosphates. Histidine is not associated with stinging or burning at injection site. The FlexPro pen offers patients with a premixed, prefilled multidose solution in a disposable pen. Benefits of the FlexPro pen include up to a 8mg per pen, multiple pen sizes to reduce waste, ease of use, and a room temperature stability formulation. Norditropin® FlexPro can be kept outside of the refrigerator (77° F) for up to 3 weeks following the first injection.

**John Howard** from Mylan presented EpiPen® Auto-Injectors. EpiPen® is indicated in the emergency treatment of allergic reactions including anaphylaxis. It is intended for infrequent use by patients and

caregivers in potentially life threatening situations. Epinephrine is first line treatment for anaphylaxis and is dosed based on weight; EpiPen® Jr. is indicated for those patients who weight between 15 and 30 kg. Failure to get epinephrine to patients who are experiencing anaphylaxis increases risk of serious side effects such as unconsciousness or death. EpiPen® packs include a training pen; patients and family members should practice to make the use of the auto-inject comfortable.

**Patricia Trefunon** from BDSI presented Bunavail®. Bunavail® buccal film is indicated for the maintenance treatment of opioid dependence. It contains buprenorphine/naloxone combination and is first and only buccal film product in its class. Unlike like other products available it contains an adhesive that allows the medication to stick on the inside of the cheek. Bunavail® has increased bioavailability compared to Suboxone®. This would allow for patients to be managed on a lower prescribed dose of buprenorphine while still being adequately managed for Opioid Addiction. Bunavail® contains both chemical and physical barriers to deter abuse.

**Shaffe Bacchus** from Janssen discussed the strengthening of preexisting warnings and adverse events for multiple medications; specifically, there has been increased warning regarding fall risk in elder adults and for severe hyperkalemia for patients taking ACE-Inhibitors and potassium sparing diuretics. Invokona® is a SGLT2 inhibitor used for treatment of diabetes. It has the ability to reduce the A1C by 1%; however, there is a greater reduction in patients who had a higher initial A1C of greater than 10. Data showed that after 6 months of use, there was a trend of decreased insulin units per day. Invokona® may be an attractive choice for those patients who continue to have elevated A1C in despite of other interventions, including insulin. Xarelto® continues to show efficacy and safety in diverse populations in both clinical and real world data. A retrospective analysis of hospital admissions showed a lower risk of re-admission in patients with VTE. Xarelto® has also showed a decrease risk of major bleed in patients with VTE and Nonvalvular A. Fib over warfarin. Prezobix® (darunavir/cobicistat) is a medication for the treatment of HIV. It's mechanism of action is through inhibition of CYP450. It is highly selective for 3A and has a lower potential for drug / drug interactions than ritonavir. Stelara® is a human monoclonal antibody that has been approved for moderate to severe plaque psoriasis. It is first in the class of 1L12/23 inhibitor. There is data from multiple studies showing safety and efficacy as well as superiority to Enbrel®. Simponi® is a fully humanized TNF blocker for the treatment of moderate to severe RA and psoriatic arthritis. It is available as both a 50 and 100 mg once-monthly self-injectable treatment.

**Francis Lobo** from Sunovion presented Latuda®. Latuda® is an atypical antipsychotic which is approved for bipolar depression and schizophrenia. Latuda® can be used either as a monotherapy to treat bipolar I disorder or in conjunction with lithium or valproic acid. Unlike other antipsychotics, Latuda® did not increase risk of cardiovascular or metabolic disease and has not been shown to cause QT prolongation. A 12 month head to head trial of Latuda® and Quetiapine XR in patients with schizophrenia showed favorable data for Latuda®. Latuda® was associated with decreased risk of relapse and lower rates of hospitalizations. The data presented could be used to suggest that Latuda® may be a cost effective treatment option.

**Lance Nicholls** from Pfizer presented Embeda® and Genotropin®. Embeda® (morphine/naltrexone) is medication use to treat chronic pain. It was designed to deter abuse and should be preserved for patients that require around the clock dosing to control pain. The product is not for break through pain and is designed as an extended release formulation. Embeda® is being presented as an option only for patients in which other options have failed or have been contraindicated. Genotropin® (somatropin) is a human growth hormone which currently has 6 approved indications – 5 in children and 1 in adults.

Genotropin Miniquick® is the only preservative free, single dose product that requires no refrigeration prior to reconstitution and use. Because it is preservative free it is a good choice for neonates.

