Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: Friday, November 15, 2013 Time**:** 9:00 a.m. – 4:00 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Perry Brown, M.D.

Committee Members Present: Perry Brown, M.D. -Chair; David Calley, PharmD.; Tami Eide, PharmD.; Mark Turner, M.D.; Troy Geyman, M.D.; Jeffrey Johnson, PA-C, PharmD.; Greg Thompson, M-D; Leigh Morse, M-D; Kelly Palmer, D.O;

Others Present: Paula Townsend, PharmD, Magellan Health Services; Jane Gennrich, PharmD., Division of Medicaid; Chris Johnson, PharmD., Division of Medicaid; Emily Perez, Division of Medicaid; Teresa Martin, Division of Medicaid, Berk Frazier, Board of Pharmacy;

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	Perry Brown, M.D.	Dr. Brown called the meeting to order.
Committee Business		
➢ *Roll Call*	*Perry Brown, M.D.*	Dr. Brown completed the roll call, welcomed the P&T Committee members and called the meeting to order.
➢ *Reading of Mission Statement*	*Perry Brown, M.D.*	Dr. Brown read the Mission Statement.
➢ *Approval of Minutes from May 10, 2013 Meeting*	*Perry Brown, M.D.*	The October 11, 2013 meeting minutes were reviewed. Dr. Leigh Morse made a motion to accept the minutes, Dr. David Calley seconded and the Motion passed. The minutes were accepted as proposed.
➢ *Update on Psychotropics in Foster Children*	*Tami Eide, PharmD*	Dr. Eide provided an update regarding the use of psychotropics in foster children. She reviewed the information from previous years in foster children vs. non foster children. All foster children in Idaho are on Medicaid. From the 2012 data the percentage shows that the ADHD drugs are the most widely prescribed drug. She compared the 2011 vs. 2012 percent of total foster and non- foster children receiving the different medications. Information reviewed showed the

		different prescribers who are prescribing per region.
➢ *Second Generation Antipsychotics*	*Marian McDonagh, PharmD Pacific Northwest Evidence-based Practice Center*	Dr. McDonagh presented a review of second generation antipsychotic drugs via conference phone. Key questions answered include: For adults and adolescents with schizophrenia and other psychotic disorders, do the second generation antipsychotic drugs differ in benefits (efficacy, effectiveness) or harms; For adults with major depressive disorder, do the second generation antipsychotic drugs differ in benefits (efficacy, effectiveness) or harm; For adults with bipolar disorder, do the second generation antipsychotic drugs differ in benefits (efficacy, effectiveness) or harms?; For children and adolescents with bipolar disorder, pervasive developmental disorders and disruptive behavior disorders – do the second generation antipsychotic drugs differ from placebo in benefits or harms; and lastly, are there any subgroups of patients based on demographics, socioeconomic status other medications or co-morbidities for which one second generation antipsychotic drug is more effective or associated with fewer harms? Dr. McDonagh reviewed the conclusions from the data presented. Those conclusions indicated that few differences were seen among the second generation antipsychotics in short-term efficacy in patents with schizophrenia or bipolar disorder; Comparative evidence was not available for adults with major depressive disorder or children and adolescents with pervasive developmental disorders or disruptive behavior disorders; In patents with schizophrenia, clozapine reduced suicides and suicidal behavior, but results in stopping drug due to adverse events more often than the others; Clozapine and olanzapine results in lower rates of discontinuation of drug for any reason over periods of up to 2 years and olanzapine may results in lower relapse and hospitalization rates than some other drugs; In adults with bipolar disorder, asenapine results in a higher risk of stopping drug due to ad verse events than olanzapine; Quetiapine was associated with lower mortality than risperidone in patients with bipolar disorder; Clozapine was associated with higher risk of myocarditis or cardiomyopathy than other drugs; Olanzapine was associated with a 16% increased risk of new-onset diabetes and results in greater risk of clinically impoirtant weight gain compared with other drugs; Risperidone resulted in a small increased risk of new-onset tardive dyskinesia and evidence of long-term harms for the newest drugs is lacking.
➢ *Aspirin for Preventative Care*	*Tami Eide, PharmD*	Dr. Eide gave a report on the use of aspirin for preventative care. Beginning in 2014, health plans are required to cover essential health benefits in ten benefit categories. The essential health benefits should be equal in scope to a typical employer health plan. Idaho's benchmarks plan for comparison is Blue Cross of Idaho – Preferred Blue PPO. Prescription drug coverage must cover the number of drugs in each category offered by the benchmark. Idaho Medicaid must offer at least one drug in USP category and class regardless of the benchmark coverage and

		preventative services must be covered even if not covered by the benchmark plan. The Director of Health and Welfare requested the approval of coverage of aspirin as on OTC to prevent cardiovascular disease in men and women. A prescription would be required for payment and daily prescription quantities are to coincide with recommended doses for cardiovascular event prevention. Dr. Thompson made a motion to approve aspirin for preventative care and Dr. Brown seconded. Motion passed by unanimous vote.
Public Comment Period	Perry Brown, M.D. Emily Perez, CPh T	**Public Comment Period** Eight (8) people signed up to speak during the public comment period. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
Dr. Riseo	Self	Chantix	
Mr. Steve Carlson	Hospital and self		
Starla Hegden			Epinephrine
Marc Salit, PhD	Baxter Healthcare	Gammagard	
Michael Dutro PharmD, BCPS	Pfizer	Chantix	Tobacco Cessation
Lyle Laird PharmD, BCPP	Sunovion	Latuda	Antipsychotics
Marc Jensen	UCB	Cimzia	
Michael Loraco			Long Acting Injectables

Drug Class Reviews and Committee Recommendations

Drug Class Reviews and Committee Recommendations
Committee members were asked to answer the following questions in each drug class.
1. Is there evidence to support clinically significant differences in efficacy of effectiveness between agents?
2. Is there evidence to support clinically significant differences in safety between agents?
3. Are there any agents that the committee feels strongly must be preferred or non-preferred?
4. Are there any recommendations for changes to PA requirements?

