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**TO:** Maine Drug Utilization Review Board
**DATE:** June 4, 2013
**RE:** Maine DUR Board **Meeting minutes** from **May 14, 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. St. Amand, R.Ph., Staff Pharmacist Community Pharmacy - Pittsfield | | | X |
| Steve Gefvert, D.O. | 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

## CALL TO ORDER: 6PM

## PUBLIC COMMENTS

**Arlene Price**, Johnson & Johnson, presented an update on **Invokana,** the first of the SGLT2 inhibitors to be approved to the market. It increases the urinary excretion of glucose, thus lowering the reabsorption into the blood stream. It also has an osmotic dieresis to get a decrease in sodium that leads to a decrease in your systolic blood pressure. You also see weight loss in the range of 2-5% due to the calories that are being excreted in the urine.

Due to the excretion of glucose the most common adverse effects reported with Invokana are common urinary infections or mycotic infections. We have data in over 10,000 patients. We have studied it in mono therapy, dual therapy and combination therapy and we have a head-to-head trial against Januvia and a head-to-head trail with Bromopride which has shown significant reductions in hemoglobin A1c with reductions in systolic blood pressure and reductions in weight. With this comprehensive program we also have seen it in patients with impaired renal functions.

The recommended starting dose is 100 mg. If patients have compromised renal function they should remain at that dose. If they have an estimated GFR below 45 than you would not use this drug in that patient. If they have normal renal function then you would increase the dose at 300 mg. Patients have tolerated the drug very well, and in terms of the efficacy profile they show a significant improvement compared to Januvia for lowering hemoglobin A1c.

**Dr. Robert Weiss** stated he had been using this drug for four to five years. It is better than most of the other drugs that have been used. In terms of sulfonylurea it is better. It has an increase in infections but it is a low percent at the 100 mg starting dose. Out of the thousands of studies, not one patient quit because of urinary infections. This drug meets the FDA criteria as a weight loss drug.

**Tom Algozzine**, Novartis, presented **TOBI Podhaler.** Looking at data from the cystic fibrosis foundation they estimated about 239 people in Maine in 2011 were living with cystic fibrosis. In looking at the Mainecare CMS utilization based on pulmazon claims we estimated 40-50 people had cystic fibrosis. The biggest thing with cystic fibrosis is that people are living a lot longer. Half the populations with cystic fibrosis are adults, which has to do with the changes in therapy that we have. People with CF take 15-20 medications daily, which is time consuming to administer and there is a lot of compliance issues.

Podhaler can help free up time by illuminating the refrigeration of viles and taking the extra 20 minutes to nebulize, clean, and sterilize. This dry power inhaler takes about 2- 5 minutes to administer 4 capsules with no special cleaning or storage, and it is portable and easy to use. It is an innovative alternative, and hopefully impacting any kind of safety issues to improve tolerability and efficacy. In a study that they did comparing to TOBI solution the side effects that were more common were cough, dysphonia, and dysgeusia. He asked the Board to consider offering this to Maine Medicaid patients to help with adherence, especially in the older patients who have a lot more going on in their lives.

**Dr. Weiss** pointed out this was a delivery system as opposed to just using it as a liquid. He asked if the company had any evidence that people actually use it more in a head-to-head comparison between the liquid medication and the inhaled medication.

**Mr. Algozzine** responded they had not seen any yet, but in a 6-month study there was no difference in adherence.

**Drew Revel**, Genzyme Corporation, presented **Kynamaro** for the treatment of homozygous familial hypercholesterolemia (HoFH), which is a genetic disorder. He explained HoFH was the deficiency of the LDL receptor, which gives you elevated LDL in the bloodstream and leads to premature death and cardiovascular disease. A recent study showed that most of these patients die by the age of 30. There is approximately one in a million reported cases for homozygous familial hypercholesterolemia in the United States.

The diagnosis is typically clinical instead of genetic even though it's a genetic-based disease because only about 60-80% of all cases can actually be identified. Traditional therapies are Statins, so mipomerson sodium was developed specifically for homozygous FH patients. It's a unique mechanism targeting apo B-100 RNA, so it is not recognizing apo B-48, which is predominately in the gut. It decreases the amount of apo B-100 protein that is produced, thereby increasing the LDL receptors as well as LDL particles. It has recently been approved by the FDA for the treatment of HoFH on top of maximum tolerated lipid-lowering therapy for the production of LDL-C, total cholesterol and non-HDL-C. Recommended dosage is 200 mg in a 1 ml subcutaneous injection once per week.

