MaineCare Services
An Office of the Department of Health and Human Services
Paul R. LePage, Governor Mary C. Mayhew, Commissioner

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TO: Maine Drug Utilization Review Board
DATE: October 14, 2013
RE: Maine DUR Board **Meeting** minutes from October 8, 2013

ATTENDANCE	PRESENT	ABSENT	EXCUSED
Robert Weiss, M.D., Cardiologist, Chair	X		
Amy Enos, Pharm. D. Waltz LTC Pharmacy			X
Lisa Wendler, Pharm. D., Clinical Pharmacy Specialist, Maine Medical CTR	X		
Lindsey Tweed, M.D., Psychiatrist			X
Mark Braun, M.D., FACP, Internist/Geriatrician	X		
Mike Ouellette, R.Ph., GHS	X		
Rebecca M. Thibodeau, R.Ph., Staff Pharmacist Community Pharmacy – Pittsfield- Co-Chair	X		
Lourie Paul, NP	X		
Linda Glass, M.D.	X		
Non –Voting			
Jan Yorks-Wright, Pharmacy Supervisor, OMS	X		
Kevin Flanigan, M.D., Internist, Medical Director, OMS			X
Roger Bondeson, Director of Operations, OMS			X

Guests of the Board: Jeffrey S. Barkin, MD, Steve Liles, PharmD

CALL TO ORDER: 1PM

PUBLIC COMMENTS

Melanie Brenner a pharmacist with Sunovion wanted to provide the board with a couple updated regarding Latuda which is an atypical antipsychotic that was initially indicated for schizophrenia in adults patients… we recently received indications for the treatment of bipolar and depression as mono and adjunctive therapy. Latuda is the only antipsychotic approved for adjunctive therapy for these indications. The dosing range for bipolar / depression is 20 -120 mg and we've also come out with a 60mg tablet…. There are five different tablets of latuda available. It's a once a day medication as a reminder and no titration is necessary so you can start on an effective dose on day 1. During trials

looking at metabolic parameters i.e. glucose, lipids, weight there has been minimal effects. The once change in important safety information in regards to the new indications… we still have the black box warning as do all atypicals for use in elderly patients with dementia. And because we now have the indication to help with depression for patients with bipolar disorder we do carry the increased risk of suicide risk for adolescents and young adults as well. So just an overview as we wanted to make sure that you were aware of the new indications and it's use as mono and adjunctive therapy. The only atypical approved in this manner.

Dr Weiss: Do you have any papers that compares it to something else directly?

Drug rep: We have two studies that used other atypical as active controls but not for head-to-head comparability but for assay sensitivity and we used seroquel XR in one and olanzapine in another. One other point that I wanted to mention is that Latuda is a pregnancy category B… this is the only atypical other than clozapine that carries this distinction.

Dr. Barkin: First congratulations on the bipolar/depression indications, second clinical trials for a uni-polar depression as an augmentation agent, where do they stand?

Drug rep: Well, we haven't really faced trials for advanced therapy in major depressive disorder and not used as an agent for uni-polar depression specifically. So just for major depressive disorder as adjunctive therapy we really haven't faced trials.

Dr. Barkin: So that's an area of active development…. Because that can impact market share a lot.

Amy Dalsania from UCB pharmaceuticals and here on behalf of the product cimzia today. As you know Cimzia is a tumor necrosis factor indicated for reducing the signs and symptoms of Crohns disease. Also for the treatment for adults with moderate-severe rheumatoid arthritis and most recently as an update to what you should have received via email is the indication approved for treatment of adults with active psoriatic arthritis. So recently these updates have been made to the prescribing information which includes our indication section which was the psoriatic arthritis indication. Cimzia has demonstrated significant efficacy in adult psoriatic patients. The ACR 20, 50, and 70 responses were higher in patients treated with cimzia verse the placebo group. Cimzia treated patients showed an improvement in physical function as assessed by the HACK-DI at week 12 as well as 24 compared to placebo. There were also clinical meaningful improvements in enthesitis. Also improvements in skin were also scene. Safety and efficacy of cimzia in patients with plaque psoriasis yet. Patients who were treated with cimzia 200mg every other week demonstrated greater reductions in radiographic reductions as compared to placebo. Patients treated with 400mg did not demonstrate greater reductions. In regards to HepB there was an update to the safety section regarding virus reactivation… it is recommended that patients are screened for active HPV infection prior to beginning cimzia. Post marketing updates… no difference was scene between cimzia and placebo when certain vaccines were administered in regards to antibody production. In an independent study conducted in 10 women with Crohns disease cimzia concentrations were measured in cord blood and maternal blood… plasma concentrations were lower by at least 75% in infant verse mother…. Suggests low placenta transfer… however cimzia is still considered a pregnancy category B. In February of 2013 UCB announced a new FDA filing to extend it's marketing authority in adults patients with active axial-spondyloarthritis. This is now under review with the FDA at this point…. Fatal infections have been reported. We would like you to add cimzia to the Maine PDL.

Ali Toumadi from Gilead and would like to discuss two drugs from two different classes… one is inhaled aztreonam for cystic fibrosis followed by letairis for patients with pulmonary arterial hypertension. For patients with cystic fibrosis as far as inhaled antibiotics goes there is really two classes of drugs available… one is the beta-lactam class includes aztreonam and the other aminoglycoside class includes tobramycin. In an active comparative trial axtreonam was shown to be superior to tobramycin. In addiction as of this past summer aztreonam was added as an option to the guidelines to patients with CF for the use against chronic pseudomonas infections. With those comments in mind we respectively request that aztreonam is added to the pdl as an inhaled antibiotic. Transitioning to letairis… the only drug that does not have a black box warning for liver toxicity in the ERA class. It also does not have a REMS program mandating liver function monitoring. Also an important update within the last couple of months to the packet update… Men do not require to be in a REMS program only women of child bearing age because it is pregnancy category X. We request that Maine continue to allow letairis to be accessible to those in the state.