**Tammy Curtis** from BMS presented Eliquis®. Eliquis® is approved for the treatment and prevention of DVT/PE and for preventing stroke in non-valvular A. Fib. New data has been collected showing medical cost avoidance in DVT/PE as compared to other novel oral anticoagulants. Also, patients who were treated with Eliquis® for nonvalvular A. Fib had a reduced risk of stroke and major bleeding events.

**Lisa Cambridge** from Pari presented Kitabis Pak®. Kitabis Pak® is a co-packaging of tobramycin inhalation solution and LC PLUS reusable nebulizer. It is indicated for the management of cystic fibrosis in patients > 6 years of age with *P. aeruginosa*. Each dose of tobramycin inhalation solution needs to be used the LC PLUS nebulizer to aerosolize tobramycin; this would ensure similar bioavailability and optimal treatment. Kitabis Pak® is the only nebulizer preparation that includes the nebulizer and cleaning system as part of the packaging. Providing the LC PLUS nebulizer part of the packaging would help to eliminate a barrier to care for patients who previously had difficulty obtaining the nebulizer.

**Laura Bartgls** from Otuska presented Rexulti®. Rexulti® is an atypical antipsychotic indicated as an adjunctive therapy to antidepressants in adults with major depressive disorder. It is also indicated for the treatment of schizophrenia. The mechanism of action is unknown but is thought to work through partial agonist/antagonist activity with serotonin and dopamine receptors. The most common and notable side effect in both MDD and schizophrenia was weight gain.

**Uri Dreckshalge** from Genzyme presented Aubagio®. Aubagio® is a pyrimidine synthesis inhibitor used to treat relapsing remitting multiple sclerosis (RRMS). There have been four clinical studies that compared safety and efficacy of Aubagio® to placebo. There were decrease relapse rates in the treatment group; Aubagio® also delayed time to disability and delayed progression. In patients with clinically isolated syndrome, Aubagio® delayed the progression to clinical MS as compared to placebo. A long term safety and tolerability profile is now available due to the 7 and 12 year follow-up from these studies; side effects and risk of infection occurred at similar rates in both the treatment and control arm.

**Tom Algozzine** from Novartis presented Cosenty®. Cosenty® is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. It is the first in class fully humanized monoclonal antibody for IL17a. In all trials, the endpoints were the proportion of subjects who achieved a reduction in Psoriasis Area Severity Index (PASI) score of at least 75% (PASI 75) from baseline to Week 12 and treatment success (clear or almost clear) on the Investigator's Global Assessment modified 2011 (IGA). Other evaluated outcomes included the proportion of subjects who achieved a reduction in PASI score of at least 90% (PASI 90) from baseline at Week 12, maintenance of efficacy to Week 52, and improvements in itching, pain and scaling at Week 12 based on the Psoriasis Symptom Diary. Most common adverse effects included upper respiratory tract infections. Cosenty® has shown early and sustained skin clearance over 52 weeks with a mild side effect profile.

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#### DUR MINUTES

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The September 2015 minutes were approved.

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#### PSYCH WORK GROUP UPDATE

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No update at this time

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### MAINECARE UPDATE

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Jan Yorks-Wright stated that due to new legislation (LD 91) passed in the State of Maine allows Dental Hygienists to prescribe prescriptions for fluoride dentifrice and antibacterial rinses. This includes anti-cavity toothpastes or topical gels with 1.1% or less sodium fluoride and oral rinses with 0.05%, 0.2%, 0.44% or 0.5% sodium fluoride and chlorhexidine gluconate oral rinse. GHS sent out a notification to all pharmacy providers on Oct 13, 2015.

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### NEW BUSINESS

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#### NEW DRUG REVIEWS

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Praluent® the common name is alirocumab in the PDL category Familial Hypercholesterolemia. Praluent® is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL cholesterol. The effect of Praluent® on cardiovascular morbidity and mortality has not been determined.

**Recommendation:** The recommendation is for Praluent® to be non-preferred. Prior authorization (PA) criteria and PA form will be drafted and presented at the November meeting

**Board Decision:** No action required

Repatha® the common name is evolocumab in the PDL category Familial Hypercholesterolemia. Repatha® is indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD) who require additional lowering of low density lipoprotein cholesterol (LDL-C) AND as adjunct to diet and other LDL-lowering therapies (e.g. statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C. The effects of Repatha® on cardiovascular morbidity and mortality have not been determined.