➢ Antipsychotics, Atypical (Second Generation)	Paula Townsend, PharmD Magellan Health Services	**<u>Antipsychotics, Atypical (Second Generation)</u>** Dr. Townsend gave an update for both the Atypical and Typical antipsychotics. She announced one new product in the class. Abilify Maintena (aripiprozaole monohydrate injection) indicated for the treatment of schizophrenia. This is a depot formulation of aripiprazole dosed as 300-400 mg monthly. There is one new indication for products in this class. Latuda (lurasidone) which is for depressive episodes associated with Bipolar 1 disorder as monotherapy and as adjunctive therapy with lithium or valproate. She reviewed one new study from August of 2013 from JAMA Psychiatry. This was a large retrospective study of medical records of patients 6-24. Patients on atypical antipsychotics had a 3 fold increased risk of developing type 2 DM within the first year and the risk remained elevated for up to 1 year following. She announced one new generic which was Clozapine ODT. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness. The committee talked about the differences in safety as far as in weight and diabetes. Dr. Palmer was asked about the effectiveness of Lorasidone and he explained that he hasn't seen this drug be any more effective than the other's. Dr. Calley asked about PA's and the failure time.
➢ Antipsychotics, Typical	Paula Townsend, PharmD Magellan Health Services	**<u>Antipsychotics, Typical</u>** Dr. Townsend **Committee Recommendations** Committee members discussed the differences between ProAir and Ventolin. Dr. Brown talked about how prices may not be the same as Medicaid receives federal rebates for some medications. The committee concluded that there were no evidence-based differences in effectiveness or safety to support preferring any agent over another in the class.
➢ Antidepressants, SSRI	Paula Townsend, PharmD Magellan Health Services	**<u>Antidepressants, SSRI</u>** Dr. Townsend announced one new product in this class. Brisdelle (paroxetine mesylate)

		indicated for vasomotor systems associated with menopause and one new generic fluvoxamine ER (Luvox CR). **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety and that Brisdelle (paroxetine Mesylate) should be preferred and the Luvox CR non-preferred.
➢ Antidepressants, Other	Paula Townsend, PharmD Magellan Health Services	**<u>Antidepressants, Other</u>** Dr. Townsend reviewed the information for two new products: Forfivo XL (buproprion HCL ER) and Desvenlafaxine ER – indicated for MDD. There were three FDA actions: The Bupropion Med Guide was updated to include the risk of hypertensive events when taken with other agents that inhibit the reuptake of dopamine/norepinephrine; Multiple updates to drugs in this class regarding serotonin syndrome and Emsam (transdermal selegiline) should not be used at any dose in those <12 years due to the increased risk of hypertensive crisis. **Committee Recommendations** The committee reviewed the prior authorization criteria and concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ Stimulants and Related Agents	Paula Townsend, PharmD Magellan Health Services	**<u>Stimulants and Related Agents</u>** Dr. Townsend announced two new products. Zenzedi (dextramphetamine IR) indicated for ADHD in patients 3-17 years and indicated for narcolepsy and then Quillivant XR (methylphenidate ER) which is an extended release oral suspension indicated for ADHD in patients 6-17 years of age. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. The committee discussed some of the safety concerns surrounding Quillivant XR. The Committee recommended that there be one representative of each drug for children. The committee discussed some of the concerns around the strengths of the drugs and titration.

➢ Sedative Hypnotics	Paula Townsend, PharmD Magellan Health Services	**Sedative Hypnotics** Dr. Townsend announced an FDA action announced in January of 2013 for Zolpidem. The FDA announced lower dosing recommendations for zolpidem due to new data showing am levels in some patients may be high enough the following morning to impair activities that require alertness, with women being more susceptible due to slower elimination. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness. The committee talked about the PA criteria and decided to remove the 15 capsules rule and to change the two preferred to one preferred.
➢ Anticonvulsants	Paula Townsend, PharmD Magellan Health Services	**Anticonvulsants** Dr. Townsend reviewed three new products in this class. The first is Onfi oral suspension (clobazam) indicated for Lennox-Gastaut in patients >2 year. The second is Oxtellar XR (carbamazepine XR) a once daily carbamazepine indicated as adjunctive therapy of partial seizures in patents>6 years and lastly, Trokendi XR (topiramate XR) a once daily topiramate for monotherapy or adjunctive therapy of partial of primary generalized tonic-clonic seizures. New generics include phenytoin chewable tablet (Dilantin Infatab), tiagabine (Gabitril) and lamotrigine XR (Lamictal XR). She reviewed the information from an FDA action for Potiga. A boxed warning was added for Potiga regarding retinal abnormalities and potential vision lost; an indication was updated: adjunctive therapy of partial-onset seizures in patients >18 who have responded inadequately to several alternative treatments and for whom the benefits outweigh the risk of retinal abnormalities and potential decline in visual acuity. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. The committee asked that the prior authorization for this class be simplified.
➢ Tobacco Cessation	Paula Townsend, PharmD Magellan Health Services	**Tobacco Cessation** Due to the Affordable Care Act, as of January 1, 2014, Idaho Medicaid will have to cover drugs in this class. Dr. Townsend announced a new study which showed the effects of varenicline on smoking