Julia Foster from Merck would like to speak on behalf of zetia. I respectfully ask the committee to continue to have access on the PDL for zetia. It works by impairing the absorption of cholesterol in the brush border in the small intestine and has a complimentary action with the statins. It's indicated for mono-therapy as well as addition to fenofibrate and bile acid sequesterants and statins. As mono-therapy we see an 18-20% reduction in LDL and a reduction in total cholesterol. LDL lowering is the cornerstone of therapy. We need a variety of choices for patients as opposed to less choices. According to data many people are not reaching LDL goals… 23% are not at goal in this country. These goals are not being attained, Maine trends show that this percentage is even greater. Maine CDC shows that this is an issue for Mainers and lists out a strategic plan that stretches out to 2020. So again mono therapy and combo zetia is recommended… we ask that zetia remain on the pdl to help patients get to LDL goals.

Justin Bakhshai from Novo Nortis speaking today in two products Victoza and Levemir… Beginning with Victoza it is a once daily laraglutide… GLP-1 receptor agonist… currently indicted for DM2 in adults. Contraindicated in patients with rare forms of thyroid cancer… What I'd like to do today is talk about some of the head-to-head outcomes research for this drug… how it's performing in the real world. A meta-analysis of 7 26-week trials of victoza verses competitors i.e. sitaglipton, sulfonylureas, etc. When looking at a composite end-point of how many patients reach A1C <7% and also did not have hypoglycemia or weight gain … 40% of patients on victoza are reaching this end-point. 25% on exenitide are reaching this end-point. To compare, sulfonylureas only 6-8% are reaching this end-point same with thiazolidinediones. The second thing is adherence…. The question is well if a drug is efficacious that's fine but what if the patients are taking it. This is a head-to-head trial of victoza verses byetta.. what we see is that when we look at medication possession ratio (retrospective manner) that it's actually 11% higher adherence with victoza verses byetta…. The third is what were calling cost control… we take the WAC divided by a composite end-point… because of the efficacy difference I spoke about earlier between victoza and exenatide we're seeing that victoza has a lower cost to get a patient to goal.

Dr Weiss: How does this drug relate to byetta.

Drug rep: I mentioned adherence earlier so we're seeing significantly better adherence with victoza verses byetta. Of course victoza is once verses twice daily with byetta. When we look head-to-head at randomized trials we see significantly better A1C reduction with victoza and a greater number of patients on victoza are reaching their A1C goals. This is a 26 week trial and we're now looking at the trial extension analysis.

Mr. Ouellette: What sort of reduction in A1C are we looking at in terms of percentage?

Drug Rep: In this trial a reduction of 1.1% was scene with victoza verses 0.9% with byetta. When we look at actual patients actually reaching their goals there's a much greater difference. There is another trial looking at victoza verses exenatide where real-world claims data across the country were examined. What we saw here was that 2/3 were reaching their A1C goals with victoza while byetta the numbers were more like 50-52%. So now onto levemir…. The major difference here is that it's the onllt basal insulin analog with a pregnancy CAT of B… and now data suggests it can be used in pediatric patients with DM1. So Lantus verse levemir…. Across trials we're seeing similar utilization across the populations 30-35 units daily. We would like to ask that both products continue to remain on the PDL.

Panel question: Can you comment on the difference of victoza verses byetta on pancreatic toxicity?

Drug Rep: I don't want to talk about byetta but I can talk in terms of the GLP1 class generally in terms of pancreatitis…. This is a difficult diagnosis because there are a lot of subjective elements involved i.e. pain. What we've scene is that there is potentially a correlation between the utilization… in this case they talked about byetta and januvia right? But there looking at the entire class…. The decision was made based on the data available there is no causality from the medications… there is of course the potential to make a correlation but given the data i.e. post-marketing surveillance that is subject to bias no patient should stop therapy at this time and should not affect clinician decisions at this time.

Rocco Zullo from GSK , would like to talk about Breo Ellipta, a new long acting corticosteroid/ beta agonist combination inhaler containing fluticasone furoate/vilanterol. Currently it is indicated for long-term, once daily, maintenance of airway obstruction in patients with COPD and chronic bronchitis… Currently 4 pivotal clinical trials… Two long function trials that looked at multiple doses of the drug compared to placebo and compared to fluticasone furoate to show the contribution of vilanterol. Those studies found Breo Ellipta 125 to have improved outcomes in 0-4 hour FEV1 when compared to placebo and fluticasone furoate. Also there were two 1-year exacerbation studies that looked at different combinations of fluticasone furoate and vilanterol to show the significance of flucticasone furoate in the combination. In those 1 year studies they saw reductions in the primary endpoint of annual rate of severe exacerbations. Most common adverse events were headache, nasal pharyngitis, oral candidiasis, and URI. Other adverse events seen were pneumonia and bone density disorders, known issues with all LABA/ inhaled corticosteroids. Based on this information, we would like you to consider the first once daily ICS/ LABA combination, Breo Ellipta.

Dr. Weiss: Isn't this just Advair with a longer patent? I mean it's a different beta agonist, but it's beta agonist steroid. Why would we think it's better?

Drug Rep: There are several head-to-head studies with Advair, right now just looking at lung function. One showed a statistically significant improvement in lung function, the other two were no statistically significant difference.

Dr. Barkin: Was it superior or non-inferior?

Drug Rep: It was a superiority trial. The one study found an 80 ml difference in FEV1 and in the two that wasn't there was one that was 25 and one was 29 ml. So it was numerically better but not statistically better.

Taner Odom, from BioGen, speaking on behalf of Tecfidera, an oral disease modifying therapy indicated for relapsing forms of MS. Three main points I want to talk to you about, Tedfidera's novel MOA, its benefit profile, and risk profile. Regarding the MOA, it has been show to activate a pathway known as the Nrf2 pathway. A naturally occurring pathway in the body…

Dr. Weiss: It would be better to talk about how it compares to something that's on the formulary, like Copaxone . Because we're not voting on whether this is a good drug, we are voting on how it compares to other drugs in its class.

