DRUG UTILIZATION REVIEW BOARD

Agency for Health Care Administration

Tampa Marriott Westshore

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PRESENT:

BOARD MEMBERS:

Anna Hayden (Chair)
Jeffrey Martorana (Vice-Chair)
Allen Moses
Diane Fagan
Vanessa Goodnow (Absent)
Larry Field (Absent)
Kevin Olson
Alfred Romay
Luis Saez
Amy Zitiello

AHCA STAFF:

Beverly H. Smith, Esquire, Medicaid Counsel
Vern Hamilton, AHCA Liaison
Arlene Elliott, RPh, Operations Administrator
Susan Williams, PharmD

MAGELLAN MEDICAID ADMINISTRATION

Rebecca Borgert, PharmD

I N D E X

P R O C E E D I N G S

THE CHAIRPERSON: Good morning. I call this meeting to order. I'd like to welcome everyone for taking the opportunity to come here this morning and provide services for the State of Florida.

Vern, do you want us to do role call, just go around the room and -- we'll just go around the room and start off with Dr. Moses there, Allen. And then, you know, just a word or two about your practice and what you do full time.

DR. ALLEN: Sure. Good morning everyone. Moses Allen. Currently I'm Director of Specialty Distribution with Lemire Health, previously with Prestige Health Choice as Director of Pharmacy.

DR. FAGAN: Good morning. I am Diane Fagan. I'm Director of Pharmacy with WellCare.

DR. OLSON: Kevin Olson, Manager in the Pharmacy at All Children's.

DR. SAENZ: Good morning. I'm Luis Saenz, I'm Director from PHC.

DR. ROMAY: Good morning. Alfred Romay,

Director of Pharmacy over at Molina Healthcare Florida.

DR. ZITTELLO: I am Amy Zittello, Medical Director for Amerigroup.

DR. MARTORANA: Dr. Jeff Mortorana, Chief Medical Officer Sunshine Health.

THE CHAIRPERSON: My name is Anna Hayden. I'm your Chair of this Board -- of the Drug Utilization Review Board. I'm a family practice physician. I work in Downtown Fort Lauderdale for Broward Health.

MS. SMITH: I'm Beverly Smith. I'm the Medicaid Counsel for the DUR Board.

MS. ELLIOTT: Arlene Elliott, Pharmacy Policy Administrator at AHCA.

DR. WILLIAMS: Susan Williams. I'm a Senior Pharmacist with AHCA.

MR. HAMILTON: And I'm Vern Hamilton, the Agency liaison for these meetings.

DR. BORGERT: And I'm Becky Borgert. I'm a Pharmacist with Magellan Healthcare.

THE CHAIRPERSON: And we have two members that are excused due to travel issues. Dr. Vanessa Goodnow could not be here due to a grounding of her plane in Fort Lauderdale

due to bad weather. And Dr. Field could not be here this morning, he's also excused due to issues as well.

Next on our agenda we have opening remarks from Arlene Elliott, she our AHCA Administrator.

MS. ELLIOTT: Good morning. Welcome everybody. Thank you for being here early on this beautiful morning. I failed to mention yesterday, so you guys can spread the word, the Agency has not made a decision yet whether the plans need to follow or not the PDL. So at this point currently all the plans should be following the Agency's PDL, the decision has not been made to change that or continue it. Thank you.

THE CHAIRPERSON: Thank you very much.

Next on our agenda is the review of the Drug Utilization Review minute from our September 26th, 2015 meeting. I make a motion to approve. Do we have a second?

DR. ZITTELLO: Second.

THE CHAIRPERSON: Any discussion?

MR. HAMILTON: Well, Dr. Hayden, I corrected the spelling of your name I believe

on page 3.

THE CHAIRPERSON: That's the editorial.

MR. HAMILTON: Thank you for pointing that out. And if there are any other corrections, let me know.

THE CHAIRPERSON: Very good. Thank you. Any other discussion? So for the final count, all those in favor of approving the Drug Utilization Review minutes with the minor editorial comment, signify by saying "aye"?

THE BOARD: Aye.

THE CHAIRPERSON: We have unanimous approval of the minutes. Thank you.

Next on our agenda we have information from the review of the P&T minutes from the November 9th, that is informational. And Rebecca will be giving us a short report of yesterday's P&T as a conduit of --

DR. BORGERT: Sure. So the P&T Committee did meet yesterday. I'm going to refer in the DUR presentation so this is here now. Now, we know that P&T normally meets the day before DUR and they did yesterday. But if you'll recall back in the fall, they had to

postpone the meeting, so P&T actually met in November. So there's one thing that came out of that November meeting that they requested that the DUR Board look into, and that was dosing of Celebrex. So we're going to talk about that today. I have that in the quarterly topics because it was requested at the November P&T Meeting. So it's just a little strange because of the timing of the last meeting.

She the P&T Committee did meet yesterday and they reviewed several classes, just things that might have an impact on the DUR Board that I'll mention.

They did review Androgenic Agents, and as you know we're going to talk about testosterone today. And they basically endorsed the DUR Board putting a ClinicalPA on the class and the DUR Board determining the criteria. So the P&T Committee did endorse the DUR doing that and we'll finalize that today.

They added Entresto which is a new -- sacubitril/valsartan, a new -- it's in the ACE inhibitor class, although not technically

an ACE -- you know, it's one of the entities that's an ACE inhibitor. Let's see, what else. For inhaled antibiotics, both Tobi and Kitabis Pak are now -- will now be preferred.

All of the -- again, we're going to talking about the novel Oral Anticoagulants today. And they -- the P&T Board voted to keep all four of the currently available commercial products on the PDL.

One thing that was referred to DUR was Xopenex because they reviewed the Beta Agonist Bronchodilators. And one member of the P&T Committee felt like the utilization was really higher then you would expect it to be, and asked us -- and referred that to the DUR Board. So that just happened yesterday, so we'll look at that in April when we meet again.

Let's see. You know, we talked in the past we looked at our P&T class, we had talked about Daliresp, and they basically were in favor of having the DUR put some criteria around that to try to tighten utilization.

I don't think there's anything else that

had -- we're going to talk today about the PCSK-9 inhibitors because you guys asked about that of the last meeting. Those were actually single product reviews yesterday, and they're both non-preferred at this time. We're talking about alirocumab which is Praluent, and evolocumab which is Repatha.

And I think that was pretty much the highlights of things that might have to do with the DUR Board from P&T yesterday.

THE CHAIRPERSON: Thank you very much.

And then other item that was on our agenda originally was Dr. Winterstein's presentation, but that's been postponed until more data is available on the Synagis vaccine and impact on our Floridians with access to that medication. So the data is not available so she's been postponed until either April or September meeting just as a follow up --

DR. BORGERT: We'll probably wait at least until the end of this RSV season so we have at least one full year of RSV data, so that won't be until the end of April, right.

THE CHAIRPERSON: And then that data may

not be available probably until our September meeting. And the main impact was reducing from 7 to 5 vaccines to see if there was any impact at all, those were questions we had. So she's been postponed. Very good.

Next, Ms. Rebecca again on quarterly DUR activity reports.

DR. BORGERT: All right. So as must of you are familiar now that you've been to at least one meeting. We typically start this meeting with -- sorry. We normally start this meeting with follow-up or updates. So during this section we talk about anything that had previously come to the Board where maybe there were additional questions by the Board about the data that was presented, so we try and follow-up with those questions.

The other thing that's presented in this section of the presentation is any post intervention analysis. So any time we do an intervention or an edit, we try to measure the impact of that. And so typically we're looking at a three-month period of time and so we always bring that back to the DUR Board in terms of looking at the impact of any

interventions that the Board has recommended. So that's what's going to be in this section.

And this first topic is one of those things. It's a follow-up on an intervention. So we wanted to look at limit the duration of therapy of skeletal muscle relaxants. We felt like patients were getting on skeletal muscle relaxants and sort of being on them indefinitely, when most of really the indications are for short term musculoskeletal type of conditions.

So what we did is we put a limit on it where patients were allowed to have six consecutive claims for -- six claims for a 30-day supply, and after that time then it would stop requiring a prior authorization.

Now, we did exempt any patients with chronic -- some diagnoses and it was diagnosed. So basically they were chronic spacticity-type conditions for baclofen and tizanidine, because those patients, it would be appropriate for them to be on long term skeletal muscle relaxant therapy.

So the edit was deployed in March. So since the way this edit worked was it allowed

six months worth of therapy, we wouldn't start having impacted claims until September. Does that make sense? The edit went in in March, but we wouldn't have had had impacted claims until September because they were allowed six months before the edit would go into place.

So when we looked at the post edit, we looked from September 25th, which would have been six months post implementation, through December 15th which was the day we did the analysis, so that was all the data that we had.

And as you can see it was a pretty substantial decrease. We had 41 percent decrease in claims, 30 percent decrease in recipients, and an overall 43 percent decrease in the number of dosage units that were dispensed, and a 37 percent decrease in the amount paid.

Now, I will have to add a caveat here. And that's I don't know the answer to this either, but, you know, back in the day when everybody was Fee-for-service and it was much a more stable population, I think maybe it

was more apples to apples. I think now maybe when we look at these numbers, I don't know, nobody knows really, on how much of an apples to apples comparison it is, because Fee-for-services are a more fluctuating population than it used to be in the past. So all we can do is take a snapshot, you know, before and after. And from what it looks like, it looks like certainly there was some effect of that edit.

So any questions?

THE CHAIRPERSON: Was there any other prior authorizations requested on any of the --

DR. BORGERT: I don't know.

THE CHAIRPERSON: Maybe we should look at that.

DR. BORGERT: I'll look.

THE CHAIRPERSON: I know that's a good point you're making about the fluctuations of the recipients.

DR. BORGERT: Right.

THE CHAIRPERSON: And the other one is, you know, the impact you can look up prior auths if it was a medical necessity or if

there was a --

DR. BORGERT: Right, right.

DR. MARTORANA: And is there any ballpark figures as far as the number of members in the Fee-for-service world that this would indicate?

DR. BORGERT: Arlene, do you know the number?

MS. ELLIOTT: Yeah. It's approximately 400,000.

DR. MARTORANA: Okay.

DR. BORGERT: And I mean the whole number is not so much this fluctuating as the individual recipient is fluctuating is what I mean when I say that.

THE CHAIRPERSON: Oh, I got it.

DR. BORGERT: Yeah. Because you might come in Fee-for-service and then go out to an MCO. So, you know, not so much the aggregate number as individuals.

This is a follow-up item from a topic that we discussed in the past. This is just a short recap. Prior to this edit we had an overall limit of 100 mls of insulin per 30-day limit, and last year the DUR Board

decreased that to a limit of seven vials of insulin and two boxes of insulin pens. Some people felt at that time that that was still a very high limit. However, when we looked at the data, it looked like the majority of patients that was kind of where the cutoff fell for the majority of patients so that's why those numbers were picked.

So not surprisingly, I don't think, when he look -- this is the slide that looked at last time -- the new dosing limits didn't really have much of an impact on the quantities that were being dispensed. Pens went down a little bit because we didn't have any real limit on pens before, so that did decrease about 13 percent.

Vials basically stayed the same, which again, is pretty much what we expected because we knew kind of that's where the cutoff was for what was being utilized.

So the Board had asked -- you know, we had some discussion last time as you recall about the fact that that seems like an awful lot of insulin for people to be using. And was it just an anomaly of the fact that that

amount was being dispensed and called it a 30-day supply and it really wasn't a 30-day supply. And so the Board wanted to look into that a little bit closer.

So what we did in -- and this was -- you know, with the DUR Board slides, kind of that's a high blood. Somebody that was getting more than 100 -- greater than or equal to 100 units per day of insulin or five or more vials per claim.

So of that same data set that we looked at originally from April to June, we looked -- and this was just strictly based on what was submitted on the claim in terms of quantity dispensed and day supply.

So if you just take that at face value, if you just take what's submitted on the claim as quantity dispensed and days supplied, then almost half the patients were exceeding 100 units of insulin per day, which seems like a lot. I think that's what the point the Board was trying to make.

I will note because one of the other questions was about the type of diabetes these patients might have. And of those high

utilizers almost 70 percent did have a diagnosis of Type 1 diabetes on file -- so at that was good -- whereas, only 28 percent had Type 2 diabetes. And 4 percent we could find neither of the diagnosis on file. Maybe some of those were gestational, I don't know, but 4 percent we couldn't find a diagnosis, so...