		cessation in adults with stably treated current or past MDD. She reviewed the information from a recent 2013 Cochrane Database system review. This review examined the efficacy and harms associated with NRT, bupropion, varenicline and other treatments in achieving long-term abstinence. Chris Johnson gave a report on the criteria for this drug class. He reviewed the information on diagnosis, prescribing criteria and exclusions. **Committee Recommendations** The committee discussed having some kind of confirmation that the patient is participating in a tobacco cessation program and receiving therapy. The committee discussed the age requirements and would like to establish a PA requirements for children under 18 years of age. Two quit attempts a year. No differences in efficacy or effectiveness. The committee concluded that there is no safety difference. The committee recommends having the availability of products in each type. Definition of heavy or moderate patients should be defined by their doctor.
➢ NSAIDS	Paula Townsend, PharmD Magellan Health Services	**<u>NSAIDS</u>** Dr. Townsend announced a new generic in this class: diclofenac sodium/misoprostol (Arthrotec) New guidelines updated for the American Academy of Orthopaedic Surgeons OA of the knee treatment recommendations is that NSAIDs or tramadol are recommended for symptomatic OA of the knee. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and that preferred status should be based on cost-effectiveness. The committee recommends having a DUR for this drug class and talked about

		this being a potential newsletter item. When writing the prescription for the NSAIDs to have no PA for Celebrex.
➢ Pain Drugs, Other	Paula Townsend, PharmD Magellan Health Services	**Pain Drugs, Other** Dr. Townsend announced an FDA action for Nucynta ER (tapentadol) has been placed into the ER/LA Opiod analgesic REMS program. . **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and that preferred status should be based on cost-effectiveness.
➢ Antihyperuricemics, Oral	Paula Townsend, PharmD Magellan Health Services	**Antihyperuricemics, Oral** Dr. Townsend announced a 2012 ACR Guidelines for the management of Gout. The applicable treatment guidelines include Hyperuricemia: Zanthine oxidase inhibitor considered first-line, combination therapy with 1 XOI and 1 uricosuric agent is appropriate when target urate has not been met. For acute gouty arthritis: NSAIDs, corticosteroids or oral colchicine are considered first-line. Goutattach prophylaxis – low dose colchicine or low-dose NSAID's w/wo PPI. If both 1st line are not tolerated, contraindicated or ineffective, second line is low-dose prednisone or prednisolone. Prophylaxis is recommended for all patients when pharmacologic urate lowering is initiated. An FDA action in this class is for Uloric (febuxostat) safety labeling updated 11/2012. Postmarketing reports of fatal and non-fatal hepatic failure. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and that preferred status should be based on cost-effectiveness.
➢ Cytokine/CAM Antagonists	Paula Townsend, PharmD Magellan Health Services	**Cytokine/CAM Antagonists** Dr. Townsend announced a new drug in this class. Xeljanc (tofacitinib) indicated for RA in adults with moderately to severely active RA who have had an inadequate response of intolerance to MTX. A new product in this class is Simponi Aria (golimumab IV) indicated for

		RA in combination with MTX. A new indication for Simponi SQ (golimumab) is for adults with moderate to severe ulcerative colitis who have demonstrated corticosteroid dependence or who have an inadequate response to or failed to tolerate prior treatment of failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine of 6-MP. A new indication for Cimzia (certolizumab pegol) is for the treatment of adults with active psoriatic arthritis. A new indication for Stelara (ustekinumab) is for the treatment of adults with active psoriatic arthritis alone or in combination with MTX. A new indication for Actmra (toclilzumab) is the for treatment of children >2 years with polyarticular juvenile idiopathic arthritis and for Kineret (anakinra) is for the treatment of neonatal-onset multisystem inflammatory disease. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. Committee recommends that there is at least one drug for every diagnosis. If Medicaid changes preferred agents, grandfather in those already on medication.
➢ Antiparkinson Agents/Restless Leg Syndrome	Paula Townsend, PharmD Magellan Health Services	**<u>Antiparkinson Agents/Restless Leg Syndrome</u>** Dr. Townsend reviewed one new product in this class: Lodosyn (carbidopa) which was added to the market basket, previously approved in 1977. She reviewed the information from the 2012 American Academy of Sleep Medicine Restless Leg Syndrome panel recommendations. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness.
➢ Alzheimer's Agents	Paula Townsend, PharmD Magellan Health Services	**<u>Alzheimer's Agents</u>** Dr. Townsend announced two new products in this class. Namenda XR indicated for moderate to severe Alzheimer's patients and Exelon Patch indicated for Alzheimer's disease and mild to moderate dementia associated with Parkinson's disease. A new generic is donepezil (Aricept).

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. No change to preferred or non-preferred and no changes to PA requirements.
➢ Immune Globulins	Paula Townsend, PharmD Magellan Health Services	**<u>Immune Globulins</u>** Dr. Townsend announced that this is a new drug class. Indications differ in the IVIG products. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. The committee recommends that there is one intravenous and one subcutaneous drug available and grandfather those in who
➢ Epinephrine, self-injected	Paula Townsend, PharmD Magellan Health Services	**<u>Epinephrine, self-injected</u>** Dr. Townsend announced that this is a new class. It contains EpiPen autoinjector, Auvi-Q autoinjector with audible instructions and epinephrine autoinjector. Drug indications are identical. **Committee Recommendations** The committee reviewed the prior authorization criteria and concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents and that preferred status should be based on cost-effectiveness. Committee recommends that we have both the epipen and the Auvi-Q available.
➢ Steroids, Topical	Paula Townsend, PharmD Magellan Health Services	**<u>Steroids, Topical</u>** Dr. Townsend announced new products in this class. For high potency, Topicort indicated for treatment of plaque psoriasis in adults and in low potency a new generic is fluocinolone acetonide oil.