There is a box warning specifically around the elevation of transaminases as well as the increase in hepatic fat which goes with the mechanism of VLDL and LDL production. Therefore, the measurement of ALT/AST as well as bilirubin and alkaline phosphatase is required at initiation and then every month thereafter. There is also the risk of hepatotoxicity, so Kynamro is only available through a restricted program (REMS). Only certified providers and pharmacies may prescribe and distribute the drug.

Safety and efficacy has been determined through 4 phase-three studies: A pivotal phase-three study on homozygous FH patients (51 in total) and 3 additional studies in heterozygous FH patients. There have been over 290 patients that have received long-term dosage of mipomersen for at least 52 weeks. Safety and efficacy have not been established in non-homozygous FH patients and the effects on long-term morbidity and mortality have not been established. It has not been done as an adjunct to LDL apheresis. But, in our pivotal study we showed an average decrease by 25% reduction in LDL-C ranging from 2-84% reduction in patients age 30. There were also 7 pediatric patients ages 12-18.

The main adverse events are injection site reactions reported at 84% versus 33% of placebo patients. It did not occur at every injection and was variable in nature. About 8% of patients did show an increase in ALT ≥ 3 times the upper normal limit; however, that did not correlate with hepatic fat increases. You can look at both box warnings, but you can't use one to definitively determine the other. We also looked at hepatic steatosis through MNRI before as well as throughout two of our studies and evaluated up to two years. There are no drug/drug interactions and it is also a category B pregnancy drug.

**Dr. Jeffrey Barkin** asked about the prevalence they were seeking to treat without using genetic markers?

**Mr. Revel** responded that what has been published is one in a million. The EA believes that it is closer to one in five hundred.

**Dr. Barkin** explained that the drug comprises pieces of codons that modify binding with MRNA.

**Dr. Weiss** pointed out that he was the first person in the United States to use the drug, so he knows it well. This drug has serious, potentially life-threatening side effects, which is why it's only approved for a group of people who are going to die at a young age. There are thought to be 80,000 to 100,000 people with homozygous FH in the United States. My guess is that it will not go beyond this because tradition is that you will have to have outcome trials. There are not enough people who have severe Heterozygous to do a study on.

**Dr. Barkin** stated that he understood it as a clinical diag, not as a genetic diag.

**Dr. Weiss** explained the genetic test is not available in the United States. It is only available in Europe because it is $10,000 per test.

**Dr. Barkin** pointed out they are also seeing a lot of mutations outside of the coding region which most of the tests don't actually diagnose. Again, it goes back to the NLA and other agencies, and for these exact reasons, it really is a clinical diagnosis.

**Dr. Weiss** added this drug is $175,000 per year, so whoever is running the PA part of it is going to have to be sophisticated in trying to classify it.

## OLD BUSINESS

### DUR MINUTES

**MOTION** by Dr. Mark Braun to approve the March 2013 minutes. All in favor. Motion passed

**MOTION** by Dr. Braun to approve the April 2013 minutes. All in favor. Motion passed.

### PSYCH WORK GROUP MONTHY UPDATE

**Dr. Lindsey Tweed** reported on the group's discussion which expressed concerns about diversion, stimulants, opiates and methadone clinics that are not collaborating well. He felt this was not so much within the DUR purview, but scattered across DHHS.

## NEW BUSINESS

### SSDC UPDATE

**Mike Ouellette** reported that the SSDC comprises 8 different states including Maine. Every year in April and May we go through a bidding process to get offers on a variety of different drug classes. Those bids are in and now going back and forth with language changes, stipulations of different tiers. So far, we received over 1,300 NDC offers, which encompass 86 classes of drugs on the PDL. Over 40% of the offers are lower than the contracted prices and over 25% are the same price as last year. We have seen some good aggressive bidding from manufacturers in regards to the PDL. The final negotiations are rapping up and the annual meeting is being held next month. We will be meeting with all the states and going through all the financial models. We will come back to the committee in October with the financial models and normal drug class reviews.