So in order to try to gain a better understanding of these high utilizers, we took those same recipients but we expanded the time range out to nine months so that we could look at subsequent fills.

So we had that the same utilizers, those ones that were identified in the past slide, and we looked at a nine-month period of time. And we tried to calculate a true day's supply based on time, actual time to the next time they filled the insulin prescription.

Now, several of the utilizers only had one claim in that nine-month period of time, actually 38 percent. I know. So I think that might speak to, again, the coming in and out of Fee-for-service. Like, you know, maybe they were Fee-for-service for a very short time, got one fill, and then moved on

to an MCO or something like that. I have a feeling that's probably the explanation for that. I don't know why there was --

So we, in terms of this analysis, we discarded those 38 because there would be no way to look at when their next fill was. In Fee-for-service we didn't have that information.

So of the remaining 1475 high blood recipients, when we looked at actual days elapsed between fills, the true average day supply was 36 days. So it was about a week longer than a true 30-day supply. I was kind of surprised it wasn't even more than, but that's what the number was.

It was when we looked at -- you know, there's always going to be a last claim, so we only could carry the data out so far. But in that nine-month period of time looking at the fills that they received in the quantities that they were dispensed, the average day supply was 36.3.

However, when we did that same type of thing, the number of patients who were receiving more than 100 units a day dropped

down all the way from 2,367 to only 270 recipients. So that seems a lot more likely, that there were 270 recipients who were truly getting 100 units if insulin or more a day.

So that's the information back to the Board. You know, I think Magellan and the State are, you know, still trying to get our mind around what's the best way to handle insulin utilization because it's really hard to know what an average dose is. And then we've also got the complicating factor of, you know, vials obviously can't be broken, they're dispensed as one size. Pens are usually -- the boxes are usually not broken, they're usually dispensed as an entire box. So somewhat of the -- you know, just the nature of the product, I think, makes it harder as well to, you know, really tighten down that quantity dispensed in day's supply.

So does anybody have any question questions or comments about that? That was just the follow-up information from the questions we discussed last time.

Okay. This is a post impact analysis. If you'll recall we looked at putting in a PA

on long-acting stimulants in children that were under six years of age. And we did this because none of the long-acting stimulants are currently FDA approved in this age group. And prior to the edit we had no age limits on this group of medications. And this list of medications that were involved in the edit are on this screen.

And, again, it seems like this impact did have a very large impact. So we looked at three months pre-edit and three months post-edit. The edit was implemented on July 1st of 2015. There was an 80 percent decrease in claims, and 78 percent decrease in the recipients, and then 80 percent overall in total spend on long-acting stimulants in that population. So that was an effective edit. I thought that was -- and maybe you were the first one to bring up that idea, so that was a good thing. And the PA for that is, of course, on the AHCA website. Questions? All right.

As I mentioned yesterday -- as mentioned earlier, excuse me, the P&T Committee yesterday did enforce putting a ClinicalPA on

this class and going with the DUR Board recommendations. The only update -- this was a slide that we went through that last time in terms of background. The only update to this slide would be the hours we met in September, the American Association of Clinical Endocrinologists issued a position statement that was actually somewhat contrary to the FDA warning about cardiovascular safety.

And what the American Association of Clinical Endocrinologists said was there is no compelling evidence that testosterone therapy either increases or decreases cardiovascular risk. And they encourage large scale clinical trials to assess that. So there's been a little bit of push back in terms of the FDA warnings on cardiovascular use.

Again, we saw this last time and we had some concerns about the fact that we had some patients who had some diagnosis of prostate cancer, very few had orders for PSAs, and that, you know, there probably needed to be tighter utilization around this class.

So this is just a summary of what was discussed last time. The ClinicalPA will require a baseline serum testosterone level, require a diagnosis verification, and we will require baseline PSAs. So that's what we will be doing and implementing in the next quarter for the top testosterone products as endorsed by the P&T Committee.

THE CHAIRPERSON: There's another online packet here for the ICD-10 codes. I'm not sure if F64 encompasses all the transgender codes as well -- you're seeing that as well -- is it something else to consider adding as a different ICD-10 code.

MS. ELLIOTT: If I may comment on that?

THE CHAIRPERSON: Yes.

MS. ELLIOTT: Yes. The Agency is going to discuss that internally and then we'll bring it to the Committee or to the members to the meeting -- next meeting. Because we don't have -- Medicaid doesn't pay for gender identity disorders, so this is a discussion that will be discussed internally and then we'll figure it out and bring it to the Board next time.

THE CHAIRPERSON: Thank you.

DR. BORGERT: Okay. Just a follow-up about Synagis. You probably hope this is the last time we'll talk about this for a while. Dr. Olson, I believe had -- he had expressed some concern that he felt like patients were not receiving their full schedule of Synagis doses. And so he asked for how many doses were these patients were receiving. So that's what this graph is trying to indicate.

So there were 445 recipients but we could only identify one Synagis claim. Out to 278 recipients that we could identify that got seven Synagis claims. The only caveat here is, like I said at the last meeting, we don't really feel like -- and this includes both Fee-for-service and encounter data, and we didn't feel like we probably were able to capture all of the medical claims.

So all of the hospital -- you know, the hospital administered doses, just really hard for us the way that billing is to capture that. I mean, If it's a claim at point of sale, super easy, we have that, that's all solid data.

But, you know, with a drug like this, it's administered sometimes in the inpatient setting, we're not 100 percent certain that we, you know, documented all the doses that were received on the inpatient side.

But I think the point is that you're right that, you know, it does look like that probably the majority of the patients fall between two and five doses, which is -- you know, five doses is now the current recommendation.

But certainly there is a significant population who looks like they've received only one or two doses and then don't go on to receive the following doses. Unless these were doses that they received late. You know, that one dose that we had is the dose that they received late after they've been hospitalized for many months or something and gotten it in-house. Kind of hard to know, but that's what the data looked like.

Another follow-up in -- and we saw this last time -- is talking about the use of morphine equivalent daily doses as a quality indicator tool. This is something that is

really a lot in the quality literature now about use this measure as a way of managing opioid strategies.

So we saw this last time. We looked at how many of our recipients were exceeding 100 milligrams of morphine daily dose. And the question that was asked about that data was how many prescribers were associated with those opioid claims.

And so the pie chart here represents, thankfully, the vast majority 1,007 of the recipients only had one prescriber that was responsible for all of their opioid claims that put them into that greater than 100 milligrams of morphine equivalent daily doses per day. So that was good.

You know, the 30 patients who had four -- no, wait. Yeah. There were 30 patients at four prescribers. And I don't think there were any that had five. That six -- seven patients had six prescribers and one patient had nine prescribers. So, you know, this again would be an additional way that we would look at this.

And, you know, certainly the recipients

who had only one prescriber would much less of a concern than patients who had three or more -- or four or more basically prescribers. And that might be a way that we identify recipients where we want to look into that utilization. And, you know, maybe even contact prescribers and say, you know, "Are you aware that, you know, these claims are -- there additional claims for your patient from different prescribers for these drugs?"

THE CHAIRPERSON: As a follow-up to that, when the Board of Pharmacy updated their Pharmacy Rules, 64B16, regarding dispensing of controlled substances, that was in just last month. So those poly prescribers or the pharmacist, before they issue that prescription, has to check that red flag at the point of sale because the pharmacist now has the ability to go to the PTMP. They have to take two extra hours of continuing medical education of controlled substance prescribing. They have to consult with the patient and collaborate with the prescribers writing the order. Those are recent updates.

So I think that number -- prescriber counts when you get into that high multiple prescribers for those patients, especially four and three, that's still 109 and 30 --

DR. BORGERT: Right.

THE CHAIRPERSON: -- almost 150 patients, they'll have to answer to that.

DR. BORGERT: Right.

THE CHAIRPERSON: So I think we'll see less of those numbers in terms of safety for our Floridians.

DR. BORGERT: Right. I mean, that's the ultimate solution is to have it stopped right there, and have the prescriber contacted at that point to be informed that, you know, there are other prescribers for those patients.

DR. ALLEN: I have a question as well. Is there any correlation to the Lock-In Program with this state? I guess just a high level thought, the patient who has nine prescribers or even six prescribers, I'm assuming those prescribers are probably prescribing different opioids. So if yes, are they being controlled in the Lock-In

Program?

DR. BORGERT: Arlene, I don't know if you want to address this or not, but currently the Lock-In Program did Sunset --

DR. ALLEN: Oh, Fee-for-service. Okay.

DR. BORGERT: -- I don't know -- a year or so ago. So there is currently absolutely no active Lock-In Program. But I think the Agency is looking into --

MS. ELLIOTT: Well, it's Sunset for Fee-for-service patients. The plans -- the criteria are our guidance. So, yes, they would follow them. And we're still reviewing and updating the criteria for the Lock-In Program for the plans. We have put in so many edits for Fee-for-service, that nobody felt -- it wasn't appropriate, or because all the edits that we put in quantity limits, age limits, a maximum of four or three. So that -- when we looked at the patients, there were no patients that we would be able to log in. So that was a good thing.

THE CHAIRPERSON: What about looking at -- we're looking at morphine equivalent doses, but looking at doses for our

intermediate- or shorter-acting controlled substances in terms of maximum daily dosages on the package insert and how many patients are exceeding that? If they're outside of that recommended package insert, could we put an edit at that also?

DR. BORGERT: I don't know with opioids if they actually have a maximum recommend dose on --

THE CHAIRPERSON: It's two tablets every four to six hours.

DR. BORGERT: Oh, because of the acetaminophen limit. Is that the product you're talking about or are you talking about just --

THE CHAIRPERSON: Just put the package insert -- I see the date on some of them. I'm looking at the shorter- or intermediate-acting as a possible mechanism of providing for patient care of those patients that are -- or prescribers that are exceeding the maximum daily dosage as in the package insert.

DR. BORGERT: I will look into that.

THE CHAIRPERSON: So that would be like

hydrocodone with the Tylenol.

DR. BORGERT: Right. Certainly the products that have acetaminophen.

THE CHAIRPERSON: Like oxycodones with Tylenol.

DR. BORGERT: Right, right. And that's the next piece of this down here in the bottom, which I don't if you can read or not. But that question came up last time as well about the amount of acetaminophen these patients would be receiving.

So of those recipients that we identified, 1500 of them that were receiving more than 100 milligrams of morphine equivalent daily dose, 42 of them did exceed the 4 grams of acetaminophen a day.

If you'll recall this time frame that we looked at was April 1st to June 30th. And an edit did go in on Fee-for-service on November 16th that would stop any -- that does an acetaminophen accumulation. So hopefully those 42 patients would get caught with that edit that was deployed in November.

THE CHAIRPERSON: Didn't we -- I think we talked about this before, Rebecca, as far as

the dose of the acetaminophen has been modified to 3 grams, I believe?

DR. BORGERT: You know, we talked about that and then we went back and looked at it and I think across the board it's still 4 grams. I mean, certainly at-risk patients, you know, liver disease or some things like that, it has been reduced to 3. But the last time --

THE CHAIRPERSON: I was thinking more of the older adults.

DR. BORGERT: Maybe there's an age with the 3 grams?

THE CHAIRPERSON: Yes, there is.

DR. BORGERT: Maybe the 3 grams is age-related, that could be. Because when we looked at it, it was still, you know, 4 grams. But we can go back and look at that.

THE CHAIRPERSON: And is it possible to do an edit on that as well? Can we can look at that?

DR. BORGERT: We can certainly look that, uh-huh. We'll look at age as it relates to acetaminophen dose.

THE CHAIRPERSON: I think it's -- I'm not

sure if it's 65 and how many Medicaid recipients are duly enrolled and are receiving that.

DR. BORGERT: Right.

THE CHAIRPERSON: I'm not sure if it's 65.

DR. BORGERT: Okay. Well, we can look it up, that's fine. No, big deal.

THE CHAIRPERSON: I know we sent out banner messages on that as well in the past.

DR. BORGERT: Okay. That was probably before my time.

Out last follow-up item for today, as I mentioned, the P&T Committee did look at this class of drugs, and we had looked at this last time. We were looking at adherence with therapy. And this is just -- we saw this last time. This is just quick reminder of the indications and the recommended duration of therapy.

When we looked at, you know, what types of diagnosis these patients were -- we carried it out for a six-month period of time and tried to look at diagnosis. Unfortunately, most of them we couldn't

identify a diagnose -- they didn't have any of those diagnoses on file. So I don't know if that really tells us anything.