		Committee Recommendations The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and that preferred status should be based on cost-effectiveness. The committee recommends having a cream, ointment and lotion in each of the potency categories.
➢ Antihypertensives, sympatholytics	Paula Townsend, PharmD Magellan Health Services	**<u>Antihypertensives, sympatholytics</u>** Dr. Townsend announced that this is a new class. There is no new significant clinical information in this class. **Committee Recommendations** The committee concluded that there were no evidence based differences to support preferring any agent over another in this class and that preferred status should be based on cost-effectiveness. The committee discussed the safety concerns for Reserpine and Methyldopa and would like to see this drug class reviewed at the DUR. The committee would like Clonidine and Guanfacine non-preferred and the patch available as a delivery system.
➢ Other Committee Business	Tami Eide, PharmD	**<u>Other Committee Business</u>** Our next P&T Committee meeting is scheduled for April 18, 2014. The committee reviewed the schedule for 2014. Meetings will be held April 18, May 16, October 17 and November 21. The meeting adjourned at 3:30 p.m.

Pharmacy and Therapeutics Committee
Public Comment
November 15, 2013

<u>Committee</u>
Okay, we'll begin with the medical practitioners. I have three of you who would like to give public comment. I'll call your name. Please, there's a little piece of

paper up here. If you can follow those steps; 1, 2, 3, 4, it would be most appreciated. Otherwise, I'll have to intervene and ask you to do it, and I don't want to do that. And if you can limit it to five minutes if possible, and I'll give you a sign to let you know that five minutes are up. So we have three medical. I do not have any public comments from the community. Then, of course, last but not least, will be the oral testimony from drug representatives. So, the first one is Dr. Rizzo? Did I say that right, doctor?

Carl Rizzo
Actually, I'm not a doctor, I'm a respiratory therapist.

Committee
Oh, a respiratory therapist, okay. Thank you.

Carl Rizzo
Okay, my name is Carl Rizzo. I'm a respiratory therapist/pulmonary function technician. I'm an asthma educator and a smoking cessation counselor. I work with Saltzer Medical Group, which is now slowly becoming part of St. Luke's. I am representing myself. I have been teaching smoking cessation classes for about eleven years. The last seven years, I've been working with the health districts. One of the things that I continually find is that we have people that will come to classes, and when they come to classes, they've basically failed in the past. They've tried to quit and it just didn't work for them. What we find is that many times they've tried using cessation medication, and in using those cessation medications, they were not properly educated. They failed on those medications based on the fact that they just didn't use them correctly. In classes, generally in my very first class, I always spend time explaining how to use medications, helping them to decide if medication is appropriate, and if it's appropriate, you know, how to decide which one they would use. What I've found in the past is the Idaho Quit Line has been helpful in supplying some of the medications, as far as nicotine replacement therapy. Again, though, they will allow you four weeks' of medication and if the medication is used improperly or inconsistently, it's not effective. Other drugs I think that are available would be the Chantix and the Zyban. All these drugs are completely effective if used correctly, so my primary comment today is we're missing the boat on the education. I think the medication is outstanding. It does a wonderful job if the education is provided previous to, and during, so that if there's a medical followup with the medications during the process, we notice a much higher success rate. So at this point, what we're hoping to see is the implementation of medications through Medicaid, which would make them available, but would also make them available with the education that's needed and the followup that's needed on a consistent basis. As far as a medication, I would like to make one comment. I have no preference in medication. As far as I'm concerned, you need to use what you need to use, or you don't need to use anything. I have found this to be so with every person that I've ever worked with. I really hope, though, that what we realize is that we don't need people to fail again on a medication to receive one that they need. In the past, I continually see people that have not done well with medication, so they say "Well it just doesn't work". Well, I truly believe any medication, if used correctly, can be effective if it's the right product at the right time, so, again, I have complete confidence that using medication in the proper time, proper place, with the proper education, is going to be phenomenally effective, and I hope that you'll move in that direction. Thank you.

Committee
Can I ask one question?

Carl Rizzo
Sure.

Committee
I haven't seen any recent statistics, but what, in your experience or in the published literature, is the quitting success rate with educationally versus with drugs only versus both? Just a ballpark.

Carl Rizzo
Well, based on the literature I've read in the last six months to a year, it appears that smoking cessation can be effective 23%-25% with education only. With the implementation of medications as well, we gain about 5%-7% without proper education. With the proper education combined, it appears that we can pick up another 10%-15% to that.

Committee
Thank you. All right, Mr. Carlson.