### AACE COMPREHENSIVE DIABETES MANAGEMENT ALGORITHM

**Mr. Ouellette** referred to the hand-out in the Board packet and explained they wanted to start a discussion about recommendations of the AACE panel in regards to diabetes management. He pointed

out more and more diabetic meds are coming out and some of the recommendations in regard to mono therapy, dual therapy, and triple therapy, and where insulin fits in with this. There was some concern when they first looked at this that the AACE guidelines were pushing the insulins further and further down the chain.

One issue with the AACE guidelines is that it tends to be prescriptive. They tell you what you should be doing for the patients. When you look at the ADA guidelines they tend to be more of a general recommendation. They offer options and it is more patient-centered. Your patient is the one who is guiding you to which second and third line agent you are using.

**Dr. Weiss** felt the reality is patients are going to want to try one or two of these medicines before they get shots. We could say as a committee that if you tried two drugs and your A1c is greater than 8, than we would try insulin instead of the third drug. Both sets of guidelines would support that, but you can't tell people that if metformin doesn't work you have to take shots. You have to develop a system to work on the dual therapy side or we build into the prescription at the pharmacy level the PA so that the Doctor doesn't have to do it. It will give the Doctor some breathing room and the patient some breathing room.

## BEERS CRITERIA RECOMMENDATION FOR SULFONYLUREAS

**Dr. Barkin** reported that Beers Criteria looked very carefully at the use of sulfonylurea in older patents and came to the conclusion, based upon an expert panel that had access to all clinical trials, that basically it is not a good idea to use sulfonylureas in older patients. The strength of the evidence is high and the recommendation is quite clear to avoid.

**Dr. Weiss** pointed out there is some evidence that one sulfonylurea is less problematic - glameperide, which used to be called ameril, has much less of these hypoglycemic side effects. You could argue that if we built something into this – really discouraging sulfonylurea use we could make a statement or recommendation that if you're really against the wall, we'll let you use glymeperide, but if you want to use something else you will have to put it in a PA. That would be a healthcare beneficial way of doing it.

He felt there was some benefit from the UK PDS Trial that sulfonylureas had cardiac effects that - had they been invented now - never would have passed the outcomes trial and never would have been on the market. Back then, there was evidence that the glameperide was safer – not just on geriatrics, but on the larger population. If you made it a general rule there may be hope that Doctors would get used to it over the years - doing the right thing. If they are allowed to do the wrong thing for younger people, they will continue to do the wrong thing for older people.

**Dr. Braun** questioned why GlipiZide XL was not on the list as well. He pointed out Lantas, long acting insulins, can sometimes be a problem. He felt they should raise the issue of what the goals are for therapy. He did not know how many elderly patients are going to be affected by these kinds of issues here.

**Dr. Weiss** reiterated it is the same Doctors that are taking care of 20 and 30 year olds as the 80 year olds in this State. So, if they learn how to do it properly in younger patients, they are going to do it properly

when those patients get older. It is the same disease – there are just more side effects in the older patients.

**Mr. Ouellette** suggested they take a look at what the utilization was on sulfonylureas and break it up by age to see exactly what utilization we are having and what drugs are the majorities of that.

## NEW DRUG REVIEWS

**Mr. Ouellette** discussed the following new drugs:

Pomalyst: For those with multiple myeloma who have received at least 2 prior therapies, including lenalidomide and bortezomib, and have demonstrated disease progression on or within 60 days of completion of the last therapy. Clinical benefit, such as improvement in survival or symptoms, has not been verified. The safety and efficacy of use in children under the age of 18 have not been established.

It is recommended that Pomalyst require clinical prior authorization to verify diagnosis and monitor appropriate lab outcomes.

**Dr. Weiss** stated we do not know anything about this drug and it is expensive, so it is going to be Non-Preferred.

**Mr. Ouellette** pointed out that in the past, cancer drugs were automatically placed as Preferred. Now, because they are so expensive, it is best to make sure that they are being used for the right indications.

