

Janet T. Mills
Governor



Jeanne M. Lambrew, Ph.D.
Commissioner

Maine Department of Health and Human Services
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TO: Maine Drug Utilization Review Board
DATE: 10/16/20
RE: Maine DUR Board **Meeting** minutes from October 13, 2020

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Linda Glass, MD			X
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Mike Antoniello, MD			X
Kathleen Polonchek, MD	X		
Kenneth McCall, PharmD	X		
Erin Ackley, PharmD.	X		
Corinn Martineau, PharmD.	X		
Non –Voting			
Mike Ouellette, R.Ph., Change Healthcare	X		
Jeff Barkin, MD Change Healthcare	X		
Jill Kingsbury, MaineCare Pharmacy Director	X		
Fran Jensen, MaineCare Medical Director	X		

Guests of the Board: Ed Bosshart, PharmD

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CALL TO ORDER: 5:30PM
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Jill Kingsbury called the meeting to order at 2:30 PM.

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PUBLIC COMMENTS
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Paul Amato from Viiv Healthcare: Highlighted the attributes of Dovato
Dr. Brad Perry from Aimmune: Highlighted the attributes of Palforzia
Paul Isikwe from Teva Pharmaceuticals: Highlighted the attributes of Austedo, Ajovy, Granix.
Mark Golick from Neurocrine: Highlighted the attributes of Ingrezza
Tyson Thompson from Pfizer: Highlighted the attributes of tofacitinib and crisaborole, Dermatologic-Atopic dermatitis
Franco Casagrande from Abbvie: Highlighted the attributes of Mavyret
Thomas Algozine from Novartis: Highlighted the attributes of Kesimpta, Xiidra
Niki Patel from Novo Nordisk: Highlighted the attributes of Rybelsus
Nicole Trask from Janssen: Highlighted the attributes of Spravato
Loretta Hothersall, Nurse Practitioner: Highlighted the attributes of Baqsimi
Ryan Gregg from Ironshore: Highlighted the attributes of
Greg Johnson from Neurelis: Highlighted the attributes of Valtoco
Crystal Henderson from Global Blood Therapeutics: Highlighted the attributes of Oxbryta
Gene Muise from Amagen: Highlighted the attributes of Aimovig, Repatha, Otezla
Kendra Davies from Greenwich Biosciences: Highlighted the attributes of Epidiolex
Tammy Martin from Biohaven Medical Affairs: Highlighted the attributes of Nurtec ODT
Afriam Botoros from Bristol Myers Squibb: Highlighted the attributes of Zeposia

Liana Kelly, Nurse Practitioner from Central Maine Endocrinology & Diabetes Center
Ken Smith from Genentech: Highlighted the attributes of Ocrevus
Jane Guo from Otsuka: Highlighted the attributes of Abilify Maintena
Steven Burch Sunovion: Highlighted the attributes of Kynamro
Matt Clark Zogenix: Highlighted the attributes of Fintepla

OLD BUSINESS

DUR MINUTES

The September DUR meeting minutes were accepted.

Board Decision: The Board unanimously approved the above recommendation.

MAINECARE UPDATE

Jill Kingsbury introduced Dr. Fran Jensen as the new MaineCare Medical Director.

NEW BUSINESS

DATA PRESENTATION: RETRO-DUR INITIATIVES FOR 2021

HYDROXYCHLOROQUINE USE PRE AND POST COVID

Purpose: To compare hydroxychloroquine use before and during the COVID-19 pandemic. Was there an increase in off-label utilization for treatment of COVID-19?

- Evaluate dispensing of Hydroxychloroquine 9/1/19-2/29/20 compared with 3/1/20-8/31/20 (6-month interval pre and post COVID-19 State of Emergency Declaration).
- Look at days' supply, frequency of prescribing, and medical diagnoses on file for members receiving prescriptions.

CODEINE USE IN THE PEDIATRIC POPULATION

Purpose: To ensure appropriate edits are in place for codeine to gauge the need for prescriber education on the topic. For many years, codeine was an acceptable option for treating pain in children, which is no longer the case.

- FDA safety alert issued 4/20/17
- Addition of FDA's strongest warning, called a "Contraindication", to the drug labels of codeine alerting that codeine should not be used to treat pain in children younger than 12 years.
- A new "Warning" to the drug labels of codeine to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.