**Recommendation:** The recommendation is for Repatha® to be non-preferred. Prior authorization (PA) criteria and PA form will be drafted and presented at the November meeting

**Board Decision:** No action required

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#### ANNUAL PDL REVIEW

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Category	Drug Name	PDL Status	VOTE	Comments
ADHD AGENTS	ADDERALL XR	NP	All in favor	Offer valid if Adderall XR is listed in non preferred position but preferred over its generic
	CONCERTA	NP		
	AG CONCERTA	P		
	DAYTRANA DIS	P		

	FOCALIN TAB FOCALIN XR CAP GUANFACINE ER INTUNIV KAPVAY PROCENTRA QUILLIVANT XR SUS STRATTERA CAP VYVANSE CAP	NP P P NP P NP NP NP NP P		equivalents and is non preferred to Vyvanse
ALLERGEN	GRASTEK SUB	NP	All in favor	
IMMUNOTHERAPY	RAGWITEK SUB	NP		
ANTIBIOTICS, INHALED	BETHKIS KITABIS PAK TOBI PODHALER	NP P NP	All in favor	
ANALGESIC, NSAIDS	FLECTOR PATCH TIVORBEX	NP NP	All in favor	
ANALGESICS,OPIOID	BUTRANS DIS EMBEDA IBUDONE TAB HYSINGLA ER NUCYNTA TAB NUCYNTA ER TAB OXYCONTIN TAB ZOHYDRO ER	P P NP NP NP NP NP NP	All in favor	
ANALGESICS,OPIOID ABUSE	BUNAVAIL SUBOXONE SUB VIVITROL INJ ZUSOLV SUB	NP P NP NP	All in favor	The Suboxone Film will not be disadvantaged to any brand or generic partial opioid agonist/antagonists for the treatment of opioid dependence
ANDROGENS/ANABOLICS	ANDROGEL GEL ANDROGEL PUMP	P P	All in favor	
ANTIANGINAL AGENTS	RANEXA TAB	P	All in favor	
ANTICOAGULANTS	ELIQUIS TAB ENOXAPARIN SODIUM VIAL ENOXAPARIN SODIUM SYRINGE LOVENOX INJ PRADAXA CAP SAVAYSA XARELTO TAB	P P P NP P NP P	All in favor	Lovenox-No step edit allowed
ANTICONVULSANTS	DIASTAT GEL FYCOMPA TAB LYRICA CAP QUDEXY XR VIMPAT	P P NP NP P	All in favor	Vimpat-Auto-PA per labels indications
ANTIDEMENTIA AGENTS	GALANTAMINE HBR TAB GALANTAMINE HBR CAP24H RIVASTIGMINE CAP EXELON DIS EXELON CAP NAMENDA XR CAP	P P P NP P P	All in favor	
ANTIDEPRESSANTS	BRINTELLIX TAB FETZIMA CAP PRISTIQ TAB VIIBRYD KIT VIIBRYD TAB	NP NP NP NP NP	All in favor	
ANTIDIABETICS-INSULIN	HUMALOG MIX 50/50 VIAL	P	All in favor	