**MOTION** by Dr. Weiss to place Pomalyst as Non-Preferred. All in favor. Motion passed.

Kynamro: Adjunct treatment to lipid-lowering medications and diet to reduce low density lipoprotein-cholesterol (LDL-C), apolipoprotein B (apo B), total cholesterol (TC), and non-high density lipoprotein-cholesterol (non-HDL-C) in those with homozygous familial hypercholesterolemia (HoFH). The safety and efficacy for use in those who do not have HoFH have not been established. The effect on cardiovascular morbidity and mortality has not been determined. Last, the safety and efficacy of use as an adjunct to LDL apheresis have not been established; therefore, its use as an adjunct to LDL apheresis is not recommended. This is a pregnancy Category B medication. The safety and efficacy of use in children under age 18 have not been established.

There is currently limited data available to suggest a place in therapy relative to current lipotropic agents. No comparator data found. Therefore, it is recommended that Kynamro remain non-preferred and be available to those who have appropriate diagnosis and have failed or are unable to tolerate any preferred medications.

**Dr. Weiss** felt this drug was scary. He tested it in heterozygous patients for a number of years, and because it's long acting – if you have elevated EFTs - it was 3-4 months before patients went back to normal and that was not reassuring to Doctors. You want to give it to the people who can benefit from it, but you don't want to give it to someone that is creep.

**MOTION** by Dr. Weiss to place Kynamro as Non-Preferred. All in favor. Motion passed.

Invokana: Adjunct treatment to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (DM). It is not recommended for use in those with type 1 DM or for the treatment of diabetic ketoacidosis. This is a pregnancy Category C medication. The safety and efficacy of use in children under age 18 has not been established.

**Mr. Ouellette** explained they are still working with the manufacturer to get an offer, so by June the landscape will change and the price may get much better.

There is no evidence at this time to support that Invokana is more efficacious or safer than the currently available, more cost effective medications. It is recommended that Invokana remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

**MOTION** by Dr. Weiss to place Invokana as Non-Preferred. All in favor. Motion passed.

Prolensa: Treatment of postoperative inflammation and reduction of ocular pain in those who have undergone cataract surgery. Due to the known effects of prostaglandin biosynthesis-inhibiting drugs on the fetal CV system, use should be avoided during late pregnancy. The safety and efficacy of use in children under the age of 18 have not been established.

There are three generic versions available:

1. Flurbiprofen sodium (Ophthalmic) drops
2. Diclofenac sodium (Ophthalmic) drops
3. Ketorolac Tromethamine (Ophthalmic) drops

There is no evidence at this time to support that Prolensa is more efficacious or safer than the currently available, more cost effective medications. It is recommended that Prolensa remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

**MOTION** by Dr. Weiss to place Prolensa as Non-Preferred. All in favor. Motion passed.

Gattex: Treatment of adults with Short Bowel Sydrome (SBS) who are dependent on parenteral support. This is a pregnancy Category B medication. The safety and efficacy of use in children under the age of 18 have not been established. It is compared to Zorbtive, a growth hormone which has the same indication and there is a price difference.

Gattex is the first in its class with this mechanism of action; however, Zorbtive and NutreStore (nutritional drink) are also approved for SBS. Comparator trials with Gattex were not found. It is recommended that Gattex remain non-preferred and require prior authorization to verify diagnosis and laboratory assessments.

**MOTION** by Dr. Weiss to place Gattex as Non-Preferred. All in favor. Motion passed.

Fulyzaq: An anti-diarrheal agent for use in those with HIV/AIDS on anti-retroviral agents. It is not FDA approved for the treatment of infectious diarrhea. It is therefore recommended that prior to initiating therapy, infectious etiologies of diarrhea are ruled out. If treatment is started without infectious diarrhea being ruled out, there is a risk of not receiving appropriate treatment and worsening of the condition.

**Mr. Ouellette** pointed out Fulyzag is compared to Lomotil and Imodium, which has a big price difference, but they are not effective because they have to change their drug regiment to be able to minimize the diarrhea effects. They are going to have to work hard to get an offer on Fulyzag because it is expensive.

As this is the first in a new class of anti-diarrhea agents, there were no comparator clinical trials. It is recommended that Fulyzaq remain non-preferred and require prior trials of preferred, more cost effective anti-diarreal agents.