Drug Rep: There are no head-to-head design trials with Tecfidera vs other trials. We have the CONFIRM trial which Copaxone, is an open label, parallel-arm. In that trial Tecfidera reduced relapse rates 44% and a portion a patient who relapsed by 34%. Copaxone performed to its label and reduced relapse rates by 29% and disability by 7%. Again you can't really compare the two products because it wasn't designed as a head-to-head trial. Can't really speak on the other platform drugs, but you should know the advantages really are the aspect of an oral medication vs injections. Two key AEs were GI and flushing. Fairly common out of 1/3%, but very mild.

Dr. Weiss: Are the side-effect profiles of this lower than the other oral agents for this?

Drug Rep: Again, it's a different profile, so there's no cardiovascular side-effect profile compared to the other, probably most used Gilenya. It doesn't have a REMS program tied around it. Very minimal monitoring, basically just the CBC, compared to the other oral therapy which have a high level of monitoring. Any other questions?

Lance Nichols a medical outcomes specialist from Pfizer, here to talk about several drugs. If I don't address your questions refer to the package insert or you can reach out to me. First I'd like to speak on Eliquis, which was reviewed in March. It is a factor Xa inhibitor indicated to reduce the risk of stroke in patients with NVAF. Recommended dose is 5mg orally BID. Evidence, efficacy and safety were derived from national double-blind studies in patients with NVAF compared with warfarin. Eliquis was superior to warfarin with a 21% risk reduction at the primary endpoint of reducing the risk of stroke and systemic embolism. And also significant lowered the rate of all cause death ($p = 0.046$). Eliquis was also superior to warfarin from the primary safety endpoint, major bleeding, with 31% risk reduction. Most common adverse reaction was bleeding. It was estimated to give a medical cost avoidance of $485 compared to warfarin mainly by reducing the incidence of stroke and a lower risk of bleeding. We request that you put Eliquis on the MaineCare PDL.

Next drug is Quilivant XR, which is indicated for ADHD, and is the first once-daily ER oral suspension approved for this condition. Recommended dose is 20mg daily. It was specifically designed to have the desired features of immediate and extended effect as a liquid methylphenidate formulation that does not need to be refrigerated and has a shelf life of 120 days once it is reconstituted. Important to note that there are many extended release stimulant tablet and capsule formulations that can't be broken, crushed, or swallowed if they are broken apart. Important to note that Quilivant is intended to address the unmet need for oral extended release stimulant that can be taken by patients who prefer liquid dosage form. Adverse reaction is similar to methylphenidate products and does have a boxed warning for abuse and dependence. We request that Quilivant be retained on MaineCare PDL.

The next drug is Chantix. Maine's current smoking rate is 17.3%, overall in the US it is 17.9%. The benefits of quitting smoking are immediate, the recommended dose is 1mg BID. It has demonstrated the likelihood from absence of smoking has been compared at 1 year of treatment compared to placebo. Most common adverse effects are nausea, abnormal dreams, constipation, flatulence, and vomiting. It

does carry a black box warning for neuro-psychotic events. There was a clinical trial done by Pfizer, that showed that patients with schizophrenia, that were stable, in the outpatient setting, benefited from Chantix and was well tolerated and effective. Based off of this information and the fact that tobacco cessation funds are coming back into the state, we request that Chantix come back with preferred status to the MaineCare PDL.

Lyrica, this is the one that is toughest to go thru. It has four neuropathic indications, fibromyalgia, painful diabetic neuropathy, post-herpatic neuralgia … Only approved agent to treat neuropathic pain associated with spinal cord injury. I would like to present some pharmaco-economic data. There was an analysis conducted in states with Medicaid population looking a prior authorization. They found in those states that had restrictions a higher disease specific cost and higher utilization of anticonvulsants, opioids, non-opioids analgesics, other antidepressants, and anxiolytics compared to those states without restrictions. Looking at the cost, the cost was a net higher cost of $270 per patient per year in the restricted states compared to unrestricted states. Based off this information we would like to request it be retained on the Mainecare PDL.

The other is Genotropin, which is a recombinant human growth hormone, indicated for treating various growth hormone deficiencies. It has 6 indications for its use; again there are a wide variety of dosing options available for patients and injection devices. Common adverse reactions include injection site reactions, lipoatrophy, and headache.

The last one is Toviaz, which is an antimuscarinic agent, used for the treatment of overactive bladder with symptoms of urged urinary incontinence. It has two doses, 4mg and 8mg, and it has been proven effective in all of these. It is fairly well tolerated, most common adverse reactions for it is dry mouth. How was that for 5 minutes?

Mr. Ouellette: Can you send us the pharmacoeconomic data on the Lyrica?

Akanksha Mittal from Genzyme, a Sanofi company, and medical liaison from Boston. I wanted to discuss Aubagio, which has previously been discussed, but I would like to present additional information that has become available over the past few months since my partner presented. So, Aubagio is a once daily oral option for relapsing MS and since your initial review of this drug more data has become available on the safety and efficacy. Specifically there is a phase 3 that consistently has shown clinical benefit in the annual MS relapse rate, around 30%-40% as well as storing the progression of disability… Most common adverse reactions since the commercially available have been GI intolerance and headache. In summary there are lots of oral options for MS now, I think that given the number of choices as well as the heterogeneity of the disease, one size fits all, which has become very difficult for clinicians. With this in mind and all the data I went over, I want to thank you for your continued consideration of Aubagio.