	HUMALOG MIX 50/50 KIWK	NP		
	HUMALOG MIX 75/25 KWIK	NP		
	HUMULIN N KWIK PEN	NP		
	HUMULIN N PEN	NP		
	HUMULIN 70/30 KWIK PEN	NP		
	HUMULIN 70/30 PEN	NP		
	LANTUS VIAL	P		
	LANTUS SOLOSTAR PEN	NP		
ANTIDIABETIC- NON-INSULIN	BYDUREON INJ	P	All in favor	Listed on PDL as preferred Automated lookback for use of either metformin or a metformin combination agent accepted Any other preferred DPP-IV must have the same or greater step-edit as JANUVIA or JANUMET
	FARXIGA TAB	P		
	GLYXAMBI	NP		
	INVOKANA TAB	NP		
	INVOKAMET TAB	NP		
	JANUMET TAB	P		
	JANUMET XR TAB	P		
	JANUVIA TAB	P		
	JARDIANCE	NP		
	JENTADUETO TAB	P		
	TANZEUM INJ	P		
	TRADJENTA TAB	P		
	TRULICITY INJ	NP		
	VICTOZA INJ	NP		
	XIGDUO XR	NP		
ANTIFUNGALS	CICLOPIROX SOL	P	All in favor	
	JUBLIA SOL	NP		
	GRIS-PEG TAB	NP		
	GRIFULVIN V TAB	NP		
	GRISEOFULVIN ULTRAMICROSIZE TAB	NP		
	GRISEOFULVIN TAB	NP		
ANTIHEMOPHILIC	WILATE INJ	P	All in favor	
ANTIHYPERLIPIDEMICS	ANTARA CAP	NP	All in favor	
	FENOFIBRATE TAB 120MG	NP		
	NIASPAN	P		
	TRICOR	NP		
	TRILPIX	P		
	ZETIA TAB	P		
ANTIHYPERLIPIDEMICS- CETP INHIBITORS	LIPTRUZET TAB	NP	All in favor	
	VYTORIN TAB	P		
	ZETIA TAB	P		
ANTIHYPERTENSIVE, ARBS	DIOVAN TAB	P	All in favor	
	DIOVAN HCT TAB	NP		
ANTIHYPERTENSIVE, ARBS/CCB COMBO	EXFORGE TAB	P	All in favor	
	EXFORGE HCT TAB	P		
ANTI-INFECTIVE AGENTS, MISC	TINDAMAX TAB	NP	All in favor	
ANTIPSYCHOTICS	ABILIFY MAIN INJ	NP	All in favor	
	INVEGA SUSTENNA	NP		
	INVEGA TRINZA	NP		
	LATUDA TAB	NP		
	SAPHRIS TAB	NP		
	SEROQUEL XR TAB	NP		

ANTIVIRALS, ANTIRETROVIRALS	COMBIVIR TAB EVOTAZ TAB LAMIVUDINE- ZIDOVUDINE TAB 150- 300MG NORVIR TAB PREZCOBIX	NP NP P P NP	All in favor	
ANTIVIRALS, HEPATITIS AGENTS	DAKLINZA TAB HARVONI TAB RIBAPAK RIBASPHERE TAB SOVALDI TAB TECHNIVIE TAB VIEKIRA PAK	NP P <i>Clinical PA</i> NP P P <i>Clinical PA</i> P <i>Clinical PA</i> NP	All in favor	
BETA BLOCKERS – CARDIO SELECTIVE	BYSTOLIC TAB INNOPRAN XL CAP ER 24HR PROPRANOLOL HCL TAB 60MG TOPROL XL TAB ER 24H	NP P P NP	All in favor	
BIOLOGIC IMMUNOMODULATORS	COSENTYX ENBREL INJ HUMIRA CROHN STARTER PK HUMIRA KIT HUMIRA PEN SIMPONI INJ STELARA INJ XELJANZ TAB	P P NP P NP NP NP NP	All in favor	Cosentyx- Preferred position with Step Edit allowing trial and failure of one preferred agent  Humira- Must fail at least 2 preferred products before authorization for non-preferred product.
BRONCHODIL, ANTICHOLINERGICS	INCRUSE ELPT SPIRIVA HANIHALER CAP SPIRIVA RESPINAT TUDORZA	NP P NP NP	All in favor	
BRONCHODIL, STEROID INHALANTS	AEROSPAN FLOVENT HFA FLOVENT DISK PULMICORT	P P P P	All in favor	
BRONCHODIL,PDE4	DALIRESP	NP	All in favor	
BRONCHODIL, SYMPATHOMIMETICS	ADVAIR DISKUS ANORO ELLIPTA BEO ELLIPTA COMBIVANT RESPIMAT DULERA FORADIL CAP STRIVERDI AER SYMBICORT VENTOLIN HFA	NP NP NP NP P P NP P NP	All in favor	
CORTICOSTEROIDS	DEXPAK	P	All in favor	
DERM, SCABICIDES/PEDICULOCIDES	ELIMITE EURAX NATROBA SKLICE	NP NP P NP	All in favor	Natroba- Allows 1 OTC step of permethrin
DIGESTIVE ENZYMES	CREON CAP PERTZYE CAP ULTRESA CAP VIOKACE TAB ZENPEP CAP	P NP NP NP P	All in favor	