Stephen Carlson
My name is Stephen Carlson, a Doctor of Pharmacy. I'm the Director of Pharmacy at Intermountain Hospital here in the Treasure Valley. I also work for Comprehensive Pharmacy Services. I am here representing the hospital, but also myself as a citizen and somebody that sees and deals with our mental health patients on a firsthand basis. I am not being compensated for coming here today. I had a couple of things: One, I do want to advocate once again, I think I was here two years ago advocating for open formulary and access for our patients. Patients that I see, I think we truly are in the infant stages of understanding Psychiatric Medicine, and we do not know what is the right fit for which patients. I don't think that binding the hands of our practitioners is helpful in that process. So for continuum of care upon discharge, I am advocating for open formulary, that you guys would continue that. Secondly, I'd like to talk for a few minutes about psychiatric polypharmacy. This is an opportunity where I do think that pharmacy and pharmacists have an opportunity to step in and be able to play a role in identifying which of our patients have hit the side of being on too many antidepressants, too many psychotropics in general, or too many antipsychotics. There are only two requirements that are out there at this time; it's [7:07] _____-4 and -5 that guide the prescribing of antipsychotics. At this time, as a pharmacist, that's the only teeth I have to push back to practitioners that you need to get justification on discharge of why you have this patient on two antipsychotics. At our hospital, we have a polypharmacy program, where you've identified multiple different classes of psychotropic medications and we identify and challenge our practitioners to identify the justification for why patients would be on three antidepressants, why they would be on three antipsychotics, even if one of them is a p.r.n., or if they are on a total of six or more psychotropics. I would encourage you guys to give pharmacists and empower us with the opportunity to either, though MTMs or through measures mandated by you, to have some teeth to be able to push back at practitioners for justification for overmedication. Are there any questions?

Committee
We've looked at the antipsychotics and particularly we're looking at them in children, and we have been discussing the idea of that you do sometimes switch antipsychotics and you have this titration thing. Do you think it's reasonable that after sixty days, then to require a prior authorization for more than one?

Stephen Carlson
Absolutely. It seems reasonable and, in other cases, things like the Beers criteria have to be challenged once every six months. There should be some documentation of, as you take the patient off, that you're challenging... On the other side, you're going to have to compensate for an additional, like, medication visit, such as they would for an ADHD child, like a medication visit to followup. Absolutely. My concern is, at our facility, we try to send people out and make sure that our practitioners are justifying why they would be on multiple antipsychotics, but what I am seeing is, on average since the beginning of this year, we

have admitted 350 patients on average every month this year. Approximately nineteen cases of polypharmacy come up each month at my facility. It's a little over 5%, so I'm not saying you have a policy that identifies all of the problems, but we feel like we're catching the worst of the worst, and we're trying to put together a plan. But, yes, that's absolutely reasonable that those people would be challenged. I understand. I'm not trying to... more than anything I'm trying to decrease the carousel of people returning to our facility because them staying three days at our facility costs the State, and it's a burden a lot bigger than if we would pay for pharmacists to evaluate and then give recommendations and ask practitioners to justify, you know.

Committee
All right. Next one is Starla Higdon.

Starla Higdon, RPH
Hello, my name is Starla Higdon, I'm a Registered Pharmacist and I'm the Founder and Director of the Treasure Valley Food Allergy Network, which is a support group for people in the Boise area that manage food allergies. I also do volunteer work for a division of the Asthma & Allergy Foundation of America. I am here speaking on behalf of patients that are at risk for anaphylaxis, including myself. I'm not receiving any compensation for this testimony, and I don't have any financial ties to pharmaceutical companies. I would like to present information that I hope will be helpful as you consider the epinephrine auto-injector drug class. Since anaphylaxis can progress extremely rapidly, an epinephrine auto-injector can save a life only if it's carried on the person at all times, and it's also administered quickly and effectively. Delays in administration of epinephrine have been proven to be a risk factor in many allergic fatalities, and making sure the patient feels comfortable with their choice of auto-injector is vital, in my opinion. The Epi-Pen is certainly an excellent product, with a long track record. It's easy to use and many people are familiar with it. The new Auvi-Q may reduce some of barriers to carrying and administering epinephrine in my opinion. It's smaller, it's lighter, and it's less bulky than the other auto-injectors on the market. This is my own personal Auvi-Q. As you can see, it's about the size of a smart phone, so it's easy to fit in the pocket, unlike the Epi-Pen, which is probably about that long, a round barrel, kind of bulky in the pocket. So it's easy for people to carry. I've received comments from our members on how teenagers, specifically, are much more likely to carry it. There's a stigma involved with food allergies and carrying fanny packs and that sort of thing is not something a teenager wants to do, so the Auvi-Q kind of has some benefits with that regard. In my experience, even adult men seem to be more willing to carry it, either for their own allergies or on their child's behalf. In addition, the voice prompts may be calming in what can be a very stressful and chaotic situation. Like I said, I've actually carried the Auvi-Q. I've also carried Epi-Pens. Both have good points. I just feel that open access to either brand is important. If the patient doesn't feel comfortable with their auto-injector, they may hesitate to use it when needed, or they may not carry it at all. Thank you.

Committee
I have one question. This just occurred to me, that I haven't looked into this. The difference in terms of life span of Auvi-Q versus the Epi-Pens?

Starla Higdon, RPH
As far as I know, both of the formulations are close to same, yeah. I believe it's about 18 months is what I've seen. Personally, when I get it from the pharmacy, it ranges. There's going to be anywhere from... mostly it's almost always over 12 months. I've had some that were 14 months.

Committee
And the Auvi-Q is a single dose?

Starla Higdon, RPH

It is.

Committee
All right, we don't have any private citizens, so we'll continue with the company representatives' approved oral testimony.