**MOTION** by Dr. Weiss to place Fulyzag as Non-Preferred. All in favor. Motion Passed.

Iclusig: Treatment of adults with chronic phase, accelerated phase, or blast phase chronic myeloid leukemia that is resistant or intolerant to prior tyrosine kinase inhibitor therapy or Philadelphia chromosome positive acute lymphoblastic leukemia that is resistant or intolerant to prior tyrosine kinase inhibitor therapy. There are no studies verifying an improvement in disease-related symptoms or increased survival. This is a pregnancy Category D medication. The safety and efficacy of use in children under age 18 have not been established.

Iclusig has two box warnings: 1) regarding the risk of arterial thrombosis with use. Cardiovascular, cerebrovascular, and peripheral vascular thrombosis, including fatal MI/Stroke, have been reported with use, occurring in about 80% of the population. It is recommended that Iclusig therapy be interrupted and discontinuation be considered in those who develop arterial thrombotic events. 2) regarding the potential for hepatoxicity with use. Hepatoxicity, liver failure, and death have all been reported with Iclusig use. It is recommended that hepatic function be monitored prior to and during treatment, and to interrupt and then reduce or discontinue treatment if hepatoxity occurs.

It is recommended that Iclusig remain non-preferred and require clinical prior authorization to verify diagnosis and prior trial of TKI therapy, as well as appropriate laboratory monitoring.

**MOTION** by Dr. Weiss to place Iclusig as Non-Preferred. All in favor. Motion passed.

TOBI Podhaler: For the management of cystic fibrosis patients with *Pseudomonas aeruginosa.* The safety and efficacy have not been determined in those under the age of 6 years, in those with a forced expiratory volume in 1 second (FEV1) <25% or >80% predicted, or in those colonized with *Burkholderia cepacia.* This is a pregnancy Category D medication.

**Mr. Ouellette** explained they are selling this to the commercial plans because it is only a 25% premium to be able to use instead of the liquid solution. For Medicaid you are looking at 300% premium, so it is difficult to justify the significant price disparity.

There is no evidence at this time to support that TOBI Podhaler is more efficacious or safer than the currently available, more cost effective medications. It is recommended that TOBI Podhaler remain non-preferred and be available to the few who are unable to tolerate any preferred medications.

**Dr. Weiss** pointed out this was a good example of rich people getting better health care than poor people. You will just have to work on a better rebate.

**Mr. Ouellette** explained that will help if you put this on the Non-Preferred side.

**Dr. Weiss** agreed.

**MOTION** by Dr. Weiss to place TOBI Podhaler as Non-Preferred. All in favor. Motion passed.

Auvi-Q: A new EpiPen for the emergency treatment of allergic reactions (Type I), including anaphylaxis to stinging insects and biting insects, allergen immunotherapy, foods, drugs, diagnostic testing substances (eg. radiocontrast media), and other allergens, as well as idiopathic anaphylaxis or exercise-induced anaphylaxis. It is intended for immediate administration in those who are determined to be at increased risk for anaphylaxis, including individuals with a history of anaphylactic reactions. It is intended for immediate self administration as emergency supportive therapy only and is not a substitute for immediate medical care. This is a pregnancy Category C medication. The safety and efficacy of use in children weighing less than 15kg (33lbs) have not been established.

Due to being cost effective, it is recommended that Auvi-Q become preferred and be available without prior authorization.

**Mr. Ouellette** explained that it was hard to tell what the rebate was going to be. It is right in line with the pricing on the EpiPen. The dosing is a little different and the packaging is different than the EpiPen. We used to have Twinject, which got bought out – now it's not on the market – they have discontinued it, so now we are down to these two agents. More than likely we will have a negotiation and one of them will be preferred over the other. He felt the recommendation was going to make both of them Co-Preferred.

**MOTION** by Dr. Weiss to place Auvi-Q as Preferred. All in favor. Motion passed.

## BUTALBITAL UTILIZATION FOLLOW-UP

**Mr. Ouellette** explained that we had done this analysis in another state that we currently work in to take a look and see what the utilization was for members in the Mainecare population. When we looked at the utilization, we had almost 800 unique members that we had claims for. We were looking at headaches, migraines, tension-type headaches to see how many members were over utilizing butalbital.