Kristin Marr from the global patient outcomes division of Eli Lily and this afternoon I wanted to spend a few minutes to address some concerns that the DUR committee had raised in light of the over utilization and potential diversion of stimulant medications in the state of Maine. I just wanted to review some of the places of where non-stimulant ADHD medications can have in application in light of some of the recent reports that I have, reporting the rates of diversion as well as the most recent public health surveillance that came out that evaluated ER visits as a results of diversions and inappropriate use of CNS stimulants, both prescriptions as well as non-prescription in the past 6 years. So Strattera is one of the non-stimulant medications for the treatment of ADHD as well as some of the alpha-2 agonists that are currently available. Today, we would like to ask the committee to consider potentially having a non-stimulant medication among your ADHD treatments that are on the Maine state PDL. The placements of non-stimulants for the treatments of ADHD have long been recognized in a lot of different guidelines. The American Academy of Child and Adolescent Psychiatry have recommended these as first treatment

options of having both stimulants and non-stimulants being available. Specifically where patients with co-morbidities such as anxiety, ticks, and also in patients with active substance abuse history when atomoxetine and other non-stimulants should be available as first-line. The more recent guidelines including the long standing comparative effectiveness, the UK national institute for healthy clinical excellence, as well as the Canadian ADHD resource guidelines reaffirms the recommendations that there are specific patient populations that are well suited. These are populations with histories of or at risk of stimulant medication misuse and diversions that are good populations for having a non-stimulant option being available. The most recent 2011, American Academy of Pediatrics specifically pointed out that there is a special concern for adolescents with ADHD and that there is a higher risk for diversion for this specific population. And that making a recommendation those clinicians should monitor symptoms as well as prescription refill requests as signs of misuse and diversion of ADHD medications. And that they may consider prescribing a non-stimulant or an ADHD medication that has a low abuse potential. In a recent review by the Oregon Drug Effectiveness Review Project, they also evaluated what the rates of diversions and misuse look like and it varies with age. Through high school 1 in 5 could potentially or reported giving away their ADHD medication, either selling them or 46% have it stolen in the past year. The college kids perhaps have the highest rates, their rates of either giving away or selling their stimulant medication is 23% to 62%, were amphetamines account for the highest having 70%. The substance abuse and mental health service administration reported that the rates of emergency room visits since 2005 to 2011 have increased by 300%, so they went from 5,000 to 23,000, as a result of inappropriate nonmedical abuse of CNS stimulants, now that includes both prescription and nonprescription. From a clinical perspective, atomoxetine or Strattera is a non-stimulant that has shown not to be a controlled substance, is it not associated with a pattern response. Our clinical data has shown over 2,000 patients (children and adults) with ADHD and 1,200 adults with depression are associated with diversions and no evidence to support symptoms rebound or adverse events that is consistent with withdrawal syndromes. I respectfully ask for the consideration of having a non-stimulant on the PDL.

Dr. Barkin: Do you have any superiority data on atomoxetine over guanfacine, clonidine, and bupropion? Because all of those drugs are preferred and are available with the stimulants on the PDL. I share your concern with diversion with the stimulants. In terms of efficacy, stimulants are about twice as effective for the core symptoms of ADD. I'd love to know if there are superiority trials.

Drug Rep: I have not seen any head-to-head data compared with the alpha-2 agonists. A lot of the effects have been put into adherence.

Dr. Barkin: Why not do superiority studies given that the cost of your drug is very high and the other generics are cheap?

John Donovan, Boehringer Ingelheim, with Health Economic Outcomes and Research group. Today I'd like to talk about Pradaxa, just give you a cursory overview, but to really talk about our persistency data against warfarin that we looked at retrospectively and actually just published. Pradaxa, as you know, is the only direct thrombin inhibitor on the marketplace. We have over 2 years of clinical practice experience. It's been included in 3 leading cardiology guidelines. It's only approved to reduce the risk of stroke and systemic embolism in patients with non-valvular a-fib. It is contraindicated in patients with hypersensitivity, mechanical prosthetic valves, as well as active bleeding. The efficacy and safety have been established within RELY, a clinical trial that looked comparatively against warfarin. We saw in the efficacy standpoint, we looked at stroke and systemic embolism there has been a 35% relative risk reduction superior to that of warfarin. If you look at the rate of stroke in general you see a superior

reduction in both ischemic and hemorrhage stroke. We're the only anticoagulant that actual has superiority in reducing ischemic stroke and we know that 9 out of 10 strokes are ischemic in nature. If you look at the safety side we know that in comparison there was also a higher rate of MI, so 0.7 per 100 patient years to 0.6 in the warfarin group. From a safety standpoint, the major endpoint was major bleeds, we were comparable against that. We had a reduced incidence of life-threatening bleeds, intracranial bleeds, and overall total bleeds. We had a higher rate of GI and total bleeds in the population as well as a trend to a higher rate in patients greater than 75 years of age for major bleeds. But if you look at that risk/benefit ratio which is important when looking at anticoagulants, we are favored over warfarin in any age population.

To talk about the persistency data, so we looked at the Department of Defense over 2 years, so it was October 2010 to June 2012, looking at new-start patients within the department's database, about 5,145 patients that had NVAF, a new-start to therapy, and then we looked at persistency rates. Of course persistency rates, it's important to at persistency based on how warfarin is prescribed. Usually it is prescribed in multiple doses, "patients get 100 to 60 tablets per day". So we looked at a 30 day gap fill rate, we did a sensitivity analysis on 30 and 60 days and found that 30 days was gap fill rate to use in the clinical trial. In the 6 month period, it was 72% for the Pradaxa group and it was 53% in the warfarin group. Certainly there are limitations, it's a retroactive study, looking at claim data, and you're not really measuring if the patient is taking the pill, it's just a measure of persistency. In light of this information, we like to request the committee to consider Pradaxa as a preferred agent.