But, you know, one thing we did kind of focus in on was the afibulizers. Now, it's a relatively small percentage of the utilizers because, you know, that age demographic tends to be, you know, less representative in Medicaid because of Medicare.

However, when we looked at a six-month period of time a lot of patients really were not receiving therapy on a continuous basis. And there's been some stuff in the literature about, you know, real world adherence data to these drugs.

And, you know, unlike warfarin, which -- I mean, these drugs haven't had any advantages over warfarin, but the flip side is, you know, they're not coming in for PT monitoring. So there's no way that sort of it's being monitored. And some people speculate because there's that less interaction between healthcare provider and patient with the monitoring of the warfarin, that adherence is actually lower with these

medications than with warfarin because of the follow-up involved.

So, you know, one of the things that we thought we might do is just pull out those recipients who had gaps in their care. So, you know, maybe they get a fill and then they don't fill it again for three months and then they fill it.

It's a small number of patients, so we could probably just letter those providers that were involved with those patients in terms of saying, "Hey, we've identified that, you know, over a period of time your patient, you know, only had, you know, adequate anticoagulation based on their claim's data for, you know, a third of that period of time," or something like that. So just kind of a heads-up to those prescribers about adherence with these medications, because obviously patients need to be anticoagulated. And adherence seems to be an issue that is coming to light with these -- with this class of medications.

THE CHAIRPERSON: You know, I think perhaps if the diagnosis was paroxysmal

atrial fib and they didn't have a test for the novel anticoagulant with warfarin, some of them are just offered Aspirin. So I'm not sure.

DR. BORGERT: Right. But these are patients who have had a fill for one of these drugs. So the concept is they filled it and then they didn't fill it, didn't fill it, didn't fill it. And then they fill it again. You know, so it's just very sporadic in terms of -- that's what I mean about the gap in care in terms of, you know, it looks like they were supposed to be taking it all the time, but based on the amount of times they're filling it, it doesn't look like they are really adequately taking the medication.

THE CHAIRPERSON: And these are continuous with the recipients?

DR. BORGERT: Uh-huh.

THE CHAIRPERSON: Okay.

DR. BORGERT: So what we'll do is we'll try to pull out those individual recipients and bring that back next time just with a letter so that you guys can see it.

And then just to follow-up -- to finish

up this section. This is a standing agenda item regarding Hepatitis C and our utilization. So as you can see there we have about equal number of recipients for Viekira Pak, which is preferred, and Harvoni. And that might be a reflection of the fact that Viekira only became preferred at the March 2015 meeting. And certainly the Viekira Pak numbers have gone up since that time.

The P&T Committee did make Daklinza and Technivie preferred yesterday as well as Viekira Pak. And this is the prior authorization information. And you can kind of just see there the number approved, the number denied, and the total numbers of requests that we received for the Hepatitis C therapies.

DR. ALLEN: A quick question for you.

DR. BORGERT: Yes.

DR. ALLEN: Is there any indication since the implementation of -- well, I guess that's making Viekira Pak preferred is the -- are the other agents -- are their uses trending downward or is the uses still similar?

DR. BORGERT: I think just relatively

speaking, yes. Because certainly the amount of Viekira Pak that we're dispense -- that we're approving has gone way up compared to what it was before March. We still see a lot of requests for Harvoni and we still get -- you know, we still really -- because Viekira Pak is a preferred agent we really try to -- and Elboni and I -- Elboni obviously is not here today. But she and I were talking about his, and, you know, I think we're going to go ahead and pull all of those PAs on Harvoni that have occurred since March and just look at them. And just, you know, kind of see what is going on with why are we still approving Harvoni in patients -- you know, there are some valid reasons sometimes.

DR. ALLEN: Sure.

DR. BORGERT: But we want to just kind of really dig a little bit deeper into that, just because of the sensitivity of this class and that sort of thing, and make sure that it's being approved appropriately.

DR. MARTORANA: I had a question. Are you seeing an uptake in requests for those individuals that don't have stage 3 or higher

disease?

DR. BORGERT: Yes. The state of Florida we maintained it at stage -- no, we have some that are F2. Which ones are F2 now? Are there any of them that are F2? I don't know. Susan will look for us.

But I will tell you that some Magellan states went down to F2 across the board. But Florida by and large stayed at F3.

DR. ALLEN: Yeah, F3 and F4.

THE CHAIRPERSON: Wasn't there a letter from CMS that we received?

DR. BORGERT: Yes, we did. And I had a link to that in your quarterly report. CMS did send out a letter encouraging Medicaid programs to broaden their approval criteria while at the same time sort of try to lean on manufactures to do their part to work with Medicaid to make this a more affordable therapy.

MS. ELLIOTT: Right. And if I could comment on that. The letter from CMS was guidance, and an e-mail was sent to all the states. And we received -- you know, it's a group -- the DEHP Group -- I don't know if

you're familiar with it. Pharmacy directors or pharmacy representatives for each state. And most of the states are just taking it as that. They're saying, "It's a guidance, we're not going to change anything at this time."

THE CHAIRPERSON: Thank you.

DR. SAENZ: I have a question on Daklinza for the -- you know. How cost effective is it? I know that it's approved -- it has a better chance for stage 3, but you still need to use sofosbuvir.

DR. BORGERT: Right.

DR. SAENZ: And it only works if they don't have cirrhosis. So if you have cirrhosis, then you have to add Ribavirin.

DR. BORGERT: Right.

DR. SAENZ: So cost effective, instead of using Harvoni, how -- you know, I understand that for a grade 3 they have no cirrhosis --

DR. BORGERT: Is Harvoni approved for Genotype 3? I think it's 1, 4, 6 -- 1, 4, 5, 6.

DR. SAENZ: They still use it. Well, they use it for 24 weeks, you know, for like

Genotype 3 it has less percentage of cure. But once it gets to cirrhosis, like they don't do as well with Daklinza. You know, it's like -- so in terms of cost Daklinza and Harvoni with stage 3 with cirrhosis, I don't know, the price.

DR. BORGERT: The Agency has made a decision more to go -- to base their approval guidelines more on FDA approved indications as opposed to the ASLD guidelines. So I'm -- can somebody look for me -- because I don't want to pull off the slides -- is Harvoni approved in Genotype 3?

DR. SAENZ: Yes. It's 24 weeks, if I recall.

DR. BORGERT: All right. I will --

DR. SAENZ: I'm just looking in the cirrhosis stage.

DR. BORGERT: Right. I know. So you're taking about Genotype 3 patients --

DR. SAENZ: Yeah. Because those with cirrhosis don't seem to do as well.

DR. BORGERT: Right.

DR. SAENZ: So it's about the same percentage as Harvoni. And I don't know how

much they cost because you have to have Daklinza, sofosbuvir, plus Ribavirin.

DR. BORGERT: Right, right, right.

DR. SAENZ: So the three. And I think you still need to do it for 24 weeks.

DR. BORGERT: Right. So I guess the question would be --

DR. SAENZ: Like for cirrhosis maybe most cost effective maybe to use Harvoni --

DR. BORGERT: Right.

DR. SAENZ: If they have cirrhosis because there may be the same chance.

DR. BORGERT: Right. I mean, obviously we only had one approval and three denials for Daklinza. Obviously this was approved later in year and this is year to date data. But, yeah, we can look at that in terms of, you know, cirrhotic versus non-cirrhotic, and what's the optimal regimen.

DR. SAENZ: And the other question I have is like now we're going to get some of -- very unlikely, but there's like very likely that people are going to get reinfected. You know, so if I look at the FDA guidelines, I think they never said this is used for

infection. So how do we handle -- I guess, in a case by case basis. How do we handle an appeal like that? How do we handle a patient that -- very few, but it's a little money.

DR. BORGERT: Currently I believe the State still has the once in a lifetime --

DR. ALLEN: Yeah. Criteria is once in a lifetime.

DR. BORGERT: -- on the therapy. I don't know that that will always remain there, but at this time that's still the situation. I have not heard of any request that we've had for retreatment but -- we've had some requests for retreatment for patients who haven't achieved an SVR, but not patients who achieved an SVR and then were reinfected. I haven't heard of that situation coming up yet. But you're right, it will eventually come up.

DR. SAENZ: It will come. But the data is showing that it's less likely for there's that -- they say it's as high as 1 to 10 percent that they may -- very unlikely, but it may happen.

DR. ALLEN: One additional question. I

also notice that there were some Peg-Intron and Ribavirin claims.

DR. BORGERT: Right.

DR. ALLEN: And I guess my question is, I guess now with the new generation Hep C agents, I really couldn't imagine a provider utilizing those agents. Are those old claims prior to the PA going into place or --

DR. BORGERT: Yeah. The date range was year to date for 2015.

DR. ALLEN: So those will just adjudicate it down.

DR. BORGERT: Yeah. I mean, the Ribavirin we'll probably continue to see because we use that still in combination --

DR. ALLEN: Sure.

DR. BORGERT: -- with several other recommended regimens. Ribavirin is still recommended. But the Peg-Intron I think will fall away to almost nothing.

DR. ALLEN: Okay.

DR. BORGERT: All right. Well, we are on to our new business section. And sometimes we take a break here, but it's only 8:45, so do you want plow on? Do you want to go on?

THE CHAIRPERSON: You want to take a break -- a 10-minute break and then we'll reconvene?

DR. BORGERT: It's up to you guys.

THE CHAIRPERSON: Yeah, we'll take a break. 10 minutes and then we'll start again at 9:00 -- or 8:50 -- 8:55.

(WHEREUPON, a brief recess was taken.)

THE CHAIRPERSON: Good morning, everyone. I'd like to reconvene the Drug Utilization Review Broad. It's 8:56. And Ms. Rebecca again.

DR. BORGERT: Okay. Just a couple things that we followed up on in the break that wanted to clarify for the minutes. We do actually -- Dr. Allen, pointed out that on the summary of limitations we do have quantity limits on products like hydrocodone A pap, we have a tablet per day limit on those things already. So those are on the summary of limitations. So we had talked about that.

THE CHAIRPERSON: So how many are the tablet limits?

DR. BORGERT: Does Dr. Allen or Susan do

you have them pulled up?

DR. ALLEN: Sure. I have them up.

THE CHAIRPERSON: I didn't think we had that. I thought we had the maximum number of scripts per month, but I don't remember tablet --

DR. BORGERT: It might be a fairly new edit in that I think the MCOs encourage that when they, you know, sort of think it's going to --

DR. ROMAY: Yeah. I think we suggested that we have a cumulative edit that takes all -- if a person is on several formations with the Tylenol, it will look cumulative and then after that it will reject it.

DR. BORGERT: Right. And that's the edit that went in in November though that I was referring to. But I think also in addition to that there are individual product tablet limits and that's what Susan is going to look it up right now and is going to tell us.

DR. WILLIAMS: For instance, Vicodin we have eight tablets per day for the 5/300. For the 7.5 we have six tablets. For Vicodin HP we have six a day. So we have them on

various products on our summary of limitations and you can find them on our website.

THE CHAIRPERSON: So for the Vicodin 5 we have the 5/300 you have eight per day? Is that what you said?

DR. WILLIAMS: It was eight per day, yes.

THE CHAIRPERSON: And the one for the 5/325 also I believe?

DR. WILLIAMS: For which one?

THE CHAIRPERSON: The hydrocodone again.

DR. WILLIAMS: The hydrocodone 7.5?

THE CHAIRPERSON: 7.5.

DR. WILLIAMS: Six per day. And the 10 milligram is six per day also. Was there another one you were interested in that I can see if we have it?

THE CHAIRPERSON: No. I didn't realize we had those edits in place already. Thank you.

DR. ALLEN: Right. And it's also the same for Percocet as well. It's also the same for Percocet as well, they have limits on them as well, yeah.

THE CHAIRPERSON: Aspirin-related products?

DR. ALLEN: Yes.

THE CHAIRPERSON: Any other limits we have? Do we have any on --

DR. BORGERT: On like single opioid agents? Is that what you mean?

THE CHAIRPERSON: Uh-huh. For the short-acting or intermediate-acting.

DR. BORGERT: Oxycodone would be the most likely one.

DR. WILLIAMS: Which one?

DR. BORGERT: Just single agent oxycodone.

THE CHAIRPERSON: And tramadol.

DR. WILLIAMS: Yeah, we have it on tramadol.

DR. BORGERT: We definitely have it on tramadol.

THE CHAIRPERSON: How many per day on the tramadol to 400 milligrams per day?