- Evaluate prescribing to see if restrictions or PA requirements are warranted.

USE OF ACUTE MIGRAINE TREATMENTS AFTER CGRP INITIATION

Purpose: To determine whether the use of preventative CGRP inhibitors are having an impact on reducing the frequency of migraines and therefore use of acute migraine treatments. This may reveal information about the efficacy of these preventative agents on our patient population.

- Evaluate use of acute migraine treatments (triptans, ergots, NSAIDs, and/or opiates) prior to and after initiation of preventative CGRP inhibitors (e.g. Aimovig, Ajovy, or Emgality) in Medicaid members.

IMMUNOLOGIC TREATMENTS FOR ASTHMA

Purpose: To evaluate the efficacy and potential pharmaco-economic benefit to DVHA for these medications. Biologics for asthma may reduce the acute exacerbation rate by 50%, but each is indicated for add-on maintenance treatment, so continued use of other controllers is important for efficacy.

- Evaluate compliance with controllers and use of oral corticosteroids while on Cinqair, Dupixent, Fasenra, Nucala.
- Use medical data to determine frequency of ER visits or hospitalizations for asthma exacerbations while on therapy.

HERPES ZOSTER VACCINATION RATES

Purpose: To evaluate vaccination rates and completion of dosing of the Herpes Zoster vaccine to identify areas of need for education and outreach.

- Evaluate patients who received Zostavax but have not received Shingrix.
- Assess how many patients received both doses of Shingrix.

LONG-ACTING INJECTABLE ANTIPSYCHOTICS

Purpose: To look at the overall rate and associated cost of prescriptions filled in the pharmacy benefit and never administered in the provider's office as intended resulting in wasted medication.

Medication is shipped directly from a specialty pharmacy to the providers office for a specific patient. If the patient refuses the medication, or never comes in for administration the result is costly waste. Alternatively, if the provider 'buys and bills' the medication could then be used for another patient. Determine if forcing a buy and bill option is warranted with these types of drugs.

Recommendation: After board discussion the following topics were chosen codeine use in the pediatric population, long-acting injectable antipsychotics, herpes zoster vaccination rates, hydroxychloroquine use pre and post covid. In addition to the board would like to look at HPV vaccination rates.

Board Decision: The Board unanimously approved the above recommendation.

PRESENT 2021 MEETING SCHEDULE

March 09, 2021

June 8, 2021

September 14, 2021

October 12, 2021

December 14, 2021

Board Decision: No action needed at this time. MaineCare will be sending out a poll to board members to poll what time of day will work best for the board.

REVIEW AND VOTE

Category	Drug Name	PDL Status	Comments
ADHD AGENTS	ADHANSIA XR DYANAVEL XR CONCERTA FOCALIN XR CAP PROCENTRA QUILLICHEW ER QUILLIVANT XR SUS VYVANSE CAP VYVANSE CHEW	NP P P P P P P P P	Methylphenidate LA and Methylphenidate CD will also be moved to P.
AHF IX	BENEFIX REBINYN VIAL	P NP	
AHF VIII	NOVOEIGHT VIAL NUWIQ VIAL WILATE XYNTHA XYNTHA SOLOFUSE	P P P P P	

ANALGESICS, OPIOID	APADAZ BENZHYDROCODONE-ACTAMIN TAB	NP NP	
ANALGESICS, OPIOID ABUSE	BUPRENORPHINE/NALOXONE TAB PROBUPHINE IMPLANT KIT SUBLOCADE SUBOXONE SUB VIVITROL INJ ZUBSOLV	P NP NP P P NP	
ANGIOTENSIN MOD- NEPRILYSIN INHIB/ CV HEART FAILURE	ENTRESTO FARXIGA	P P	
ANTIBIOTICS, INHALED FOR CF	BETHKIS KITABIS PAK TOBI PODHALER	NP P NP	
ANTICOAGULANTS	ELIQUIS TAB PRADAXA CAP XARELTO	P P P	
ANTICONVULSANTS	APTIOM BRIVIACT EPIDIOLEX FYCOMPA TAB FYCOMPA SOL NAYZILAM VALTOCO VIMPAT TAB VIMPAT SOL XCOPRI	NP NP P NP NP P P NP NP NP	Vimpat-Auto-PA per labels indications Epidiolex will require a clinical PA
ANTIDEMENTIA AGENTS	EXELON	P	
ANTIDIabetics-INSULIN	FIASP FIASP FLEXTOUCH TRESIBA VIAL TRESIBA FLEXTOUCH NOVOLOG NOVOLOG MIX	NP NP NP NP P P	
ANTIDIABETIC- NON- INSULIN	BYDUREON PEN BYDUREON BCISE FARXIGA GLYXAMBI OZEMPIC INVOKANA	P NP P NP NP P	Bydureon Pen will be discontinued effective March 2021.