Eric Hecht form Novo Nordisk to talk about Norditropin Flexpro being considered for the PDL. There are five different factors I'd like to talk to you about very briefly. The buffers and preservatives, as a histidine buffer instead of a citrate salt or phosphate which has been know, according to a hormone research study in 2008, it was associated with injection site reactions. When you look at it from a preservative standpoint, it uses phenol instead of benzyl alcohol which is contraindicated in neonates. Second is the dosing, it can go with the fine doses up to 25mcg with the 5mg, which always the pediatric endocrinologist to tailor the dose, while still taking care of those kids who are in pre-puberty that required large doses, 6, 7,8mg with one shot instead of two like other products. The third difference is the easy use. There was a poster that was presented at PENS in 2012, where they compared Norditropin, Easy-trope, Genotropin, Nuspin, and Omnitrope and they found that Norditropin was overall the easiest to use and associated with the fewest errors. The fourth being the stability outside of the refrigerator, today with so many things going on kid may forget to put it back, so with the 5 and 10mg syringe it is stable outside of the fridge up to 3 weeks. Also important when looking at how many people are traveling and where parents are split between households. The last thing Nordicare, which is the patient support program we have, they employee 30 case-managers to help either the caregiver or the patient's institutions. We also contract out to over 500 nurses to offer free teaching and education for patients. And with that I'd like to thank you for your consideration.

Tom Algozzine, Novartis, regional account scientific director. Two things I want to talk about, Ilaris and Gilenya MS. Quickly about Ilaris, I thought there might need to be some clarity about its place in therapy. So Ilaris, or canakinumab, is Il-1 beta monoclonal antibody recently approved for systemic juvenile idiopathic arthritis (SJIA), also indicated for cryopyrin-associated periodic syndromes. Both very uncommon, CAPS about 400 to 500 people in the US and SJIA about 4000 to 5000. There are lots of different types of juvenile idiopathic arthritis subtypes, SJIA makes up about 10 to 12%. The American College of Rheumatology recommendations do not include all subtypes, but develop treatment groups. The recommendations are that TNF-inhibitors were not considered in the task force panel in the treatment of active systemic features due to relatively poor effectiveness. TNF-alpha inhibitors have not

been shown to be effective in SJIA as opposed to juvenile idiopathic arthritis where they work. Also Ilaris is subQ administered, but it has to be reconstituted, only at this point given in the doctor's office.

In regards to Gilenya, compared to the other therapies on the Mainecare PDL, Gilenya is non-preferred, it's an 8. Now natalizumab, or Tysabri, which is a second line therapy treatment for MS is a 6. And I bring that up only because Gilenya is the only oral medication that has demonstrated superiority, producing annualized relapse rates of compared to an active treatment in one of your preferred agents, Avonex. That study was a transform study, 52% relative reduction vs. Avonex. And the extension study, 12 month study up to 24 months, they switched people from Avonex to Gilenya, again 29% reduction in annualized relapse rates when they switched, but those patients never caught up who were on Gilenya and stayed on Gilenya. Additionally we have some long term data, going out 5 years, 59% of people remain relapse-free and that's really what we are trying to do in these people, is keep them relapsing and getting disabilities. Safety data, the drug has been on the market for 3 years, 71,000 patients worldwide, 87,000 patient years of experience. Still no new safety signals, there is the upfront monitoring required, most notable observation is the cardiac bradycardia and making sure they are up to date with their chicken pox vaccinations, eye examines, some other labs tests. Some data out of Europe, one survey that was done, about 300 patients where they were looking at reasons that patients switch. This survey found that tolerability and lack of efficacy were the most notable reason patients switched their MS therapies, and fingolimod was the least likely agent that patients would switch off of, because it is generally well tolerated once the patient gets past that first dose observation. The disease is not easy to manage and there aren't many formal treatment guidelines out there, so it really becomes a provider-patient decision on what treatments they use. When I looked at a 4 year snapshot of Mainecare data, it was interesting that there wasn't much fluctuation in the number of total prescriptions in this class. So that tells me with all the new agents on the market, you're not getting the huge influx of people with MS in Maine Medicaid. Also most of the agents utilized, haven't had much fluctuation in their utilization, with the exception of Betaseron which has gone down by about 100 prescriptions from 4 years ago to now and Gilenya, which at the time was not on the market and is now up about 100 prescriptions from then. So with that I'd just like to ask the you consider making Gilenya in a better position on the PDL, especially compared to Tysabri, which as mention is a second-line therapy for MS. And also noticed that Gilenya is the only MS treatment on your dosage consolidation list, and I'm not quite sure what impact that has, I can't imagine anyone using Gilenya more than once a day. I've never heard of any doctors doing that.

Contessa Ventura a manage care specialist from Teva, presented two products Copaxone and Q-nasal. So for Copaxone, it's the longest, continuous product for patients with relapsing and remitting that has been followed for 10 years. Patients followed over this 10 year span, 62% were improved or unchanged from their baseline. And over 90% of the patients on Copaxone were walking unassisted. There have been 3 randomized open-label, comparative trials, comparing Copaxone to Betaseron and Rebif. More recently, there has been a 3 year National Institute of Health funded study called CombiRx, so Teva was not a supporter of that research. Copaxone treatment lead to significantly fewer relapses compared to Avonex directly. And in the combinations arm, where patients received both Copaxone and Avonex it had more relapse rates compared to using Copaxone alone. Unlike other immunomodulatory agents, Copaxone doesn't require the routine monitoring or testing for liver enzyme function, blood chemistry, neutralizing antibodies, and doesn't have warnings about depression, hepatic injury, or serious infections. It does have a pregnancy category B rating and that's the only one for relapsing/remitting MS. During the 10 years of use of continuous Copaxone no unexpected safety issues have emerged requiring discontinuation. When discontinuation does occur it is usually for common adverse reactions, which is injection site reactions, rash, dypnsea , and chest pain.