DR. WILLIAMS: On the oxy IR we have 12 tablets per day.

THE CHAIRPERSON: Is that per package insert or is that for all doses or for --

DR. WILLIAMS: That is for 5 milligram it's 12 tablet per day. For the 7.5

milligrams it's eight tablets per day. For the 10, 15, and 30 milligrams it's six tablets per day. And for the 20 milligrams it's nine tablets per day.

THE CHAIRPERSON: Thank you.

DR. WILLIAMS: And then the tramadol.

DR. ALLEN: One per day.

DR. WILLIAMS: One per day. I'm sorry.

THE CHAIRPERSON: How many again?

DR. WILLIAMS: One per day for the tramadol. That's the extended release.

THE CHAIRPERSON: Oh, extended. But the short-acting?

DR. WILLIAMS: Eight per day.

THE CHAIRPERSON: And the 50 milligram dosage?

DR. WILLIAMS: That is eight per day.

THE CHAIRPERSON: And these edits went into place --

DR. BORGERT: I can't tell you exactly when the individual product limits went into the place. They've sort have been put in over time. Some of them I think have been in for quite a long time. The one that was the most recent is the one that Dr. Romay was

talking about with the cumulative across different product lines. If you were getting, you know, prn hydrocodone; prn oxycodone, you know, Percocet, Vicodin, cumulative.

THE CHAIRPERSON: So if the recipient had to exceed this dose there would be a prior authorization?

DR. WILLIAMS: Right.

DR. ALLEN: Correct.

THE CHAIRPERSON: And have we looked at data on this? Because we looked at morphine total. Have we looked at --

DR. WILLIAMS: The short-acting?

THE CHAIRPERSON: Yeah.

DR. WILLIAMS: No, I don't think we've ever done that.

THE CHAIRPERSON: We haven't had an issue with that.

DR. BORGERT: Not that I'm aware, yeah. I think we kind of -- you know, I think that's what the quantity limits do for us is kind of try to keep that under control.

THE CHAIRPERSON: Okay. Very good. Thank you so much.

DR. WILLIAMS: No problem.

DR. BORGERT: And just for the minutes also just to note that Harvoni is not approved for Genotype 3 for -- FDA. It is recommended in the AASLD guidelines but it's not FDA approved for Genotype 3 for Harvoni.

THE CHAIRPERSON: Thank you, Rebecca, so much.

DR. BORGERT: All right. Moving on to new business. The first thing we usually do in new business is we look at upcoming P&T classes. And just see if there's anything that the DUR wants to have input with regard to that.

A class that's coming up in June for review is Mucolytics. There's really only two drugs in that class, acetylcysteine both as the 10 percent and 20 percent, and then Pulmozyme. And as you can see there, there's a huge cost factor associated with Pulmozyme. And, of course, it is only approved for -- the FDA indication is for Cystic Fibrosis, it is non-approved for other types of general Mucolytic therapy.

And so one thing that we might

potentially recommend to the P&T Committee was to create a very easy AutoPA that would look back for a diagnosis of Cystic Fibrosis to ensure that it was being limited to patients with Cystic Fibrosis.

THE CHAIRPERSON: Do you want us to vote on that?

DR. BORGERT: Yes.

THE CHAIRPERSON: So the motion would be to have --

DR. OLSON: Motion.

THE CHAIRPERSON: The motion is for easy PA for Cystic Fibrosis look back for a time period of --

DR. BORGERT: Well, I mean, typically with our diagnosis look back, I typically -- think we actually typically look back two years.

THE CHAIRPERSON: 24 months? Do we have a second.

DR. ROMAY: Yeah, second.

THE CHAIRPERSON: Any discussion. All those in favor signify by saying "aye"?

THE BOARD: Aye.

THE CHAIRPERSON: That's a unanimous

approval.

DR. BORGERT: That we can -- what's the word I want to say? Told to the P&T Committee. I forgot what I wanted to say.

Another class that will be reviewed in June are the Oral Glucocorticoids. And, again, here I think the thing that kind of jumps out at you a little bit is the Budesonide EC in 3 milligram capsules. So look a little bit more closely, we broke down the utilization.

And just as a background, the indication for that product is mild to moderate Crohn's Disease. And the way it's dosed it is a 3 milligram capsule. And the way it's dosed is patients take 9 milligrams once daily for up to eight weeks. And then they can repeat that eight-week course if they have recurring episodes for active disease. And so that's the active disease dosing regimen.

And then maintenance of clinical remission. So, you know, with steroids or however they've achieved remission, for maintenance of clinical remission the dosing is 6 milligrams once daily for up to three

months.

And the important part here is that continued treatment with Budesonide EC tablets for more than three months has not been shown to provide a substantial clinical benefit. There was actually a trial that looked at this in patients who were on -- who continued on therapy did not receive any additional clinical benefit. So that's where that recommendation comes from.

So we pulled the data and there were 46 recipients of this product from September through November of this past year. And so -- obviously that's only three months, so we expanded it to a six-month time frame to look at those 46 recipients claims. And there were on only six of those patients who did receive more than three consecutive months of therapy.

So it doesn't seem to be a huge problem. But we thought, you know, maybe one thing we would do is -- since it's just six patients, is maybe letter those prescribers regarding, you know, these guidelines and the study that supports that data and that sort of thing.

So that's what we looked at with Budesonide EC. Because, you know, initially we talked about maybe doing a length of therapy edit of three months. But when we looked at, you know, what was actually going on, at least in Fee-for-service, it was a very small number of recipients who were being prescribed outside of what's recommended. So probably not worth, you know, creating a whole edit just for the small number of patients.

THE CHAIRPERSON: So you want to vote on the letter or --

DR. BORGERT: Sure. I mean, actually we can write the letter and bring that back for the next time so you don't have to vote on it, because you'll be voting on the letter at the next meeting.

THE CHAIRPERSON: Is there an age cutoff for this? I'm not quite familiar with it because I don't use it for -- so a letter is fine.

DR. BORGERT: Okay. Like I said, when we initially started going down this path, we were thinking we would do an edit, but we

just saw that it was so few. Now, if the MCOs are seeing something different in their data set, then, you know, we might reconsider it, but that is what we saw in Fee-for-service.

DR. MARTORANA: And I guess going back to my original question is, what are the numbers that we're dealing with as the Fee-for-service numbers continue to come down, this is not really indicative of what we're seeing out there --

DR. BORGERT: Right.

DR. MARTORANA: -- in the market place because there's, you know, another million and a half --

DR. BORGERT: Right.

DR. MARTORANA: -- recipients out of the managed care arena. So we maybe have to look at is there something that we're going to have to do to bridge, or when we're bringing these classes to maybe have a template to have the MCOs bring some of their utilization --

DR. BORGERT: That would really -- yeah, that would be --

DR. MARTORANA: -- of those products so that we get a better picture --

DR. BORGERT: Right, right. I mean, we have --

DR. MARTORANA: -- of what's happening across the state.

DR. BORGERT: -- encounter data, but --

DR. MARTORANA: It's tough to sort that out.

DR. BORGERT: Right. Exactly. Yeah. I mean, that's another thing we can do -- not to give you all homework, but, you know, if you guys wan to go back to your plans and those of you that are affiliated with MCOs and look at your utilization and then you can bring that feedback back to the next meeting. And then we can certainly say if you guys are seeing that it is a problem, we could reconsider an edit.

MS. ELLIOTT: Just to piggyback on that, for the next P&T Meeting we have been requested to run data from the plans to -- for the next recommendations from now on is to include utilization from the plan. So we have our data analytics group already warned

that we're going to give them the Agency numbers and that we're going to include that utilization from the plans for the next future meetings.

DR. MARTORANA: Yeah. I think if we just -- both for P&T and DUR if we just have -- you know, if the request, then obviously with three months is probably ample time for the plans.

I mean, I don't think I'm speaking out of turn, but anyone can throw something at me if they think otherwise, that we very happily would -- you know. So we just need to go ahead and get that published. Say, "Okay, this is what we're looking for." And then everyone can kind of bring it in that same format so that we can compare apples to apples.

DR. BORGERT: Right. Exactly. I mean, I think this is all new territory for all of us. So we're trying to figure out what works best.

For the quarterly activities for this quarter. The first one was looking at metoclpramide dosing. And specifically

focusing on the risk of Tardive Dyskinesia. Metoclopramide does have a black box warning that it can cause Tardive Dyskinesia. The risk of developing Tardive Dyskinesia increase with the duration of therapy and the total cumulative dose.

And specifically in the black box warning they say that treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases where therapeutic benefit is thought to outweigh the risk of developing Tardive Dyskinesia.

So since this is associated with both high dose and duration therapy, we decided to look at both dose and duration of therapy. And it appears that we're not having a big problem with patients receiving high doses. Only 16 adult recipients and two pediatric recipients who exceeded the recommended dose -- or we did have 255 recipients who got more than 12 weeks of therapy.

So, you know, we went from July -- so July, August, September, October. So we looked at four months worth of -- and there were -- 255 in that four months who got more

than 12 weeks of therapy. So it was a pretty substantial number.

So I think maybe the recommendation here would be to implement, you know, a 12-week or 84-day continuous supply maximum duration of therapy and then require a prior auth once they exceed that just for safety purposes based on the black box warning.

DR. ZITTELLO: Did you look at diagnosis at all?

DR. BORGERT: We did not. We did not. Are you thinking about like --

THE CHAIRPERSON: Gastroparesis.

DR. ZITTELLO: Exactly.

THE CHAIRPERSON: Because sometimes we may have to. So I would exclude -- consider --

DR. BORGERT: You want to go back and look at it and exclude the gastroparesis?

THE CHAIRPERSON: Yeah. I think so.

DR. BORGERT: Okay.

THE CHAIRPERSON: You know, I think --

DR. BORGERT: Because those patients are on continuous never ending therapy.

THE CHAIRPERSON: At the lowest possible

dose --

DR. BORGERT: Right.

THE CHAIRPERSON: -- while monitoring. I think we sent out a banner message a while back.

DR. BORGERT: Again, it must have been before my time.

THE CHAIRPERSON: Yes, we did. Because it was a concern then.

DR. BORGERT: Okay. I will go back and I will exclude those patients and then I will bring that information back.

THE CHAIRPERSON: And then we'll look at creating an edit then?

DR. BORGERT: Yeah. Right.

THE CHAIRPERSON: Because I think it is a good idea, definitely. Do you want to vote on that also or --

DR. BORGERT: I mean, since we're going to have to follow-up next time, I don't think we really need to take a vote right now because we're going to bring it back up next time.

THE CHAIRPERSON: Very good.

DR. BORGERT: The next thing that the

Board expressed an interest in -- and I think this was good that the Board brought this to our attention -- was about the brand preferred. And specifically we decided to look at Pulmicort Respules.

And so just for background so that we're all understanding about the generic drug life cycle. In certain cases -- and it depends what the FDA awards. But they can award a generic manufacture a 180-day exclusivity for their generic product. It's basically there to incentivize generic companies to challenge weak patents or whatever and to reward them for doing so.

So sometimes when a generic comes on the market there's only one. And when it comes on the market, it's typically -- that first generic is typically priced at about 90 percent of brand. Basically pretty -- I think legally it can't be more than 90 percent, so it is 90 percent. All right. So it's at 90 percent of the brand name.

And so if they have -- especially if they have that 180 days exclusivity, it's at least six months before more players come into the

market. And in those situations it generally takes about a year for the price of the generic to drop. So that's the market forces that are in play there.

And with Medicaid, based on the federal rebate and supplemental rebate, oftentimes the brand product is still net-net cheaper to the State then the generic product. Based on the rebate contracts. Federal and supplemental rebates that the State is collecting back, because, again, those generics are priced almost as much as the brand name and the rebates aren't in place.

So that's what creates this dynamic of why the State brand prefer things at a certain time. So the Committee was concerned that patients -- you know, (a) that lots of calls were coming back into the practitioners, so it was, you know, a workload issue in terms of the pharmacist having to call the prescribers. And ultimately the concern was that patients weren't just getting their meds. Because it would reach out to the pharmacy and they would just leave.

So for this particular product multiple generics only become available about mid-2015 and there are currently three generic manufacturers of Pulmicort or generic budesonide inhalation on the market. And currently the net-net cost still is lower for the branded Pulmicort Respules than for the generic.

The class review of this class is due in the March P&T meeting, so it's possible that it will switch at that time. It might switch from brand preferred to generic at that time. But I can't see in the future, so I don't know if that will happen or not.