	INVOKAMET	P
	RYBELSUS	NP
	SYNJARDY	P
	SYNJARDY XR	NP
	TRIJARDY XR	NP
	TRULICITY	P
	VICTOZA	P
	XULTOPHY 100/3.6	NP
ANTIHYPERTENSIVES		
ANTIHYPERLIPIDEMICS	REPATHA	NP
	REPATHA PUSHTROMEX SYSTEM	NP
	REPATHA SURECLICK	NP
ANTIPSYCHOTICS		
ANTIPSYCHOTICS	LATUDA TAB	P
	VRAYLAR	NP
ANTIPSYCHOTIC, LAI		
ANTIPSYCHOTIC, LAI	ABILITY MAINTENA	P
	ARISTADA	P
	ARISTADA INITIO	P
	INVEGA SUSTENNA	P
	INVEGA TRINZA	P
	PERSERIS	P
	ZYPREXA RELPREVV	NP
ANTIVIRALS, ANTIRETROVIRALS		
ANTIVIRALS, ANTIRETROVIRALS	BIKTARVY TAB	P
	CIMDUO	P
	DELSTRIGO	P
	DESCOVI	P
	DOVATO	NP
	EVOTAZ TAB	NP
	GENVOYA	P
	JULUCA	NP
	NORVIR TAB	P
	NORVIR POWDER	P
	ODEFSEY	P
	PIFELTRO	NP
	PREZCOBIX	P
	SYMFI	P
	SYMFI LO	P
	SYMTUZA	NP
	TRIUMEQ	NP
	TROGARZO	P

ANTIVIRALS, HEPATITIS AGENTS	EPCLUSA HARVONI TAB LEDIPASVIR/SOFOSBUVIR MAVYRET SOFOSBUVIR/VELPATAVIR SOVALDI TAB VOSEVI	P NP NP P NP NP NP	Epclusa and Mavyret will require a clinical PA.
ANTIVIRALS, INFLUENZA AGENTS	XOFLUZA TAB	NP	
BIOLOGIC IMMUNOMODULATORS	COSENTYX ENBREL INJ KEVZARA HUMIRA OLUMIANT TALTZ XELJANZ TAB XELJANZ XR	NP P NP P NP P NP	Xeljanz for RA and UC. Taltz for PSA with step thru Humira.
CV- BETA BLOCKER	HEMANGEOL SOL	P	
DERM, ATOPIC DEMATITIS	EUCRISA ELIDEL CREA	NP P	
DERM, CORTICOSTEROIDS	DERMA-SMOOTH-EFS BODY DERMA-SMOOTH-EFS SCALP	P P	
DERM, LOCAL ANESTHETICS	ZTLIDO	P	
DERM, SCABICIDES/PEDICULOCIDES	NATROBA VANALICE	P NP	
DIGESTIVE ENZYMES	CREON CAP PERTZYE CAP ZENPEP CAP	P NP P	
ENDOMETROSIS/UTERINE FIBROIDS ORAL	ORIAHNN ORILISSA	NP NP	
ESTROGENS	EVAMIST SPRAY	P	