So for Q-nasal, first available non-aqueous, nasal steroid, with an aerosolized HFA deliver. Q-nasal is indicated for seasonal and perennial allergic rhinitis in adults and adolescents 12 years and old. No pediatric use at this time. The efficacy has been demonstrated in 3 randomized, double-blind, placebo trials with over 1,000 patients were included. There was a significant decrease in the nasal symptoms of these patients and they did show some quality of life measures and symptoms based off of physician ranked scales went down as well. Adverse events experienced were generally nasal discomfort and headache. A common question on Q-nasal has been retention rates, and essentially 99% is retained in the nasal cavity over 45 seconds and only 1% gets deposited in the throat and after 14 minutes 79% remains in the nasal area. Unlike other sprays, they can actually track their use with a built in counter. There has been a retrospective claims data base, with Florida State Medicaid, that when they looked at non-aqueous vs. aqueous nasal sprays, those patients on the non-aqueous had a higher adherence rate, 53% to 34%. And the non-aqueous patients actual had the lower overall pharmacy costs over 18 months compared to aqueous solutions. So we would like to thank you for considering Q-nasal as an option to choose for allergic rhinitis.

Panel: Are you working on indication in the younger age of pediatrics?

Drug Rep: Yes, we are, I think in one more year. (Other drug rep in audience: should be in the fall of 2014)

Ann Woloson from Maine Equal Justice Partners. MEJP is a nonprofit, legal aid provider that represents the interests of low income people in the courts, in front of administrative agencies, and legislature. We are members of the MaineCare advisory committee, which is required by federal law to advise on matters related to the administrative benefits of the MaineCare program. I'm here today to make two requests or recommendations, depending on how you want to look at it. The first request, I ask if you would consider adding a consumer representative to the committee and I brought along a copy of a report from the Kaizer Foundation that did an analysis of seven states P&T committees. They provided information on how they used evidence based information in their decisions and it also provides an analysis of the makeup of the committee. In 5 out of the 7 states studied included at least one consumer representative. And given the focus on consumer engagement in a variety of projects the state is currently involved in (help homes initiative). We believe that consumer representation on this DUR would be helpful for some of the decisions you will likely make.

Dr. Weiss: The state legislature decides who is on this committee.

Ms. Woloson: Well it's in rules but I don't think the rules forbid you from adding…

Dr. Weiss: It is supposed to be half physicians and half pharmacists. That's how it is set up. The policy is pretty specific. It would have to be a legislative change to add a consumer.

Panel: They are more than welcome to come to the public comment portion of every meeting.

Ms. Woloson: The real reason I'm here today, I've handed out a chart, there are a group of people that are slated to lose their MaineCare coverage come January 1 because of cuts that were made by the legislature. I know you don't have any control over that, but part of your charge is to make recommendations to the department on issues related to prescription drug coverage. What I'm asking you to do is make a recommendation to the department, which they provide people who are going to lose their coverage, very poor people, many of whom, 9,000 people make less than $11,000 a year, with

some information about how they might be able access prescription drugs at an affordable rate. There are all kinds of programs out there, Maine has a good medication program through the hospitals, and there are other things that can be done in terms of therapeutic equivalence that are less expensive. So I'm hoping that in the effort to avoid people not getting the medications they need and end up in the hospital.

Dr. Weiss: We don't see how that would actually work because these people are not just going to pharmacy coverage, they're not going to see their doctors anymore either. Because they are going to lose coverage for that part as well. The doctor is no longer given the opportunity, because of this, to say to the patient let us try a different drug, lets us drug company samples. The patients are being completely disenfranchised by this system. So it's not clear to me what method people would have to communicate anymore with these patients since they are no longer patients.

Ms. Woloson: What we would suggest is that when people are being notified that they will be losing their coverage that the department sends out a resource list for people currently taking medications these are some resources that you may be able to access to continue receiving medications.

Dr. Weiss: If you want to come back with some specific idea that we could try to kick around and then discuss, but as a physician, I personally can't think of how to help these people if they can no longer see a physician.

Ms. Woloson: I'm thinking about someone who might currently be on insulin and they may not be able to afford that insulin. If they could go to the Maine health prescription program, where people go and apply, and if they're below the poverty level the hospital will help them apply to the pharmaceutical industry, so they can get that insulin for free…

Dr. Weiss: But those people still have doctors that control the prescription.

Dr. Barkin: If somebody were to leave my practice with no follow-up, I would feel clinically uncomfortable giving someone a year's worth of medication.

Dr. Weiss: You would be legally responsible. There's no legality for no longer seeing the patient if the patient stops coming. There is legality for writing a prescription for something and then the patient becoming dramatically different and taking all of the pills at once and dying four months later on his prescription. Most of the hospitals and practices have free care and some people might fall into that category. The patients have to be willing to do that, and some patients don't like that. They are willing to take MaineCare, but no charity or something. It's a problem.

Mr. Ouellette: We can make a recommendation. Our role is not to tell MaineCare how to do their policy.

Dr. Weiss: We something like in each county, you might want to call. But we'd have to sit down and formally do it, and maybe you could help us with that. Alright thank you.

OLD BUSINESS

DUR MINUTES

The September 10, 2013 minutes were approved.

PSYCH WORK GROUP MONTHY UPDATE

The psych work group is working with LD-716. Dr. Tweed is starting a multidisciplinary task force, which will start next Tuesday. This is the bill regarding control of stimulants in young kids. LD-338, which is antipsychotics in young children, is also in process.