Arlene, do you have a comment?

MS. ELLIOTT: Just to clarify. The meeting is in April. It's April 1st.

DR. BORGERT: I'm sorry, I keep saying that. She tells me, "Don't say March. Don't say March."

MS. ELLIOTT: P&T is April 1st and DUR is April 2nd. But just to clarify one point is we -- or Magellan -- Celemonzel (phonetic) rebate factor, which used to be provider Synergis, you're familiar with that name

better. They give us an update every month when it's time to switch.

So, for example, if Pulmicort was to be the generic cheaper in June, we would be able to switch it before, you know, the next P&T or whatever. So every month they give us a list of it's time to switch or not.

THE CHAIRPERSON: It happened also for nimodipine and valsartan a while back. And the claims were being denied at the pharmacy because it went brand one month and it went generic. Same situation again. So I think -- I'm not sure if it's the providers that need the letter. I think it's the pharmacists, because they'll enter the data there and it stops it at the point of sale.

DR. BORGERT: Right. And so we looked at it and you guys were right. We looked at there were -- we looked at denied nebulizer suspension for inhalation claims. We had 2,000 claims in a three-month period for 1700 recipients, and only 841 of those subsequently had a paid claim for Pulmicort Respules within a seven-day period. So we think some more of them might have gotten it

farther on down the road. But we wanted to look at, you know, a time in a period of time. So we looked at seven days.

And that played, you know, half or less received the Pulmicort suspended. So I think that's true that what is happening is that claims are being denied at the pharmacy and then the patients just aren't receiving the drug.

So based on this data -- and I don't want to get into the nuts and bolts of coding because that's not the role of this Committee. But we have some limitations because of other legislatively required messaging that has to go back to the pharmacies. We had some limitations because I mean the thing -- the easy solution would be to say to the pharmacy dispense -- you know, reprocess or dispense brand name Pulmicort. Because if the pharmacy saw that message, then that would be fine.

We've had some challenges with that just based on other requirements that we have. But we did sit down and put our heads together and we think we've come up with a

solution. I won't get into the nitty-gritty of the solution by using a State class code. But we're going to try to implement a solution for this that we think will work, that we think will get the message to pharmacies at that exact time so that they will know what they need to do.

And so what we'll do is we'll work on implementing that solution and then we'll go back -- you know, if Pulmicort Respules have become preferred by that time, then we'll pick a different, you know, brand preferred, and we'll go back and we'll measure -- try to measure if this new solution that we're still in the works, still being vetted, will solve this problem basically.

THE CHAIRPERSON: Logistically is it possible -- I'm not quite sure about the logistics behind this -- but for the electronic prescribing system for people that are using electronic health records, will that alert the prescriber at that point also? Can that also be done, or is that beyond the --

DR. BORGERT: Yeah. The solution --

THE CHAIRPERSON: -- capability? I know you have preferred drugs. Sometimes in my prescribing it says "preferred." I'm not sure if it's up to date, but it will give me my preferred on the patient's profile based on their plan.

DR. OLSON: How is this handled in Prev -- the same issue was Prevacid a few years ago, how did we handle that? I mean, that didn't seem to be an issue at that time of the denied claims. Brand Prevacid was --

MS. ELLIOTT: Was it preferred?

DR. OLSON: -- rebated, so -- yeah, preferred.

MS. ELLIOTT: What we did -- and I don't know if this will answer your question because I don't know if this is what really resolved it. But we did have both, brand and generic, paid for like maybe two, three months, either one. But an alert was sent like four months in advance to allow pharmacists to get used to buying the generic so -- and then they could use their brand that was in stock.

So that was -- because we had

30-something thousand patients on prevacid. I don't know if this is as many patients. But that was a big one. And that we never had -- because we overlapped the coding, you know, the reimbursement, that was not an issue after they switched. So it was a well thought process because it was so big.

DR. BORGERT: We also do big letter campaigns for every single drug that we do this for. I'm not sure -- you know, we might be on information overload it we tried to. But, like I said, we do -- we have a solution that we think is going to work and we're in the process of sort of working through that process.

And then we will go back and if at that branded Pulmicort Respules are still preferred, we will do a post impact analysis once we get that solution implemented and we'll see if we've improved this number here.

DR. ZITTELLO: I appreciate you coming back to the Committee with that information.

DR. BORGERT: Sure.

DR. ZITTELLO: And hopefully it help a lot of kids in the state of Florida.

DR. BORGERT: Right.

DR. SAENZ: I have a question and I talked to Kevin about it. You know there is going to be a new class of drugs called Biosimilars.

DR. BORGERT: Right.

DR. SAENZ: So how is the Agency going to handle -- I guess based on the price, you know, because it's going to be an in between price, between the brand and the generics. Generics are now becoming expensive, they're not as cheap anymore.

DR. BORGERT: Yeah. We could spend hours talking about drug pricing issues. But there actually is already one Biosimilar on the market, Zarxio, the generic filgrastim, Biosimilar filgrastim. And that actually was looked at by P&T yesterday because the Colony Stimulating Factors were one of the classes that were looked at yesterday.

DR. SAENZ: And what happened?

DR. BORGERT: And based on pricing, Neupogen is still the more favorable for the State. So I think we're going to handle it just like any other generics on this market

because Zarxio was talked about at P&T yesterday.

MS. ELLIOTT: But to clarify on that, Zarxio as of now the ACA, you know, the Affordable Care Act, we are not -- the pharmacists are not allowed to substitute.

So if you get a prescription for Neupogen, you have to dispense Neupogen. If you get one for Zarxio, you have to -- so they are all -- even the Zarxio is still more expensive, they're all PA. So they'll have ClinicalPA.

So if we get a prescription for Zarxio, we would have to -- the reviewers would have to look at the criteria and approve it or not, depending, you know, if they meet criteria. But they could not tell them, "No, dispense Neupogen." At this point they cannot do that.

DR. BORGERT: Yeah. And just to expand a little bit more one that, not to get too far off on a tangent. It kind of depends on the way the FDA approves it. If they approve that they are interchangeable -- because they have the option to approve Biosimilars as

interchangeable, Zarxio is not approved as interchangeable. I think not because it's not interchangeable, but just because they weren't ready to go there yet, and they're still, you know, working through all their process.

But, you know, how the FDA designates it, if they designate it as interchangeable or not. And all of the individual states are looking at this legislatively as substitution. You know, what could be substituted and what can't.

So, yeah, we're still kind of in the process of figuring all that out. But that's what happened with Zarxio yesterday.

MS. ELLIOTT: And one more thing, if I may add for Dr. Hayden's comment about the electronic prescribing. That's a different vendor, that's not the Agency, but they have our PDL, so -- you know. And the other PDLs also from the other plans.

THE CHAIRPERSON: It gets updated elec -

MS. ELLIOTT: Yes. When we update the PDL, the electronic vendor will update it.

THE CHAIRPERSON: I see it come up.

MS. ELLIOTT: Yes.

THE CHAIRPERSON: Sometimes I see patients every 90 days and then the prescription is already written. So then the concern is bridging that change in the PDL to the patient's timing of the prescription.

DR. SAENZ: It's basically your vendor for the EMR also. So like if it's cloud-based, it would do it. But if it's like an EMR that's not cloud-based, sometimes there might be a delay of a week, a month. It depends when they update that. It's not automatically, sometimes there's a delay. And it has nothing to do with them, it's just the vendor that your company is using for the EMR.

THE CHAIRPERSON: That would be interesting. Thank you. Thank you.

DR. BORGERT: So we'll continue to keep you guys abreast of what's going on with this.

As I mentioned at the top of the meeting, the P&T Committee that met in November specifically asked the DUR Board to look at maximum daily dose limits of Celebrex based

on the available efficacy and safety data.

And their concern was that the current quantity limit that we had on Celebrex was two capsules per day. And Celebrex is available at 50, 100, 200, and 400. So since there was a two capsule per day limit, that would in essence allow people to get 800 milligrams of Celebrex a day. So that was the concern.

So we went back and looked at it. And those are the currently approved FDA indications for celecoxib; osteoarthritis, rheumatoid arthritis, JRA, and spondylitis, acute pain, and primary dysmenorrhea.

I think what has happened here is that the current approved FDA dosing ranges from 100 milligrams per day up to 200 milligrams a day. So the current approved indications their recommended dose is anywhere from 100 milligrams a day to 400 milligrams a day.

And the history of that in December of 1999 it was actually approved as adjuvant treatment of familial adenomatous polyposis, FAP, at a dose of 200 milligrams BID or 400 milligrams BID.

And then, 12 years later, the FDA actually came back and rescinded the approval of celecoxib for FAP based on two long term safety studies which revealed an increased incidents of cardiovascular events in patients on long-term celecoxib as compared to placebo.

So at that time the FDA determined that the risks outweighed the benefits for patients with FAP.

And there is no currently FDA approved indication for celecoxib at 800 milligrams a day. So we would recommend implementing the 400 milligram per day maximum daily dose.

And P&T just didn't have time to dig into all these details. You know, that's why they refer this type of thing to the DUR Board so we can look at it more closely and say, "Well, you know, why is this?" So that's why.

It seems a little bit straightforward but, you know, that's why P&T referred it to us because they were like, "Well, we think that, you know, the risks are higher with higher doses and we're allowing patients to

get 800 milligrams a day, so let's refer that to DUR and see what they want to do with it."

THE CHAIRPERSON: So there are three exceptions there. So the impact would be --

DR. BORGERT: I'm sorry?

THE CHAIRPERSON: On the data that's presented in our -- I have three.

DR. BORGERT: Okay. I didn't even realize I had put that in the quarterly report. So there weren't -- the bottom line is there weren't many patients who were receiving that, so thankfully, but there were a few. So probably the thing to do at this point, since there are no FDA approved indications for 800 milligrams a day, is to put a limit -- change that two capsule per day limit to a 400 milligram per day limit.

THE CHAIRPERSON: So do you want to put an edit in place?

DR. BORGERT: Yeah. Change the edit from two capsules per day of any dose of celecoxib to a maximum of 400 milligrams of celecoxib.

THE CHAIRPERSON: So we'll make a motion for that?

DR. BORGERT: Correct.

DR. MARTORANA: So moved.

THE CHAIRPERSON: Second.

DR. ZITTELLO: Second.

DR. SAENZ: Second.

THE CHAIRPERSON: Any other -- the other interesting thing is for these drugs are, you know, the guidelines and the FDA indications and dosing changes, we probably should look at all that in our --

DR. BORGERT: Yeah. There's a lot of that stuff that comes through. We get like --

THE CHAIRPERSON: There's a lot.

DR. BORGERT: At Magellan we do a weekly summary of basically all those type of FDA updates and that sort of thing. But I can -- so I get that report every week so I can look at that more closely and see if there are things that probably should come to DUR. I haven't really looked at that report with the thought of DUR in mind, so I can try to do that.

THE CHAIRPERSON: And also other drugs on our preferred drug list if there are high outside of those limits. I'm not sure

if we can look at that and bring it back. I mean, just for safety, I mean that is the purpose of this Committee.

DR. BORGERT: Right.

THE CHAIRPERSON: And when drugs are added to our PDL if there are limits on dosage, I'm not sure if there's an edit. I mean, do you look at that in terms of --

DR. BORGERT: Yeah. It's probably sort of on a case by case basis. You know, like when new drugs are added. When we're going about programing to be preferred, you know.

THE CHAIRPERSON: When we looked at HIV drugs I mean in terms of contraindications with certain things, I mean, we had those edits in place. But as new agents come out and drug to drug interactions.

DR. BORGERT: Right, right.

THE CHAIRPERSON: Okay. So that's unanimous.

DR. BORGERT: The next few items that we're going to look at are really just more -- as opposed to analysis, are just more data that the Committee requested at the last meeting to be brought.

So one of the things that the Committee asked -- or the DUR Board asked about was Daraprim utilization. And I think we're all familiar with the story, but just as a recap, on August 11th of this past year the manufacturer of -- the only manufacturer of Daraprim increased the price of 25 milligram tablet from $13.55 a tablet to $750 a tablet. That's based on wholesale acquisition. So that happened in August.

On October 8th, so you know, pretty much as fast as we can move as a governmental agency, we did implement a ClinicalPA program for Daraprim, instead of -- because before you could get it, anybody could get it.

And can see there the dramatic increase in spend that happened with Daraprim. We went from spending $21,548 for 15 recipients to less than half of the same number of recipients cost us $335,574.