ANAPHYLACTIC DEVICES	AUVI-Q EPIPEN EPIPEN JR.	P P P	All in favor	
FIBROMYALGIA AGENTS	SAVELLA TAB	NP	All in favor	
GROWTH HORMONE	GENOTROPIN INJ NORDITROPIN INJ NUTROPIN AQ INJ	P P NP	All in favor	Clinical PA is required to establish diagnosis and medical necessity.
HEMATOPOIETIC, GROWTH FACTOR	ARANESP INJ PROCRIT INJ	NP P <i>Clinical PA</i>	All in favor	
HEMATOLOGIC OXYGEN TRANSPORTERS	KALBITOR VIAL	NP	All in favor	
IBS AGENTS	MOVANTIK LINZESS CAP	NP NP	All in favor	
INFLAMMATORY BOWEL AGENTS	APRISO CAP CANASA SUP COLAZAL CAP DIPENTUM CAP LIALDA TAB PENTASA CAP 250mg PENTASA CAP 500mg	P P NP NP NP P NP	All in favor	
IVIG	GAMMAPLEX INJ	NP	All in favor	No restrictions
MIGRAINE PRODUCTS	RELPAK TAB RIZATRIPTAN ODT	P P	All in favor	Dosing limits apply
MULTIVITAMINS, PRENATAL	CITRANATAL 90 DHA COMBO. PKG CITRANATAL ASSURE COMBO. PKG CITRANATAL B <sub>6</sub> CALM TAB SEQ CITRANATAL DHA COMBO. PKG CITRANATAL 90 DHA CITRANATAL HARMONY CAP CITRANATAL RX TAB	P P P P P P P	All in favor	
MS AGENTS	AUBAGIO TAB BETASERON INJ COPAXONE 40MG INJ EXTAVIA KIT GILENYA CAP PLEGRIDY INJ TECFIDERA CAP	P P NP NP P NP NP	All in favor	Clinical PA is required to establish diagnosis and medical necessity.
NASAL ANTIALLERGY	ASTEPRO DYMISTA PATANASE	NP NP NP	All in favor	
NASAL STEROIDS	OMNARIS NASONEX ZETONNA QNASL	P NP P NP	All in favor	
OP. ADRENERGIC	SIMBRINZA SUS	P	All in favor	
OP. BETA – BLOCKERS	COMBIGAN	P	All in favor	



OPHTHALMIC ANTIALLERGICS	LASTACAPT PATADAY PATANOL PAZEO	NP P P NP	All in favor	
OPHTHALMIC ANTIBIOTIC- ATINFLAM	TOBRADEX OINT TOBRADEX ST DROPS SUSP TOBRADEX DROPS SUSP	P P NP	All in favor	
OPHTHALMIC ANTI- INFECTIVES	BESIVANCE MOXEZA VIGAMOX ZYMAXID	P P P NP	All in favor	
OP. PROSTAGLANDINS	TRAVATAN Z TRAVOPROST	P NP	All in favor	
OP. ANTI-INFLAMMATORIES	ACUVAIL ILEVRO NEVANAC LOTEMAX GEL LOTEMAX OINT PROLENSA	NP NP NP P P NP	All in favor	
OTIC ANTI-INFECTIVES	CIPRODEX CIPRO HC CIPROFLOXACIN DROPERETTE	P P NP	All in favor	
PHOSPHATE BINDERS	CALCIUM ACETATE TAB CALCIUM ACETATE CAP ELIPHOS FOSRENOL CHW PHOSLYRA SOL RENAGEL VELPHORO CHW	P P NP NP P P NP	All in favor	
PH-PHOSPHODIESTERASE INHIBITORS	ADCIRCA TAB	P	All in favor	
VASOPROTECTANTS	ORENITRAM	NP	All in favor	
PLATELET AGGREGATION INHIBITORS	BRILINTA TAB EFFIENT TAB ZONTIVITY	NP NP NP	All in favor	
PULMONARY HYPERTENSION-ERAS	LETAIRIS TAB OPSUMIT TAB TRACLEER TAB	P NP P	All in favor	Requires WHO Group 1 diagnosis of primary PAH (Primary Pulmonary Hypertension) and functional class 2 or 3 symptoms.
SEDATIVE HYPNOTICS	BELSOMRA	NP	All in favor	
SMOKING DETERENTS	CHANTIX PAK CHANTIX TAB	NP P	All in favor	
ULCER DRUGS, H PYLORI	PYLERA	NP	All in favor	
ULCER DRUGS, PPIS	ACIPHEX SPR CAP DEXILANT CAP PRILOSEC OTC	NP NP NP	All in favor	
URINARY ANTISPASMODICS	MYRBETRIQ TAB TOVIAZ TAB VESICARE TAB	NP P P	All in favor	

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ADJOURNMENT: 5PM

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The next meeting will be held on **November 10, 2015** 6:00p.m. – 8:00p.m at the Augusta Armory.