NEW BUSINESS

NEW DRUG REVIEWS

Liptruzet (Ezetimibe and Atorvastatin) – Antilipemic Agent: 2-Azetidinone, HMG-CoA Reductase Inhibitor
Non-preferred: all approved

Ilaris (Canakinumab) – Interleukin-1 Beta Inhibitor; Monoclonal Antibody
Non-preferred: all approved

Rescula (Unoprostone) – Ophthalmic Agent, Antiglaucoma; Prostaglandin
Non-preferred: all approved

Mekinist (Trametinib) – Antineoplastic Agent, MEK Inhibitor
Non-preferred and require clinical prior-authorization to verify dx: all approved

Tivicay (Dolutegravir) – Antiretroviral: Integrase Inhibitor
Non-preferred with a clinical PA to verify dx and it being used in combination therapy: all approved

Fabior (Tazarotene) – Acne Preparation: Retinoid Prodrug
Non-preferred and only available to those who can't tolerate preferred medication: all approved

Trokendi XR (Topiramate) – Anticonvulsant
Non-preferred: all approved

Breo Ellipta (Fluticasone and Vilanterol) – Beta-Adrenergic Agonist, Long Acting/ Inhaled Corticosteriod
Non-preferred: all approved

Cometriq (Cabozantinib) – Antineoplastic Agent: Tyrosine Kinase Inhibitor/ VEGF Inhibitor
Non-preferred and require PA to verify dx: all approved

Tafinlar (Dabrafenib) – Antineoplastic Agent: BRAF Kinase Inhibitor

Non-preferred and require PA to verify dx: all approved

Emergency Epinephrine – Alpha/Beta Agonist (more of a class review)

A motion was made to have sole epinephrine pen: Epipen preferred, Avi-q non-preferred

All in favor

ANNUAL PDL REVIEW

ADHD	Daytrana – Preferred Focalin Tab – Preferred Focalin XR Cap – Preferred Quillivant Sus XR – Non-preferred Strattera Cap – Non-preferred

- All in favor

Amphetamines	Adderall XR Cap – Non-preferred o Preferred over its generic equivalent Procentra Sol – Non-preferred Vyvanse Cap - Preferred

- All in favor

Analeptics	Caffeine Cit Inj – Non-preferred

- All in favor

Analgesics	Orbivan CF Tab – Non-preferred

- All in favor

Analgesics, Opioid	Exalgo Tab – Non-preferred Ibudone Tab – Non-preferred Nucynta Tab – Non-preferred Nucynta ER Tab – Non-preferred Opana ER Tab – Preferred Suboxone MIS – Preferred

- All in favor

Androgens/Anabolics	Androgel Gel – Preferred Testim – Preferred

- All in favor

Anorectal – Misc	Rectiv Oin – Non-preferred

- All in favor

Antianginal agents	Ranexa Tabs – Non-preferred

- All in favor

Antiarrhythmics	Multaq tabs – Non-preferred

- All in favor

Anticoagulants

Eliquis Tab – Non-preferred
Pradaxa Cap– Non-preferred
Xarelto Tab– Non-preferred
Lovenox Inj – Preferred

- All in favor

Anticonvulsants

Diastat-Preferred
  - Preferred over its generic equivalent

Levetiracetm Inj – Non-preferred
Lyrica Cap – Non-preferred
Oxtellar XR Tab – Non-preferred
Potiga Tab – Non-preferred
Vimpat – Non-preferred
Diastat – Preferred

- All in favor

Antidementia Agents

Exelon Dis – Preferred
Namenda – Preferred

- All in favor

Antidepressants

Prestiq – Non-preferred
Viibryd – Non-preferred

- All in favor

Antidiabetics – Insulin

Humalog KWIK Inj – Non-preferred
Humalog Mix Inj – Non-preferred
Humalog N Pen - Non-preferred
Lantus Inj – Preferred
Lantus Inj Solostar – Preferred
Levemier – Preferred

- All in favor

Antidiabetic – Non-Insulin

Bydureon Inj – Non-Preferred
Invokana Tab - Non-Preferred
Kazano Tab - Non-Preferred
Komibiglyze Tab - Non-Preferred
Nesina Tab - Non-Preferred
Oseni Tab - Non-Preferred
Victoza Inj - Non-Preferred
Tradjenta Tab - Non-Preferred
Janumet Tab -Preferred
Janumet XR Tab-Preferred
Januvia Tab-Preferred
Jentadueto Tab-Preferred
Juvisync Tab-Preferred
Onglyza Tab-Preferred

- All in favor

Anitdotes — Vivitrol Inj –Non-Preferred

- All in favor

Antihemophilic — Koate DVI Inj-Preferred
Wilate Inj-Preferred

- All in favor

Antihyperlipidemics — Niaspan Tab-Preferred
Simcor Tab-Preferred
Tricor Tab-Preferred
Trilpix Cap-Preferred
Vytorin Tab-Preferred
Welchol Tab-non-Preferred
Zetia Tab-non-Preferred
Liptruzet Tab-non-Preferred

- All in favor

Antihypertensive, ARBS — Benicar Tab-Preferred
Benicar HCT Tab-Preferred
Diovan Tab-Preferred
Diovan HCT Tab-non-Preferred

- All in favor

Antihypertensive, ARB/CCB Combo — Azor Tab-non-Preferred
Tribenzor-non-Preferred
Exforge Tab-Preferred
Exforge HCT Tab-Preferred

- All in favor

Anti-Infective Agents , Misc — Tindamax Tab-Preferred

- All in favor

Anti-inflammation, NSAIDS — Celebrex Cap-non-Preferred
Nalfon Cap-non-Preferred

- All in favor

Antineoplastics — Amifostine Inj-non-Preferred
Docefrez Inj-non-Preferred
Leuprolide Inj-non-Preferred
Oxaliplatin Inj-non-Preferred

- All in favor

Antiparkinsonian Agents — Neupro Dis-non-Preferred
Stalevo Tab-non-Preferred

- All in favor

Antipsychotics

Abilify Main Inj-non-Preferred
Fanapt Tab-non-Preferred
Invega Tab-non-Preferred
Sapris Tab-non-Preferred
Seroquel XR Tab-non-Preferred
Latuda Tab-Preferred
- If tablet splitting is used

Abilify Tab-Preferred

- All in favor

Antivirals, ART's

Norvir Tab-Preferred

- All in favor

Antivirals, Hepatitis Agents

Incivek Tab-Preferred
Victrelis Cap-Preferred
Pegasys-Preferred
Ribapak-Preferred