He referred to the second page of the handout which shows the member counts for those greater than 18 units per month, greater than 60 units per month, greater than 120 units per month, and greater than 240 units per month.

Part of the discussion at the last meeting was to look at providers that were writing some of these scripts and to look at some of the members. He referred to the hand-out showing a list of providers with members having prescriptions of Butalbital greater than 120 units per month and greater than 60 units per month. He pointed out they had slightly over 100 prescribers that were doing it at 60 units per month. When we looked at the specialty of providers, the majority of prescribers on the list were family practitioners or internal medicine. There were some that were emergency medicine or rehab and a couple of neurologists.

**Dr. Braun** asked what they wanted to do with this? Do we want to tell the practitioners that we have concerns that patients are addicted to these?

**Dr. Weiss** felt that they would get the same lack of response that they get every time they send a letter, but suggested they send a letter to the group of twenty practitioners who are giving patients 200 or so of the drug per day and ask them "why" because it is too much. It is an addictive drug, which has been repeatedly proven not to be efficacious. You have the worst of both worlds.

**Dr. Braun** felt that most practitioners know this already, but the biggest issue is that they are stubborn. They do not know where to turn because they need to get people off these things. You can send a letter to them, but it would be more useful if they could have a recommendation for what to do with the people.

**Dr. Weiss** suggested the first thing to do is ask them if they even realize this and why. If they answer you, then you can give them a response.

**Dr. Braun** asked what was the hubbub?

**Dr. Barkin** responded the hubbub is you can let the outliers know that we know they are outliers and warn them about the chronic use of high doses of butalbital.

**Dr. Tweed** felt this was a different situation than the stimulant benzos because they are doing this as a matter of course and something that they do. This is something I doubt anybody got here on purpose. They somehow just got stuck.

**Dr. Weiss** we don't know that they got stuck. This may have been the path of least resistance. You don't know which it is – that's why it is worth asking them. Doctors do not like being singled out, and there is the hope that if you tell them they are giving an obscene amount of useless narcotic they might try to do something about it.

**Dr. Braun** asked Dr. Weiss what he suggested they do?

**Dr. Weiss** responded they have to get off this drug.

**Dr. Braun** felt the problem was how to do this. I have one of these patients and I have sent them to neurologists. I can't get them off of it.

**Dr. Weiss** explained there were addiction specialists. At St. Mary's there are four certified addiction specialists who make a living answering your questions.

**Dr. Barkin** asked Dr. Braun what happened when his patient tried to get off the drug.

**Dr. Braun** responded when they try they get rebound headaches. My contention is that I would love to get them to an addiction specialist that was appropriate. I think we have to be proactive. We could say to the Doctors there is a high chance that these patients are not benefitting from this because they are having medication induced headaches. We could also say we would like to point this out to you and offer that these people might be of help to you. That would be much more useful than asking them why

they are prescribing this. We can also send out something to discuss how patients get to this point. That would be more useful because that would be helping them to figure out what to do with this.

**Dr Weiss** asked if they wanted to take this on.

**Dr. Barkin** pointed out the good news on the analysis was that most of the Doctors had one patient. Some of them had two patients, and one of them had four patients. The person who had four patients is a neurologist. It might be helpful touching base with that neurologist and seeing if there is something unique about the patients. Or it might be helpful to come with a process to block this from snagging more people while also letting existing prescribers know.

**Dr. Weiss** felt he did not mind doing this, but argued they should ask what the problem is before trying to create the solution. We don't even know if they care about it. Nothing that we've tried in any of the other diseases has worked at all. If they say we do not know how to get these people off, then we would then be empowered to do that.

**Mr. Ouellette** referred to the handout and explained there were drug profiles attached of members picked at random.

**Dr. Barkin** pointed out the first patient who was on high doses of Butalbital, Oxycodine and Fentanyl. He felt this was not a good profile.

**Mr. Ouellette** referred to the second patient who was getting 120 every month. He pointed out there were multiple site issues.

**Dr. Braun** explained that these people did not get there easily. This problem is that this practitioner does not know where to turn.

**Dr. Barkin** felt this is what you would read in the newspaper about an overdose. This is the classic opiate plus sedative that has tripled the number of deaths in the State of Maine over a past two years.