I'd like to say something on that point. So for the pharmacy representatives, we appreciate everyone's submissions, and what we do, as all of you know, is filter out the ones that have information that won't otherwise be presented and haven't already been analyzed. What we ask you to do during your presentation is please really try to stick within the confines of what you've been approved to talk about, it being that information that we otherwise wouldn't be exposed to. We'd appreciate that, and thank you.

All right, first one is Mark Salit.

Mark Salit
Good morning, my name is Mark Salit, and I have a PhD in Immunology. I'm employed by Baxter Healthcare Corporation Biocides Division. Baxter manufactures and distributes immune globulin and other biological products worldwide. I am representing Baxter Healthcare. I am receiving compensation for my testimony, as I am an employee and that is my tie to the pharmaceutical company. Baxter Healthcare processes and distributes two immune globulin preparations, known as Gammagard Liquid and Gammagard SD. Gammagard Liquid is a 10%, ready-to-use preparation that has no added sugar, no added salt, has physiologic osmolality, is prepared without preservatives, and has no latex in its packaging. This product is indicated in the United States to prevent infection in primary immune deficiency and to reduce disability and improve strength in patients with multifocal motor neuropathy. Our Gammagard SD product is an older formulation that is indicated to prevent infection in primary and secondary immune deficiency, to help prevent or reverse coronary artery lesions in Kawasaki disease, and to raise platelet counts in the hematologic condition immune thrombocytopenic purpura. Gammagard SD is especially useful in that it has an IgA concentration of >1 mcg/ml in a 5% solution, meaning it may be useful in certain patients with low endogenous IgA levels. Now, I've pointed out the physical characteristics of our immune globulin preparations, because, as this committee has already ready in the excellent drug utilization review prepared for it by Magellan Provider Synergies, immune globulin products are not generic and are not interchangeable. All approved immune globulin products will reduce infection rates in immune deficiency. However, the individual products are all prepared by different manufacturing processes that may introduce certain physical chemical parameters into the individual product brands, and some of these physical chemical parameters may make use of a certain brand unsuitable in patients with certain comorbidities. So, for example, a product that is high in sodium, because salt has been used in processing, should be avoided in patients with hypertension and renal disease. Sugar, used to stabilize immune globulin, may raise sugar levels in diabetic patients, and may cause falsely elevated blood glucose determinations in such patients. These [17:36] _____-induced false positives over the last couple of years have, in fact, led to hypoglycemia and death in several circumstances.

Committee
Sir, I'm sorry to interrupt, but what we were under the impression that you would be speaking about is this subcutaneous infusion, reaction rates, and...

Mark Salit
Yes, one more sentence and we'll be right there. No problem at all. Hyperosmolar products have been associated with hyperviscosity and thrombogenesis, and should probably be avoided in patients with cardiovascular risk factors. The association between immune globulin use and heart attack and stroke rates was the subject of a paper published by investigators from the FDA in 2012. Daniel & Colleagues reviewed data on about 12,000 patients exposed to immune globulin,

and analyzed immune globulin brand-specific arterial and venous thrombosis rates associated with the individual brands. Baxter's Gammagard Liquid product was chosen as the reference brand against which all product pharmacogenesis rates were compared, because more patients received Gammagard Liquid in this analysis than any other brand. Gammagard Liquid also had the lowest rate of arterial and venous thrombosis among all of the brands studied. One immune globulin product had a 2.4 times higher adjusted risk of thrombosis in women compared to the Gammagard brand. The authors concluded that immune globulin dose infusion rate and product characteristics introduced in manufacturing may be responsible for the differences in pharmacogenesis seen with the individual brands, thus the immune globulin products are not interchangeable. In many cases, the immune globulin products should be matched to the patient's comorbidities. This stance agrees with guidelines published by the American Academy of Allergy, Asthma & Immunology, as well as the Magellan DUR. While immune globulin products may function similarly, the brands are not generic and are not interchangeable. Open access to all brands improves the ability of a physician or a clinical pharmacist in the patient supply chain to choose the right product for the right patient. Open access also promotes sufficient product supply to physicians of this rare, very difficult to prepare biological therapy. While all immune globulin brands are indicated for intravenous administration in the United States, there are four brands of immune globulin that are indicated for administration by the subcutaneous realm. Subcutaneous administration may provide certain advantages to patients, including a low systemic adverse reaction rate. Systemic reactions like headache, fatigue, fever and chills can make monthly intravenous infusion of immune globulin unpleasant for susceptible patients. The subcutaneous administration route reduces these systemic adverse reactions, but now some patients will suffer local infusion site reactions. In its pivotal trials, Gammagard Liquid demonstrated a low local infusion site reaction rate of about 2.4%, and after 52 weeks in the study, no patient demonstrated an infusion site reaction. Summarizing this brief testimony, then, immune globulin products are not generic and are not interchangeable. Baxter's Gammagard Liquid is a safe and effective immune globulin that is well tolerated by the intravenous and subcutaneous routes of administration. I think the Committee for their time and consideration. Questions, please? Thank you.

Committee
All right, the next speaker will be Michael Dutro from Pfizer?