And, you know, there was some pressure on the manufacturer at the beginning, and they had stated that they were going to re-evaluate the price. They have since stated they are not going to change the

price. So $750 a tablet is here to stay.

There are some -- I will tell you that some PBMs, some large PBMs in the country are looking at compounding pharmacies who are compounding this in combination with Leucovorin. And some of the PBMs in the country are going that route in getting the compounding product from a pharmacy I think in California who is offering it as opposed to, you know, going with this scenario.

DR. ALLEN: Question.

DR. BORGERT: Yes.

DR. ALLEN: So this story, to your point, was sensationalized. I mean, I think everyone knew about it. But is there any way that the Committee can be notified in the event that there's subtle price increases? So every manufacturer is probably going to increase their drug, you know, to some extent, you know, at the end of the year.

But for things that are anomalies, for example, doxycycline on the generic side, that was one. You know, I don't know. If we just pick a number and just say, "Hey, if a drug increased by 50 percent," or something

of that nature, can we just be notified so we could, you know, keep an eye with it?

DR. BORGERT: The thing about that and -- yes. The answer is yes. But we actually at Magellan -- since this kind of has starting to be -- we have a process where we actually get a weekly report of generic price increases that have increased more than -- there's a cutoff. I think it's 10 percent or something.

But what typically happens is there's multiple NDCs for generics, and only some of the manufacturers have increased their price dramatically. But there are still other NDCs on the market that haven't increased so dramatically. And so we look at what percent of our utilization was the product that -- product increase and spend a lot or the others to know whether or not we need to take some action.

So I think the thing that made this situation so unique was there was only one manufacturer. But I agree that we can -- because we are already doing it. We're already monitor -- Magellan's already

monitoring that in terms of across the board if there is very few manufacturers or if all the manufacturers of a product or both, let's say. Most manufacturers have had a similar increase, then that would be something that we could bring. Would that be okay?

DR. ALLEN: Yeah. I think that would be great.

DR. BORGERT: Because I think there a lot that do have these dramatic price increases, but in most cases what we're finding is that there are other manufacturers, other NDCs that are available that haven't increased their price. So as an aggregate the price of that drug hasn't bumped up so much.

Dr. Olson, were you going to say something? Okay. So I will -- I took down that 50 percent and I will make a note about that and we'll bring that back if we find that. Okay.

The Committee also asked us to look at top therapeutic classes by claims count and by total spend. And so, again, this is Fee-for-service. I think it's probably -- the numbers are probably different, but I

think overall similar in terms of placement with claims count; anticonvulsants, antipsychotics, narcotic analgesics, SSRIs, beta-androgenics, NSAIDs, Penicillins, anti-anxiety, and second generation antihistamines.

So the Committee hasn't done a lot with anticonvulsants, but certainly we've done a lot with antipsychotics, and certainly we've done a lot with narcotic analgesics. But in terms of number -- just sheer number of claims, this is what the top ten basically looks like.

THE CHAIRPERSON: Do we have any edits in place for maximum daily dosage of anticonvulsants? Have we looked at that data --

DR. BORGERT: Susan -- I don't know.

THE CHAIRPERSON: -- for package inserts, can we do that?

DR. BORGERT: Not off the top of my head if we have a limitation on anticonvulsants. I don't know. Let's pick one.

DR. WILLIAMS: Yes, we do.

THE CHAIRPERSON: Can you talk into the

mic?

DR. ALLEN: Yeah. We have one Lamictal. I don't know if it's across the board. But there's a few on fee.

DR. BORGERT: We can look at that. I mean, we can look at PDL preferred anticonvulsants and we can look at all of them and see --

THE CHAIRPERSON: Maximum daily dosage.

DR. BORGERT: -- how many of them have maximum daily dosages on them. We can do that, yeah.

DR. ZITTELLO: I'd also be curious to the diagnoses here.

THE CHAIRPERSON: Yeah. Because we use it for neuropathic pain.

DR. BORGERT: Right. Progesic is used for, you know, all different kind of psychiatric.

THE CHAIRPERSON: Migraines. We use it a lot of them.

DR. BORGERT: So it is hard to them pin down how many of them have --

DR. ZITTELLO: And they might be on it for long term and it might not make any

difference and things like that.

DR. BORGERT: So maybe look at how many of them we can actually find a diagnosis of epilepsy on file for, or just look at what the diagnosis is.

THE CHAIRPERSON: I'm not even sure if it would make -- I mean, just look at what -- those are important things. I mean, we use anticonvulsants. But I think it's -- I mean, in terms of protecting the safety making sure that the maximum daily dose doesn't exceed the number that it's indicated for, package inserting. I think that would be -- because we have so many uses of anticonvulsants.

So bring back the data on the multiple uses is one thing, but I think it's the safety issue and poly -- I don't know if we can do polypharmacy or a drug -- you know, the paid for interactions, that's rejected at the point of sale. We had an edit in there at one point on that.

Any other ideas?

DR. ROMAY: Currently anticonvulsants are on AutoPA, correct, so it looks back for a diagnosis?

DR. BORGERT: That's correct. For the branded products. The generics I think they go through --

THE CHAIRPERSON: They're preferred.

DR. BORGERT: Yeah, they're preferred and they go through the AutoPA.

DR. ROMAY: Because I mean I'm concerned like topiramate, for example, that's being used for obesity, for weight loss. So that would be something to look at to see if those people are truly have the right diagnosis because we don't cover it.

THE CHAIRPERSON: Which drug was used --

DR. ROMAY: Topiramate, Topamax. Yeah, it's also in combination with another -- with phentermine as well. So, I mean, when it comes in like that, I mean obviously it doesn't get paid, but...

DR. BORGERT: I'm aware of that. So is there an edit on the combination of topiramate and phentermine?

DR. ROMAY: I'm not sure about that.

MS. ELLIOTT: Well, if the indication is weight-loss, it's not --

DR. BORGERT: Well, I don't think it's an

FDA approved indication. But I don't think we're looking for the -- I'm not aware if we looked at the combo, but...

THE CHAIRPERSON: I don't think it's mentioned on our preferred drug list.

DR. BORGERT: No, it's not. No, no, no.

THE CHAIRPERSON: But if they filled a claim, you could look at that. But it wouldn't have been filled --

DR. BORGERT: We wouldn't have.

THE CHAIRPERSON: -- so how can you do it?

DR. BORGERT: Yeah.

THE CHAIRPERSON: And then looking at the SSRIs, do we have maximum daily doses for adults as well? You knows we have --

DR. BORGERT: Yes. Yes, we did maximum daily doses of antidepressants for adults I think within the past calendar year we might have done that.

THE CHAIRPERSON: I think it was children.

DR. BORGERT: We've had children for a long time. But we did adults just this past year, uh-huh.

THE CHAIRPERSON: All right.

DR. BORGERT: And then the other way to look at the data is by total paid out. The antihemophiliac factors are not going to be an issue for the MCOs because those are carved out to Fee-for-service. But, again, you can see it kind of mirrors the number of claims in terms of anticonvulsants, antipsychotics. Insulins, which we're actively working on. Orally inhaled glucocorticoids. Attention deficit disorder drugs, which we we've worked a lot on in this Committee and has some new edits in place on those.

THE CHAIRPERSON: We don't use them. It's not approved for adults over -- Medicaid doesn't cover it for adults over 18?

DR. BORGERT: No. We do. We do. We just have -- but we did put in those maximum daily dose limits on the adults for the ADHD drugs. But we do cover it.

THE CHAIRPERSON: And then the last one is antineoplastic systemic enzyme inhibitors.

DR. BORGERT: I think that's like Gleevec type of thing in that -- for CNL.

THE CHAIRPERSON: We had an edit or a safety --

DR. BORGERT: Yeah. We have it across the board on all oral oncology -- anytime you have a new oral oncology agent that comes on -- I mean, they're not preferred, but we still put quantity limits on them based on the fact --

THE CHAIRPERSON: Yes.

DR. BORGERT: -- it's right when they hit the market.

THE CHAIRPERSON: Yeah, we did last year and it worked out fine.

DR. BORGERT: Yes. And we continually update that. We had like seven new oral oncology drugs in 2015, and we added all those to that edit.

THE CHAIRPERSON: And I don't see in terms of the HIV drugs in here.

DR. BORGERT: Yeah. Interestingly or not. I guess it's the era of generics. I don't know. More of the HIV drugs are available generically. So from a total cost standpoint, they're not --

DR. ROMAY: I'm curious to know about the

human growth factor, the human growth hormones, did that make the list, because that was -- I think that was -- last time it was up for review.

DR. BORGERT: It was up for review yesterday. No. When I'll pulled the data, it didn't show up. But I'll go back and look at where it falls.

DR. ROMAY: But I think that would probably make the list because that's their -- it's up for utilization.

THE CHAIRPERSON: Yeah. That had a prior auth on that.

DR. ROMAY: Well, it has an AutoPA on it just to check the diagnosis, but...

THE CHAIRPERSON: Right.

MS. ELLIOTT: Which --

DR. BORGERT: I'll pull it and I'll find out where it falls in the scheme.

MS. ELLIOTT: Yeah. Just to follow-up in P&T on the human growth hormone, it was voted to keep Genotropin and Saizen as preferred, but it's going to be a ClinicalPA for all.

DR. ROMAY: Okay.

MS. ELLIOTT: And -- are you going to

bring that up?

DR. BORGERT: Yeah. You're right. I skipped that. I somehow missed that on P&T review. They did -- P&T did request that DUR look specifically at idiopathic short stature syndrome. And it's really -- it's kind of going to be difficult because one of the preferred products has an FDA approved indication for that. And we're pretty much mandated to cover FDA approved indications, so if that's going to be a preferred product.

And the point that was made at P&T is well there are other drugs that are preferred and had an FDA approved indication that -- so, for instance, they mentioned, you know, like the PAH drugs, but we don't cover them for erectile disfunction.

So they were looking at -- you know, the question to the DUR -- that they wanted to bring to the DUR Board was, you know, is that -- is idiopathic short stature, does it fall sort of into that box? And, you know, it's sort of an Agency decision as well.

But, you know, I don't know, it's gray. I'm not even sure how we'll tackle it, but

I'm certainly open to thoughts and ideas of the DUR Board surrounding that issue.

DR. ROMAY: I mean, I think personally -- not personally. I think from a standpoint of, you know, making sure that that person has proper -- you know, initial work up for a growth hormone to see to make sure that they really do meet -- because a lot of little patients we have a short stature obviously fail their stimulation test.

I mean, they way are over the 10 mark. So we need to look to see to make sure that they didn't get an adequate follow up. Because I know for a fact a lot of members are just seeking these drugs for -- you know, because they want to be at a particular parental or maternal height. And obviously if that's not there genetically, really it's hard to kind of base the need for that member to use that drug.

So we just want to make sure that those people are adequately being -- they truly need the drug and they have -- and the idiopathic short stature that's something, as you say, is very gray. Because, you know,

you don't want to not give them therapy, but you also want to make sure what truly is happening. Is the IDF level, you know, really low? Is it really showing that they're are at -- you know, division at IDF.

DR. BORGERT: So what you're saying is that perhaps with putting a ClinicalPA on the class and really looking -- you know, having, you know, a pharmacist review those tests and that sort of thing that maybe will sort of take care of the problem. At least somewhat address the issue.

DR. MARTORANA: Right. Because we review a lot -- to Dr. Romay's comment that you get these requests and they come in. And genetically, you know, mom's 4'11", dad's 5'1", and their mid parental height is 5-foot, and they're on track to be 5'2", and all of a sudden you're getting a request for the growth hormone. You know, what are you trying to do? You know, it's obvious that the kid is genetically predisposed and unfortunately he's got short parents.

DR. ROMAY: And a lot of times they're growth velocity is going to be right there.

It's, you know, on track to get them where they're going to be. So even looking at their growth velocity and looking at their bone age to see to make sure that they really truly two standard deviations below the norm.

DR. BORGERT: Well, I think then it sounds to me like maybe what we should do here at the DUR Board is, we will bring back to you all the ClinicalPA data -- the specifics of the ClinicalPA that get designed. And then we will do a pre and post. And we'll look at the diagnosis mix, and we'll also just look at overall utilization and we'll kind of see what impact that had on it. So I think that's probably the way the DUR Board should go at this point.