- All in favor

Beta Blockers – Cardio Selective

Bystolic-non-Preferred

- All in favor

Biologic Immunomodulators

Cimzia-Preferred
Enbrel-Preferred
Humira-Preferred
Simponi-non-Preferred

- All in favor

Bronchodil, Anticholinergics

Spririva Handihaler Cap-Preferred
Tudorza-Non-Preferred

- All in favor

Bronchodil, Steroid Inhalants

Daliresp Tab-non-Preferred
Flovent-Preferred
Pulmicort-Preferred
Qvar-Preferred

- All in favor

Bronchodil, Sympathomimetics

Advair-Preferred
Dulera-Preferred
Symbicort-Preferred
Proventil-Preferred
Combivent Respimat-non-Preferred
Proair-non-Preferred
Ventolin HFA-non-Preferred

- Move to single albuterol inhaler

- All in favor

Calcium Regulators-Osteoporosis — Binosto Tab-Non-Preferred

- All in favor

Cephalosporins — Suprax-non-Preferred

- All in favor

Derm, Acne Products — Aczone Gel-non-Preferred

- All in favor

Derm, Anti-inflammatory — Pennsaid Sol-non-Preferred

- All in favor

Derm, Antipsoriatics — Stelara Inj-non-Preferred
Tazorac Cre- Preferred
Tazorac Gel-Preferred

- All in favor

Derm, Scabies/Pediculocides — Natroba-Preferred
Sklice-non-Preferred

- All in favor

Digestive Enzymes — Creon Cap-Preferred
Zenpep Cap—Preferred
Pancreaze Cap—non-Preferred
Pertzye Cap-non-Preferred
Ultresa Cap-non-Preferred
Viokace Tab-non-Preferred

- All in favor

Direct Renin Inhibitors — Amturnide-non-Preferred
Tekamlo-non-Preferred
Tekturna-non-Preferred
Tekturna HCT-non-Preferred

- All in favor

Diuretics — Chlorothiaz Inj-non-Preferred

- All in favor

Fibromyalgia Agents — Savella-non-Preferred

- All in favor

Growth Hormone — Genotropin-Preferred
Norditropin-Preferred
Humatrope-non-Preferred

Nutropin AQ-non-Preferred

- All in favor

Hematopoietic, Growth Factor — Procrit Inj –Preferred
Aranesp Inj-non-Preferred

- All in favor

Hematopoietic Mixtures — Ferralet –Preferred
Maxaron-non-Preferred

- All in favor

Hyperparathyroid Treatment Vit D — Zemplar Cap-Preferred

- All in favor

Hypnotics — Zolpimist-non-Preferred

- All in favor

IBS Agents — Linzess Cap-non-Preferred

- All in favor

Infammatory Bowel Agents — Apriso Cap-Preferred
Canasa Sup-Preferred
Delzicol-Preferred
Pentasa Cap 250mg-Preferred
Lialda Tab-non-Preferred
  - Asacol removed from market
  - Pentase 500mg non-preferred

- All in favor

Migraine Products — Relpax-Preferred
Sumatriptan-non-Preferred

- All in favor

MS Agents — Gilenya-Preferred
Rebif-Preferred
Copaxone-Preferred
Betaseron Inj-Preferred
Avonex-Preferred
Extevia-non-Preferred

- All in favor

Multivitamins, prenatal — Citranatal-non-Preferred

- All in favor

Nasal antiallergy — Astrpro-non-Preferred
Patanase-non-Preferred

- All in favor

Nasal Steroids
Nasacort AQ-non-Preferred
Qnasl-Preferred

- All in favor

Opthalmic Antiallergics
Pataday-Preferred
Patanol-Preferred
Lastacaft-non-Preferred

- All in favor

Opthalmic Anti-infectives
Zymaxid-non-Preferred
Moxeza-Preferred
Vigamox-Preferred

- All in favor

Op. Beta Blockers
Combigan-Preferred
Cosopt PF-non-Preferred

- All in favor

Op. NSAIDS
Acuvail-non-Preferred
Ilevro-non-Preferred
Nevanac-non-Preferred

- All in favor

Op. Prostaglandins
Lumigan-non-Preferred
Zioptan-non-Preferred
Travatan Z—Preferred

- All in favor

Otic Anti-infectives
Ciprodex-Preferred

- All in favor

Phosphate Binders
Renvela-non-Preferred
Fosrenol-non-Preferred
Eliphos-Preferred
Phoslyra-Preferred
Renagel-Preferred

- All in favor

Ph-Phosphodiesterase Inhibitors
Adcirca-non-Preferred

- All in Favor

Platelet Aggregation Inhibitors
Aggrenox Cap-Preferred
Brilinta Tab-non-Preferred
Effient Tab-non-Preferred

- All in favor

Progestins
Megace ES-Preferred

Makena-non-Preferred

- All in favor

Pulmonary Hypertension-ERAS — Letairis-Preferred
Tracleer-Preferred

- All in favor

Somatostatic Agents — Octreotide Inj-non-Preferred

- All in favor

Ulcer Drugs, Misc — Pylera Cap-non-Preferred

- All in favor

Ulcer Drugs, PPIS — Prilosec OCT—non-Preferred

- All in favor

Urinary Antispasmodics — Myrbetriq Tab-non-Preferred
Toviaz Tab-Preferred
Vesicare Tab-Preferred

- All in favor

Urinary Prostatic Hypertrophy — Avodart Cap-non-Preferred

- All in Favor

Vasopressors — Epipen-Preferred
AuviQ-non-Preferred

- All in favor

Vaginal Anti-infectives — Clindessa Cre-Preferred
Gynazole1-non-Preferred

- All in favor

ADJOURNMENT: 6PM

The next meeting will be held on **November 12, 2013**, 6:00p.m. – 8:00p.m at the Armory.