**Mr. Ouellette** pointed out the summer newsletter is going out to all the providers. He suggested putting the analysis in stating how many folks we have and what the concern is from the DUR. The second thing would be to reach out to the neurologists and your contacts [addiction specialists] at St. Mary's.

**Dr. Weiss** reiterated they should write 10 of these letters and ask why they are doing this and see what they say. Then we will see if we can help.

**Dr. Braun** agreed that there is not a problem with asking them how we can help. He felt this was a proactive approach, but they needed to be prepared for what there answer will be. And if they ask us for things we need to be prepared to act out on them.

**Dr. Weiss** agreed that was fair.

## ADJOURNMENT: 8PM

The next meeting will be held on **September 10, 2013**, 6:00p.m. – 8:00p.m.

## J-CODE MEDICATION

**Roger Bondeson** explained that he was approached by a colleague who is looking for some guidance on J-Codes.

**Dr. Barkin** explained that J-Codes were physician administered drugs typically given in the Doctor's office, which typically do not run through the PLS. With these physician administered drugs, is there a way to come up with a preferred drug list. J-Codes tend to be very expensive. They are different than the way we usually conceptualize drugs in the pharmacy. With J-Code drugs you need to do conversions for dosing units.

**Mr. Ouellette** added on the pharmacy side everything is in real time. On the J-codes side, the drug has already left with the patient before the prior authorization even gets processed.

**Dr. Barkin** felt the DUR may not be the right forum for J-Codes because it involves taking on high cost drugs in different units.

**Dr. Weiss** asked why you couldn't use the same model using different costs. We do this the same basic way that Anthem does. They have a formulary; they have a committee; they have preferred drugs and co-pays. They have the exact same process, just different dollar signs.

**Dr. Braun** asked what their role in this was. Are we here to redesign a way of pricing these?

**Mr. Ouellette** explained the original understanding was that we need to have criteria specific for these drugs. What should be the clinical criteria that they should be using on the medical side? They also want to mirror it as closely as possible to the pharmacy side. Most of these drugs would only be seen on the medical side. They would never be seen on the pharmacy side.

**Dr Weiss** asked who is doing this now?

**Mr. Ouellette** responded in the past the medical director has done it. They were looking at a variety of health plans to see what the criteria was.

**Dr. Weiss** asked if this resembled a one-person DUR?

**Mr. Ouellette** replied yes, essentially.

**Dr. Barkin** explained these drugs go through the medical side, so the way they are adjudicated is they go - not through the POS, but through the MEMS system and GHS is the subcontractor.

**Mr. Ouellette** pointed out one of the issues they are having is looking at rates per unit. So, if something is $9.00 per milligram - or even worse- when you are looking at factor drugs and units. The dosage is $10.00 per 1000units, but the individual doses are 240,000 units. When they are getting their prior authorizations they don't know what a substantial dose is or what a recognized dose is.

**Dr. Weiss** asked if these drugs were rebated.

**Mr. Ouellette** responded that some were. They get the standard rebates.

**Dr. Barkin** asked if they could begin to apply supplemental methodology in the development of the J-Code drug list to capture the savings.

**Mr. Ouellette** explained the problem with this is that it's much more complicated than it is at the point of sale with the pharmacies.

**Dr. Weiss** felt it could not be that complicated. A Rheumatologist makes a significant percentage of his income giving these drugs to Medicare patients - somehow they have figured this out. There is no separate way of getting drugs from Medicare. Anthem must have figured it out because they do it.

**Dr. Braun** explained there were a lot of different parts to this that have to be thought through. What we could do as a Board is to look at whether one should be preferred or not. The thing that I am unsure about is when is the last time we had a preferred drug? We mostly follow the recommendations of whoever is doing the pricing. I would much prefer we spend our time figuring out the Hepatitis issues.

**Dr. Weiss** felt creating this idea of a preferred plan is only worth doing if there is some way of applying it. The way to save money is to create a structure and that does not cost that much.

**Mr. Ouellette** recommended getting a clearer expectation of the DUR and how it fits within the DURs responsibilities, the DHS responsibilities and others responsibilities, and to figure that whole piece out because it does overlap a lot of different things. We can then come back and have a discussion.