MS. ELLIOTT: Yes. And this has been a topic on every single meeting that we've had with the plans, is the tightening of the criteria for the human growth hormones, specifically ISS. So we -- I told them yesterday that we're going to bring it to the Board, we're going to look at parameters so it's not going to be open access like it is

right now, or at least that's the goal.

DR. BORGERT: So we should have those parameters developed by the April meeting of the DUR Board and we'll bring that back for the DUR Board to review and comment on.

THE CHAIRPERSON: Good.

DR. BORGERT: Any other comments about the topic of classes?

THE CHAIRPERSON: I think we streamlined everything.

DR. BORGERT: We're going to revisit growth hormone. Okay.

Another question that was asked the last time was about the PCSK-9 inhibitors, Praluent and Repatha. So my hyperlink is not working. You know why? Because I'm not on the Internet.

THE CHAIRPERSON: The package insert has parameters in place for most of these drugs.

DR. BORGERT: Right, right. So in -- to cut to the chase, we really have had very little uptake with these medications I think is really what the Committee was interested in asking.

We've had zero inquiries regarding

Praluent. And we have had, you know, a total of seven inquiries regarding Repatha. None of which -- none were approve and two were denied. So I don't know if the MCOs are seeing some of sort of the same thing, but that's what we're seeing in Fee-for-service is little uptake.

DR. ROMAY: I just want to go back. I don't know if we can go back, but looking to the oral oncology I mentioned that these are up and coming -- the updates?

DR. BORGERT: Correct.

DR. ROMAY: Are you looking to update also continuation of therapy criteria? Because there are, you know, some parameters that we do feel that the members should be hitting to make sure that the drug is really actually working, that there's no progression of disease. So looking at markers -- not really markers, but looking at, you know PD-1 analysis for different types of drugs, especially for the Opdivo and things like that. I know Opdivo is a medical benefit, but there's other drugs out there as well that have -- you know, looking at those

particular parameters to make sure that those drugs are actually really working?

DR. BORGERT: I'm trying to think of an example, because actually I'm board certified in oncology, so that's kind of my wheelhouse. I'm trying to think of an example of --

DR. ROMAY: Like for instance it's the -- like the Revlimids and things like that that you're looking for particular, you know, molecular remission.

DR. BORGERT: Right, right, right. Yeah. I think we do have that for the most part in our continuation of therapy criteria. Again, like I said, we do get a list of all FDA changes every week. So if there is some change in, you know, the recommendation, we will -- we do update criteria and address that.

I have to go back and look at it across the board. But off the top of my head I can't really think -- I mean, a lot of the drugs are -- you know, you look at the biomarker up front before you put them on. You know, whatever, there's several of them. You know, whether it's a EGFR or -- all the

TPIs basically that you look for that.

And, you know, now there's several new -- like if you failed Revlimid and now there's two other alternatives. So, you know, looking for that factor up front. But in terms of continuation of therapy --

DR. ROMAY: So it we would be running kind of restaging to make sure that there's a continuous progression up towards becoming, you know, in remission or destroying some kind of -- because we don't want to -- these drugs are very expensive to be put on. And at lot of times if there's resistance, members don't respond and they have to changed to another agent.

So where do you kind of make sure that the patient is really truly on continuation? Because the least we want to do is not approve it, obviously we want to make sure that that person gets clinically -- you know, clinically stable.

THE CHAIRPERSON: So the prior authorization, is that done annually with the submission of data by the oncologist or --

DR. BORGERT: Typically the length of

approval varies between three and six months for oral oncology agents and then they have to resubmit for a --

DR. ROMAY: And that's how we do it. We do it on a three to six month basis just to make sure that there is that response.

DR. BORGERT: Right.

DR. ROMAY: But where there's really no continuation of therapy criteria to go by and we're just looking on submission, there's really -- some of them do, but not all of them do.

DR. BORGERT: Right, right. You know, I think maybe the other maybe catch 22 you could run into there is, patients who are terminal or, you know, have an incurable disease a lot of times they will continue on therapy just until they have clinical progression.

You know, they're not scanning these patients all the time, they're not doing all that sort of stuff because -- I mean, what's the point, really. There's nothing more to offer them and they have an incurable disease, so they're basically just going to

continue on the drug until, you know, it's obvious that they have clinical symptoms of progression, so... I don't know.

But I can go back and look at that and see if there's anything that we need to tighten up there. And maybe we can talk up on some other specific examples --

DR. ROMAY: Sure.

DR. BORGERT: -- that we can take a look at.

DR. ROMAY: Sure.

THE CHAIRPERSON: Very good. And as far as the question for -- on this request for the PCSK-9 inhibitors, we don't have a prior auth -- I mean, it says here "prior auth request." I mean --

DR. BORGERT: We have prior auth criteria established. And I'm sorry, I forgot to get online so that my hyperlinks would work. I had a hyperlink to the ACHA website, but I forgot that I needed to get online to access that. So I'm sorry about that.

DR. MARTORANA: That is probably one we want to bring in. I mean, there's care numbers on requests, denials, and approvals

and we are starting to see some pressure from that.

DR. BORGERT: And, you know, basically the same type of thing with CF therapies which the Committee asked about, both which is Kalydeco and Orkambi. And, again, my hyperlinks, I'm sorry. I was going to show you the specific criteria.

But for those of you who aren't familiar with these medications, these are CF patients who have a specific mutation that has to be identified in order to qualify to receive these therapies. Like I know with Orkambi it's the 508 -- they have to have homozygous F508 for a patient or something like that.

So they have very specific criteria in terms of which CF patients and the mutations that they have that would respond to these drugs. So that's the basis of the criteria is making sure that these --

THE CHAIRPERSON: Or, yeah, the failure at regular statins with the combination.

DR. BORGERT: For the PCSK-9s, right, that's part of the FDA labeling is that they have -- they're on maximally tolerated statin

therapy.

THE CHAIRPERSON: Along with bococizumab as well.

DR. BORGERT: I think bococizumab is in our criteria for --

THE CHAIRPERSON: And that's on our preferred drug list as well?

DR. BORGERT: Yes, yes.

DR. CHAIRPERSON: So that would satisfy that.

DR. BORGERT: With the CF meds, we are having more uptake with those. We have approved five Orkambi requests and six Kalydeco requests in calendar year 2015, and that's just what we saw in Fee-for-service. So, again, that might be something that the MCOs want look at their utilization and see if it mirrors what we're seeing in -- we did not deny any requests for those two drugs. So it seems like when they're requesting it, it's appropriate. You know, they're requesting it for the appropriate patients.

We have had some discussions with outside groups regarding a few nuances to the criteria that we're evaluating changing, but

for right now we haven't denied anybody based on our current criteria. So it would be hard to make the argument that our criteria are too restrictive.

DR. ROMAY: Can I just go back to -- I know you mentioned at the beginning of our meeting today that Tobi was now -- it's now PDL, so there's no criteria to follow in terms of having a sputum culture or anything of that nature?

DR. BORGERT: We do have, don't we?

MS. ELLIOTT: AutoPA.

DR. BORGERT: Oh, AutoPA. It's going to be AutoPA.

DR. ROMAY: It's going to AutoPA. So it's not going to require any.

DR. BORGERT: Right. All right. That's all of the information that was requested for this quarter.

So just moving on to proposed topics for next quarter. I'll talk about what I've heard and then we'll open it up for the Committee members to make suggestions.

What I heard last time was talking about, you know, looking into some of the asthma

quality measures. Having this Board look into some of the asthma quality measure. You know, kind of a springboard conversation from the Pulmicort conversation.

And so looking a little bit into what those quality measures are, percent days covered for inhaled corticosteroids in patients with a diagnosis with persistent asthma. Percent based covered for long-acting beta agonists in patients with a diagnosis of persistent asthma. Those were two quality measures that are recommended for asthma. Another -- and then those obviously are evaluating adherence.

And then an asthma -- something called an asthma medication ratio, is the recommended asthma quality measure. And that is the percentage of patients with persistent asthma who had a ratio of controller meds to total asthma meds of greater than 0.5 or greater.

So, you know, basically that these patients aren't just being treated with short-acting beta agonists symptomatically. That they're on underlying therapy, you know, corticosteroids, first line, to manage it if

they have a diagnosis of persistent asthma.

And one of the nice things about the ICD-10s it does break out asthma by mild, moderate, and severe, persistent -- and it specifically talks about persistent asthma. So we can hone in on those patients that have persistent asthma as opposed to exercise induced asthma or things like that. So I think we can identify that population and look at one or all of those quality measures surrounding asthma if anybody is interested in doing that.

THE CHAIRPERSON: Well, the other thing when you look at this data sometimes the leukotriene inhibitors are also used to measure inhaled corticosteroids. So I think I would add that drug in there because a lot of -- some patients can't coordinate and some of them are intolerant due to thrush or side effects, you know.

DR. BORGERT: Right, right.

THE CHAIRPERSON: Some of the things that we see --

DR. BORGERT: Right.

THE CHAIRPERSON: -- that may or may not

be on there.

DR. BORGERT: And since we're going to narrow it down to the persistent asthma population, I think we can do that. I mean, in the past we've struggled a little bit with that because so many people are on it for seasonal rhinitis or that sort of thing with Singular. But we're going to just specifically look at the persistent asthma patients. So, yeah, we'll look at the leukotriene anti-agonists.

DR. ZITTELLO: Based on the quality measures it's a controller medication it's considered so we do need to look at that.

DR. BORGERT: Okay.

DR. OLSON: And I think we asked last time, can we tie this into ER visits or hospital admission data?

DR. BORGERT: I will do my best.

THE CHAIRPERSON: Admissions or visits period? Because I think there's more visits.

DR. OLSON: Well, I think tied into ER -- yeah, well --

THE CHAIRPERSON: ER visits.

DR. OLSON: Yeah.

DR. BORGERT: Well, with hospital admissions we do have the ability usually to get an admitting diagnosis. So, you know, we can look at hospital admissions specifically with an admitting diagnosis of asthma exacerbation or whatever the terminology is. So we can do that.

DR. OLSON: That would be great, yeah.

DR. BORGERT: We can do that.

THE CHAIRPERSON: Any other proposed topic? We have anticonvulsants, we talked about that.

DR. BORGERT: Right, right.

DR. ROMAY: I wanted to bring also, I know we've talked about this a lot in the past, the antipsychotics. We continuously see a huge epidemic of multi-pharmacy on those agents. We see people on three atypicals, which is very frightening to see that going on.

And it's really -- it's a hard sell when you reach out to that physician and try to, you know, kind of understand what the therapy is. And it's just very hard to, you know, break down that door and try to get them back

down to at least a single agent.

So there's a lot of mishandling of those. So I just want to see if maybe we can hone in on that a little bit more details on that.

THE CHAIRPERSON: I thought we had an edit in place for that already.

DR. BORGERT: We do. I'm trying remember what the antipsychotic polypharmacy edit is.

DR. ROMAY: Yeah, it is. But I just continue to see requests come through for that, for PA. And so --

DR. BORGERT: Yeah. Susan, I think that's -- I agree, I think that's the issue. I think the edit hasn't actually been -- it's Fee-for-service, yet it hasn't actually been programmed or implemented now. MCOs were --

DR. ROMAY: We have. We have in our local plan and we started seeing a huge influx, you know, of those members on two or more.

DR. BORGERT: So how does your edit work? Doe sit stop -- you know --

DR. ROMAY: It will message out. You know, but still we're seeing these physicians adamant about having them on three. So it's

hard to kind of -- from an educational standpoint to get them to --

THE CHAIRPERSON: And what's the justification on the prior auth? What are they writing on there?

DR. ROMAY: They're member is stable and they understand that the member been there -- you know, haven't been to the hospital, there's no decompensation. So it's kind of hard. But I think it's very dangerous to have a member on three of those.

THE CHAIRPERSON: Are they maxed out doses?

DR. ROMAY: Yeah, pretty much. I mean, we have a psychiatrist that we run them by, but still it's just very hard to kind of address that behavior.

DR. BORGERT: You know, in the pediatric population obviously we have USF on board that helps us with that, but with the adult population we don't have that luxury.

DR. ROMAY: Yeah. Inappropriate use too they use the Seroquel Extended -- Immediate Release for sleep which really doesn't have that indication. So that's another one they

add in there as kind of an adjunct to --

THE CHAIRPERSON: We had looked at that a few years back.

DR. BORGERT: Okay. Any other suggestions. Dr. Allen?

DR. ALLEN: Sure. I just wanted to say thank you this morning for running a very thorough and efficient meeting here. I think we're getting out on record time.