GI- ANTIEMETICS	BONJESTA DICLEGIS	P P	
GI-BOWEL EVACUANT COMBINATIONS	CLENPIQ SOL	NP	
GOUT AGENTS	COLCRYS COLCHICINE CAP MITIGARE	P NP P	
GROWTH HORMONE	GENOTROPIN GENOTROPIN MINIQUICK NORDITROPIN FLEXPRO NUTROPIN AQ NUSPIN 10 NUTROPIN AQ NUSPIN 20 NUTROPIN AQ NUSPIN 5 ZOMACTON VIAL	P NP P NP NP NP NP	
GROWTH HORMONE RELEASING FACTOR	EGRIFTA	NP	
HEMATOPOIETICS-CSF	GRANIX VIAL GRANIX SYRINGE NEUPOGEN VIAL	P NP P	
HEREDITARY ANGIOEDEMA	CINRYZE BERINERT KIT FIRAZYR HAEGARDA RUCONEST VIAL TAKHZYRO TAVALISSE	P P P P NP P NP	
HEMATOPOIETIC MIXTURES	FERRALET 90 INTEGRA F INTEGRA PLUS	NP NP NP	
HEMATAPOIETIC, GROWTH FACTOR	ARANESP	NP	Epogen and Retacrit are preferred.
HYPOGLYCEMIA TREATMENTS	BAQSIMI ONE PACK GVOKE SYRINGE GVOKE HYPOPEN	P NP NP	Baqsimi will require a step through Glucagen.

Medication Class			
IBS AGENTS	MOVANTIK VIBERZI	P NP	Movantik offer permits class step through OTC laxatives
NEUROLOGICS- SMA	ZOLGENSMA 10.1- 10.5	P	Zolgensma will require a clinical PA.
NEUROTOXINS	BOTOX DYSPORT	P P	Botox and Dysport will require a clinical PA
MIGRAINE PRODUCTS CGRP INH	AIMOVIG AJOVY SYRINGE AJOVY AUTOINJECT EMGALITY SYRINGE EMGALITY PEN NURTEC ODT REYVOW UBRELVY	P P P NP NP P NP NP	Aimovig, Ajovy and Nurtec ODT will require a double step through a triptan. Reyvow and Ubrelvy will require and step through Nurtec ODT.
MOVEMENT DISORDER	AUSTEDO TAB INGREZZA	P P	Clinical PA required
MULTIVITAMINS, PRENATAL	All Offers	NP	Reject all offers SMAC in place.
MS AGENTS	AUBAGIO TAB AVONEX KIT BETASERON INJ COPAXONE 20MG GILENYA CAP PLEGRIDY PLEGRIDY STARTER PACK TECFIDERA VUMERTY	P P P P P NP NP NP NP	Clinical PA is required to establish diagnosis and medical necessity.
NARCOLEPSY AGENTS	SUNOSI	NP	
OPIOD WITHDRAWL AGENTS	LUCEMYRA	NP	

OP. ADRENERGIC	RHOPRESSA DROPS ROCKLATAN SIMBRINZA SUS	P P P
OPHTHALMIC ANTIALLERGICS	PAZEO ZERVIATE	P NP
OPHTHALMIC ANTIBIOTIC-ATINFLAM	TOBRADEX DROPS SUSP TOBRADEX ST	P NP
OP. ANTI-INFLAMMATORIES	ILEVRO	P
OPHTHALMIC MISC	XIIDRA	NP
OTIC ANTI-INFECTIVES	CIPRODEX	P
OTIC STEROIDS DERM	DERMOTIC DROPS 0.01%	P
POTASSIUM REMOVING AGENTS	LOKELMA	NP
PITUITARY SUPPRESSANTS, CPP	TRIPTODUR VIAL	NP
PROGESTINS	MAKENA AUTO INJ	P
PLATELET AGGREGATION INHIBITORS	BRILINTA TAB	P
PULMONARY HYPERTENSION-ERAS	OPSUMIT	NP
RESP- ANTICHOLINERGICS	COMBIVANT RESPIMAT SPIRIVA RESPIMAT	P P
RESP- ANTIINFLAMMATORY AGENTS	CINQAIR DUPIXENT PEN INJ FASENRA SYRINGE FASENRA AUTO INJECT NUCALA XOLAIR	P NP P P NP P
RESP- STEROID INHALANTS	QVAR REDIHALER	P

RESP- ADRENERGIC COMBO	ADVAIR DISKUS ADVAIR HFA ANORO ELLIPTA BREO ELLIPTA BEVESPI AEROSPHERE PULMICORT FLEXHALER PULMICORT NEB BUDESONIDE NEB STIOLTO RESIMAT	P P P NP P P P NP P
RESP- BETA AGONIST INHALERS	PROVENTIL HFA STRIVERDI RESPIMAT	NP NP
RESP- PULMONARY FIBROSIS AGENTS	ESBRIET OFEV	NP NP
SICKLE CELL ANEMIA AGENTS	DROXIA SIKLOS	P NP
URINARY ANTISPASMODICS	MYRBETRIQ TAB TOVIAZ TAB	NP P
VAGINAL ANTI-INFECTIVES	CLINDESSE GYNAZOLE-1 NUVESSA GEL SOLOSEC	P NP P NP

Board Decision: The Board unanimously approved the above recommendation. In addition, the board would like a notice to be send out to providers letting them know that Bydureon will be discontinued as of March 2021 and grandfather established Cosentyx users.