Michael Dutro
Hello, I'm Michael Dutro, I'm a PharmD from Pfizer Medical Affairs, and I'm here to update you on varenicline or Chantix. Since April, 2013, when Magellan prepared the review for smoking cessation agents, there has been significant new scientific evidence published concerning varenicline. Specifically, new data on comparative efficacy and neuropsychiatric adverse events. An independent Cochrane Network meta-analysis was published in May of this year. It evaluated the relative efficacy and safety of smoking cessation therapies. Varenicline was found to be more effective than both bupropion and single NRT, and equally effective with combination NRT. There was no increase in serious adverse events or neuropsychiatric adverse events, and a marginal, nonsignificant increase in cardiovascular adverse events in varenicline users versus placebo. Varenicline has a box warning on its label concerning neuropsychiatric adverse events, primarily based on spontaneous adverse events reported to Pfizer and the FDA. Interpretation of spontaneous adverse events is limited in establishing a causal relationship, and using this type of data is not possible. Therefore, the next two recently published studies that I'm about to summarize are sentinel studies that provide important, new scientific information and evidence evaluating the possible relationship between varenicline and neuropsychiatric adverse events. An independent meta-analysis of seventeen randomized controlled clinical trials evaluating over 8,000 patients was published in the American Journal of Psychiatry in September. It showed that varenicline did not increase rates of neuropsychiatric adverse events in patients with or without a history of psychiatric illness compared with placebo. It also showed varenicline to be significantly more effective for smoking cessation than bupropion or placebo at twelve weeks. In October, an independent observational cohort study was published in the British Medical Journal. This study evaluated about 120,000 patients receiving varenicline or nicotine replacement therapy in a real-world primary care setting. If found no evidence that varenicline increased the risk of depression or suicidal behavior compared to NRT. There are two important Pfizer-sponsored randomized control studies that also don't appear in the Magellan review; one evaluating varenicline in patients with depression and another in patients with schizophrenia, both important to the Medicaid population. We were not asked to present data

on these studies to you, but citations and summaries for both are included in the testimony request submission that we posted on the website. The body of evidence support the first-line use of varenicline as an aid for smoking cessation treatment, is shown to be effective, comparing favorably to other pharmacotherapies, with a positive benefit/risk ratio. We respectfully ask that varenicline be added as a preferred agent on the PDL. Anybody have any questions?

Committee
Is the actual study that's designed to assess neuropsychiatric ADRs still due to be completed in 2017?

Michael Dutro
It is. The 8,000-patient, randomized, controlled study comparing varenicline with placebo, NRT and bupropion, is still scheduled to be finished in 2017, yes. Yes?

Committee
Just a quick question. Can it be used concurrently with bupropion or no?

Michael Dutro
Well, according to the label, it's not recommended that it be used with bupropion. There are investigators now looking at that combination and I believe there's going to be a paper coming out in the next six months or so that evaluates that combination, but there's been nothing, other than a pilot study published by the Mayo Clinic, which kind of showed promise, but it was a very small study. There isn't any other data available currently, but that data will be coming out soon. Any other questions? I didn't know if you wanted me to comment on the combining behavioral therapy with medication therapy, but you asked previously, or... Okay. I think essentially the PHS guidelines say that both, and I'm not talking about Chantix now, I'm just talking about medication therapy in general and behavioral therapy in general, and I'm not talking about a specific behavioral therapy program which might have quit rates that are higher than others, but generally, the PHS guidelines state that you will essentially double your quit rates with either medication therapy or behavioral therapy, and that so both are effective alone. However, if you use the two together, you will then double the double, essentially, and so that's essentially what the PHS guidelines say. All right? Thank you.

Committee
All right. Next speaker will be Lyle Laird.

Lyle Laird
You got it. Good morning, everyone, my name is Lyle Laird. I am a PharmD, a licensed pharmacist, and an employee of the Sunovian company, pharmaceuticals. I am the MSL that covers this region, and I will be presenting today on lurasidone hydrochloride, as you know, it is Latuda, in consideration of its status on your formulary. As you also know, lurasidone is indicated for the treatment of schizophrenia in adults, and this is supported by five pivotal trials, all of which are now published in the journals. On June 28, 2013, the FDA approved lurasidone for the treatment of major depressive episodes associated with bipolar-1 disorder, also known as bipolar depression, as both monotherapy and as adjunctive therapy to lithium or valproate, so this is two new indications for this medication. Lurasidone is currently the only medication approved both as monotherapy and adjunctive therapy with lithium or valproate for this use. As you also know, bipolar depression is a serious and often debilitating condition. Before I summarize bipolar depression data, please note that lurasidone carries class-wide box warnings against use in elderly patients with dementia-related psychosis and the increased risk of suicidal ideation, thinking and behavior in

children, adolescent and young adults who are taking antidepressant medications. Please see the full PI already made available to you for complete safety information, including these box warnings. The efficacy of lurasidone 20 mg-120 mg, once daily for bipolar depression in adults was established in two six-week controlled pivotal trials that are now available as e-publications ahead of print in the American Journal of Psychiatry. Lurasidone met the primary endpoint of depressive symptom reduction compared with placebo as measured by the Montgomery-Asberg Depression Rating Scale, and on the key secondary outcome measure of the clinical global impression scale severity version. It also reduced anxiety symptoms as measured by the Hamilton Anxiety Scale, the HAM-A, also at secondary endpoint in these studies. In the pivotal studies, the most common adverse events, that is at least 5% of the patients plus two times the placebo rate, in the monotherapy study were akathisia, extrapyramidal symptoms, somnolence, nausea, vomiting, diarrhea and anxiety, while on the adjunctive study, they were akathisia and somnolence. The discontinuation rates secondary to any adverse event, including those in the monotherapy and in the adjunctive lurasidone treatment groups were between 6.7% and 5.4%, and these were very similar, if not almost identical, to the placebo rates of dropout. Other safety and tolerability outcomes including weight changes and metabolic parameters were also similar to that seen with placebo, and the safety and the tolerability of the lurasidone in bipolar depression are further supported by an additional short-term study and a longer-term safety study that went out six months. To summarize the safety and tolerability observed in these studies, these bipolar depression studies, was consistent with the data that you've seen for the schizophrenia studies on lurasidone in the Provider Synergy document. Lurasidone is a pregnancy category-B medication and it carries no warnings regarding QTC or conduction abnormalities in its label. So please consult the full PI or go to the LatudaHCP.com for more information on these and other safety information. Thank you so much for this opportunity to present to you today, and I ask you to consider this evidence and these data in your consideration on the decision of lurasidone status. Thank you. Questions?