I just wanted to ask if we could take a look at Prevacid Solu Tab? After I'm looking at the data, the Q3 data. I noticed that the -- certainly from an economic perspective, the cost of Prevacid Solu Tab actually, you know, is more than Prevacid, or omeprazole, pantoprazole combined. And I think we're at about 2500 claims for Q3.

And I guess my question would be, are there that -- certainly with this Medicaid population there's going to be a lot of kids. But are there that many patients that actually need the solu tab? So for Zollinger-Ellison Syndrome, I mean, right, there is a -- I don't think there's a closed window on it. But the FDA indicates and

generally supports 8 to 12 weeks and then it can be stopped.

So I mean, after a review of the data perhaps there's an opportunity to implement an edit to stop it.

DR. BORGERT: We can look at the age group. We have an age limit, I think. But we can look at age group. And also if we kind find out if the have a G-tube or something like that. Because I think in that population that drug gets used in that population too. But we can try to look into that and just look at what the utilization picture looks like.

DR. ALLEN: And second in here is Bromfed DM. It certainly it doesn't have the same economic impact of Prevacid Solu Tabs, but I noticed that there's -- obviously there's a generic for the Bromfed DM cough syrup, and we had about -- close to about 200 claims in Q3 for the brand. So I can't imagine why 200 people would have to use the brand, but I might be missing something.

MS. ELLIOTT: I'm sorry, Moses, what was the drug?

DR. ALLEN: Bromfed DM, B-r-o-m-f-e-d.

DR. BORGERT: That wasn't one of the ones they had the recall on recently, was it?

DR. ALLEN: It might be.

DR. BORGERT: There was a recall on cough syrups, so...

DR. ROMAY: Was it probably Cardec DM?

DR. BORGERT: I'm sorry?

DR. ROMAY: Maybe the Cardec DM?

DR. BORGERT: It was on the manufacturers. I think it had to do with the unit dose cups not being accurate so that's they were worried about that.

DR. ALLEN: Because the Q3 compares as to generic from a utilization standpoint is at 29.28, and the brand is at 1.87 or something. So it's not going to break the bank or anything, but just something to keep an eye on.

And, lastly, from me I promise.

DR. BORGERT: That's fine. It's good to have input.

DR. ALLEN: Just from a OTC standpoint, so just right practically all over the non-sedating antihistamines are now on the

PDL, the desloratadine, the loratadine, et cetera. And I was just asking, is that the same approach with the Board or should the Board consider it the same approach with PPIs, of course Nexium and Prevacid and whatever else is over-the-counter now? And I just want know if there was ever an opportunity to do an economical comparison to see if it may be beneficial to have those products on the OTC?

DR. BORGERT: You know, I think we can take that back to provider Synergis and ask them that question and bring you back what we find out.

THE CHAIRPERSON: That's a recent update to the formulary because that wasn't on there a while ago. It was taken off and back on in terms of the Prevacid.

DR. OLSON: You know, tying into that, I know last meeting talked about even the acetaminophen over-the-counter and those products as well. Did we ever -- did that go anywhere?

DR. BORGERT: Remind me.

DR. OLSON: We talked about the Medicaid

approving pain for acetaminophen, or pain for ibuprofen.

DR. BORGERT: Oh, yes. I'm glad you brought that up. Yes, thank you. Yes, we did do that. For children under six. There are now acetaminophen products available on the PDL for children under six, specifically for -- to address the codeine issue. The removal of codeine approval in children under the age of six, there's now acetaminophen available and ibuprofen as well.

DR. OLSON: Still with a prescription under six they can get it?

DR. BORGERT: Yes, yes, yes.

DR. OLSON: Was that --

THE CHAIRPERSON: Do you remember when that went in, Arlene?

DR. OLSON: -- communicated out?

THE CHAIRPERSON: I got the letter a month ago, right.

DR. BORGERT: Yeah.

DR. OLSON: Did you?

DR. BORGERT: Yeah.

DR. OLSON: The providers got a letter on that one?

DR. BORGERT: Yeah. Well, it surrounded the whole coding thing and in there it mentioned the fact that -- it was actually a banner message. It was a banner message, not a provider letter. I misspoke.

But if you go and look up on the banner messages, you'll see it. And as part of that whole coding thing they have availability of acetaminophen for children under the age of six.

Just to follow-up on that, I don't know if anybody saw that the FDA Pulmonary Advisory Committee recently refuted it. And I think where it's going is, I think they're going to restrict it in anybody under 18, but we'll see. I mean, they really -- they recommended really, really narrow. So I guess we're a little bit ahead of the curve in terms of --

THE CHAIRPERSON: I actually looked at -- when you put it in the -- I actually looked it up and I'm like "what?"

DR. BORGERT: Yeah. So --

THE CHAIRPERSON: Very good. Any other input or any other --

DR. ROMAY: I wanted to just mention opioid antagonist the naloxones and that type of drugs. I just wanted to know if there's -- I know we want to, you know, have access -- our members have access to that drug, but right now currently it has a ClinicalPA but it doesn't really -- the criteria doesn't really allude to any kind of like what's required from the prescriber in terms of how the drug screen should be reported.

Right now a lot of times we have self-reporting from the doctors, and it's really kind of hard sometimes to really truly, you know, interpret whether it's really coming from the doctor's office or it's just -- because it's kind of like, "yes," "no," you know, the check off here or the check off there. And we find out over the course of time that sometimes those patients come back positive for, you know, either ecstasy or heroin.

So it kind of leads me to believe that a lot of times I don't know how true those results are coming from the physician. So I

don't know if we can mandate some kind of like -- it's okay to do a random drug screen, obviously, if they come in and you want to do a random drug screen in the office. But really they should be utilizing an outside lab to actually really do the analysis.

DR. BORGERT: And you want to see the drug screen as part of their continuation for therapy.

DR. ROMAY: Exactly. Right. Versus it just being a checkmark on bupropion or -- you know. Because a lot of times we get requests back that the members even negative to bupropion. So what are they doing? Are they selling it -- you know, that's a red flag for us. I mean, obviously those get denied, but truly to get an accurate result from a lab versus just a regular "yes/no" checkmark grid would be maybe something that we may want to consider just to substantiate the justification for the PA.

MS. ELLIOTT: So you're saying follow the condition with -- the checkmark with documentation?

DR. ROMAY: Right. Or actually have the

actual lab either from LabCorp or from -- showing the actual drug screen showing that they're negative for all these things.

DR. WILLIAMS: With them Fee-for-service they already look at those labs.

DR. ROMAY: Yeah, but I don't know for -- I don't know for -- when we see RPAs we get a lot of physicians just sending in that little grid that just says -- they check off "yes" on or "no" positive or negative. But it's not truly an actual lab analysis report coming back from either LabCorp or, you know, from Quest.

DR. WILLIAMS: That's a requirement with them Fee-for-service. If they don't have that lab attached, they'll ask for it. They'll send it back and say send us the labs.

DR. ROMAY: Right. But I don't think it's defined on the actual forms that we have now that it actually has to truly be from a lab.

DR. BORGERT: Okay. I will -- Susan, I'll delve into exactly the procedure for Fee-for-service and maybe look into updating

that PA form to reflect that requirement.

DR. ROMAY: Great. Thank you.

DR. MARTORANA: But that could just be a qualitative -- quantitative lab result.

DR. BORGERT: Right.

DR. WILLIAMS: On the PA form under the requirements it says that they have to send in the random drug screens. It's listed.

DR. ROMAY: As well?

DR. WILLIAMS: Yeah. It's under the prescriber's signature.

DR. ROMAY: Right. But we get those random drug screens but we actually don't get the -- they should be supplementing with an actual -- they should be sending out the drug screen out.

DR. WILLIAMS: So you want to request --

DR. ROMAY: I just want to --

DR. WILLIAMS: -- the labs, not --

DR. ROMAY: Right. Just to make sure that it's, you know, an adequate result versus an in office.

MS. ELLIOTT: Do you have a recommendation of how often you would like to see the random test?

DR. ROMAY: I would -- I mean, random I guess is something as it is random. So I don't know if you want to do it -- I think it depends on how that member has been in the past. If they have a history or relapse, I would do it more often, and so maybe every three months. I don't know.

DR. BORGERT: We can look into that. Any other requests, suggestions? I think it's a good idea like you guys were talking about where possible to follow up with, you know, how much the MCO data looks like the Fee-for-service data and that's something that we can consider here.

DR. MARTORANA: Just I guess the last time, the anticonvulsants we'll be bringing that back when we have the individual products, so are at least the top 5 or 10 in that class?

DR. BORGERT: Okay. We can do that.

DR. ROMAY: Just to add, in terms of like I know we mentioned having the MCOs bring back utilization data. Are we going to get like some kind of follow-up e-mail stating what exactly is required of us so we can

bring it to the next meeting?

MS. ELLIOTT: No. We're going to run that utilization. If we get in a bind, then we'll contact you.

DR. ROMAY: Okay got you. Thank you.

THE CHAIRPERSON: Okay. Does that close that topic? Any other suggestions? Very good.

Then next on our agenda is -- we had open discussion.

And next would be public comment. Do we have anyone from the audience that wishes to comment? No. Very well.

Vern our next meeting?

MR. HAMILTON: Wow. You all have really moved fast this morning. It's hard for me to keep up. I'm still asleep. You will note -- and I have already sent to all of you -- the schedule for the remainder of the year. But I think I put on the list that -- to be announced on the location you will notice that we are moving these meetings to the Tampa Hilton over on Lois Avenue, and that's where we will be meeting for the April, June, and September, I have contracts in place for

the Hilton. And we're looking forward to that. They have been very accommodating to our meetings. And I think the facilities will be very nice there. If you're not familiar with that location, it's not terribly far from here.

THE CHAIRPERSON: Just for the record, the June meeting date is --

MR. HAMILTON: The weekend of -- is it June 17th and 18th? I believe that's correct. The 17th is a Friday for P&T and the 18th is a Saturday for DUR.

THE CHAIRPERSON: And September's meeting date?

MR. HAMILTON: The last weekend of that month. Is that the 25th and 26th? No?

MS. SMITH: It's the 23rd and 24th.

MR. HAMILTON: 23rd and 24th.

MS. SMITH: The last day of the month is Friday the 30th.

MR. HAMILTON: So September 24th is a Saturday.

MS. SMITH: Yes.

MR. HAMILTON: But I sent all that to you in the e-mail previously.

THE CHAIRPERSON: Very good.

MR. HAMILTON: Because you all are such busy professionals, and we have not done it this way in the past, I'm going to be working to try to secure for a whole calendar year at a time. We've not done that traditionally here before, but it's getting more and more difficult to secure a location and the dates that we need for these meetings here in Tampa. And it helps you, I believe, in planning your calendar for these meetings. So hopefully by around late August, early September I will try to secure the dates for 2017.

THE CHAIRPERSON: Very good. Thank you.

MR. HAMILTON: Any questions? I think you noticed I passed out a new travel form. Christine Freeman is no longer in our unit and is not processing those, so we're moving to a new form that the bureau prefers. And it's just a guideline for sending those. You'll still use me to send those in and I will give them to another person now who will be processing them. I'm sorry I don't process your travel. But any questions that

come up, please send me an e-mail and I will follow up. I don't follow them unless I hear from you.

So I'm sorry about that, but I will be as communicative as possible in the processing of those.

THE CHAIRPERSON: Thank you, Vern. Thank you, Rebecca. And thank you everyone for serving and taking the time out of you busy Saturdays. I'd like to make a motion to adjourn.

DR. ALLEN: Second.

DR. MARTORANA: Second.

THE CHAIRPERSON: Very good. Thank you.

(WHEREUPON, the DUR Board Meeting adjourned at 10:55 a.m.)

CERTIFICATE OF REPORTER

STATE OF FLORIDA :

COUNTY OF HILLSBOROUGH :

I, Jacqueline L. Reichert, Court Reporter, Notary Public in and for the State of Florida

DO HEREBY CERTIFY that I was present at the foregoing proceedings at the time and place set forth in the caption thereof; that I was authorized to and did stenographically report the foregoing proceedings; and that the foregoing pages constitute a true and complete computer-aided transcript of my original stenographic notes to the best of my knowledge, skill and ability.

IN WITNESS WHEREOF, I have hereunto set my hand at Tampa, Hillsborough County, Florida this 26th day of January 2016.


JACQUELINE L. REICHERT
Notary Public, State of Florida
Commission No. EE 160968
Expires 3/27/2016