FDA SAFETY ALERTS

Clozaril, Fazaclo ODT, Versacloz (clozapine): Drug Safety Communication - FDA Strengthens Warning That Untreated Constipation Can Lead to Serious Bowel Problems
https://www.fda.gov/safety/medical-product-safety-information/clozaril-fazaclo-odt-versacloz-clozapine-drug-safety-communication-fda-strengthens-warning-untreated?utm_campaign=FDA%20MedWatch%3AClozaril%2C%20Fazaclo%20ODT%2C%20Versacloz%20%28clozapine%29-%20Drug%20Safety%20Communication&utm_medium=email&utm_source=Eloqua

FDA Approves Three Drugs for Nonprescription Use Through Rx-to-OTC Switch Process
<https://www.fda.gov/news-events/press-announcements/fda-approves-three-drugs-nonprescription-use-through-rx-otc-switch->

[process?utm_campaign=022420_PR_FDA%20Approves%20Three%20Drugs%20for%20Nonprescription%20Use&utm_medium=email&utm_source=Eloqua](https://www.fda.gov/safety/medical-product-safety-information/singulair-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-restricting-use?utm_campaign=FDA%20MedWatch%20Singulair%20%28montelukast%29%3A%20Strengthened%20Boxed%20Warning&utm_medium=email&utm_source=Eloqua)

Singulair (montelukast) and All Montelukast Generics: Strengthened Boxed Warning - Due to Restricting Use for Allergic Rhinitis

https://www.fda.gov/safety/medical-product-safety-information/singulair-montelukast-and-all-montelukast-generics-strengthened-boxed-warning-due-restricting-use?utm_campaign=FDA%20MedWatch%20Singulair%20%28montelukast%29%3A%20Strengthened%20Boxed%20Warning&utm_medium=email&utm_source=Eloqua

FDA Approves Label Changes to SGLT2 Inhibitors Regarding Temporary Discontinuation of Medication Before Scheduled Surgery

<http://s2027422842.t.en25.com/e/es?s=2027422842&e=312214&elqTrackId=376c7bc788024cd5a73d955f2e3dcdbc&elq=d700e2d071b343878fdbe02a4ebbf19&elqaid=11643&elqat=1>

FDA alerts patients and health care professionals of EpiPen (epinephrine) and EpiPen Jr (epinephrine) auto-injector errors related to device malfunctions and user administration

https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-patients-and-health-care-professionals-epipen-auto-injector-errors-related-device?utm_campaign=FDA%20alerts%20patients%20and%20health%20care%20professionals%20of%20EpiPen%20auto-injector%20errors&utm_medium=email&utm_source=Eloqua

FDA Requests Removal of All Ranitidine Products (Zantac) from the Market

https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market?utm_campaign=040120_PR_FDA%20Requests%20Removal%20of%20Ranitidine%20Products%20%28Zantac%29%20from%20the%20Market&utm_medium=email&utm_source=Eloqua

FDA Approves Label Changes for Montelukast (Singulair) Regarding the Potential Risk of Serious Mental Health Side Effects

<http://s2027422842.t.en25.com/e/es?s=2027422842&e=328327&elqTrackId=376c7bc788024cd5a73d955f2e3dcdbc&elq=bb3dd6d269764f269f7b497fd4704f1b&elqaid=12344&elqat=1>

FDA cautions against use of hydroxychloroquine or chloroquine for COVID-19 outside of the hospital setting or a clinical trial due to risk of heart rhythm problems

<http://s2027422842.t.en25.com/e/es?s=2027422842&e=326625&elqTrackId=376c7bc788024cd5a73d955f2e3dcdbc&elq=ac707a3bff784a399dcd62181c0aa736&elqaid=12264&elqat=1>

Board Decision: No formal action required

ADJOURNMENT: 8:30PM

The next meeting will be held on **December 8, 2020** 5:30pm –8:30pm at the Augusta Armory.