Committee
All right, last one. Marc Jensen?

Marc Jensen
Good morning. My name is Marc Jensen, a PharmD, and I'm a Medical Science Liaison with UCB Pharma. My employer is UCB Pharma, a pharmaceutical company, and, of course, that being the case, I am working for UCB and employed by them. I'm here on behalf of UCB Medical Affairs to discuss Cimzia or certolizumab pegol. Cimzia is a tumor necrosis factor blocker indicated for reducing signs and symptoms of Crohn's disease, treatment of adult patients with moderately to severely active rheumatoid arthritis, and we have two new indications: Treatment of patients with psoriatic arthritis and treatment of adult patients with ankylosing spondylitis. Cimzia was approved for treatment of adults with psoriatic arthritis in September of this year. Cimzia has demonstrated efficacy in active psoriatic arthritis, adult patients, despite being previously treated with disease-modifying anti-rheumatic drugs. ACR-20, -50, and -70 response rates were higher in patients treated with Cimzia versus psoriatic arthritis patients treated with placebo. Among patients receiving Cimzia, clinical responses were seen in some patients within 1-2 weeks after initiation of therapy. Cimzia treated patients showed improvement in physical function as assessed by the HAQ-DI at week-24, and clinically meaningful improvements in enthesitis and dactylitis were also seen in Cimzia-treated patients versus placebo patients at both weeks -12 and -24. Treatment with Cimzia resulted in improvement in skin manifestations in psoriatic arthritis patients. Patients treated with Cimzia 200 mg every other week demonstrated greater reduction in radiographic progression compared with placebo-treated patients at weeks -24 as measured by change from baseline in modified total Sharp score. Cimzia was approved for treatment of adults with ankylosing spondylitis in October of this year. Cimzia has demonstrated efficacy in active ankylosing spondylitis adult patients, and at week-12, a greater proportion of ankylosing spondylitis patients treated with Cimzia at 200 mg every two weeks or 400 mg once a month, achieved a status-20 response compared to patients treated with placebo. Responses were similar in patients receiving Cimzia at 200 mg every two weeks and Cimzia 400 mg every four weeks. Among patients receiving Cimzia, clinical responses, again, were seen in some patients within 1-2 weeks of initiation of therapy. In addition to these new indications, I would also like to make you aware of some recent changes to our prescribing information. Post marketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma that is a very aggressive disease course, and is usually

fatal, have been reported in patients receiving anti-TNF therapy, including Cimzia.

Committee
I'm sorry. This is going outside the approved area when they were asking for testimony. I'm sorry to interrupt.

Marc Jensen
All right. I'm still obligated to provide some safety updates as well also. There is one more clinical piece of information I'd like to provide. In an independent clinical study conducted in ten pregnant women with Crohn's disease, treated with Cimzia, concentrations were measured in maternal blood, as well as in cord blood and in infant blood at the day of birth. Plasma Cimzia concentrations were lower by at least 75% in infants compared with maternal concentrations, suggesting low placental transfer or Cimzia. Cimzia does remain, though, pregnancy category-B. So those are the three new pieces of clinical information in our package insert outside of the safety changes that were also added within the last year. Any questions? Thank you.

Committee
Thank you very much. Dr. Brown? I do apologize, we do have one last public comment, if that's possible. It's a private citizen public comment, Michael Larocco. If you could just answer those two questions please.

Michael Larocco
My name is Michael Larocco, I'm a licensed clinical social worker with Affinity in Personal Development, and I'm on the payroll, so I am being compensated, but no ties to any pharmaceutical companies. I wanted to make comment today about long-acting injectable medications, specifically Invega Sustenna and Vivitrol. Affinity, for those who are not familiar, is a mental health clinic in Boise, and we also have a facility in Nampa. Personal Development is the substance abuse component of that company. Throughout the past 3-4 months, it's been very problematic helping our clients obtain the injectables because of the different switches in terms and conditions because of the Optum takeover and confusion with the Medicaid pharmacy regulations. I know from personal account anecdotal information. Unfortunately, I don't have any raw data for you. These injectables have been beneficial with helping to prevent rehospitalization, specifically Intermountain and St. Al's Behavioral here in Boise, and then at West Valley Medical Center out in Caldwell. We have actually had a few clients in the past year who were not able to access the injectables and have repeated hospitalizations; the revolving door issue. One client that comes to mind in particular came in with six black garbage bags full of medications because he could not medication compliant on his own. He needed that extra help, and he was one of the ones that did the revolving door, whether it be jail or the hospital. So, severe and persistently mentally ill clientele need some extra help, and that's when the injectables can play a pivotal role, and those clients that are able to get the long-acting injectables have shown improvement, have shown a significant decrease, again, just anecdotal information though, no hard facts, no studies, so I apologize for that. From what we have seen in our clinic, the ones with the long-acting injectables have a decrease in the need for hospitalization or the consequence of going back to jail. So in your discussions and in your deliberations, I hope that you take a serious look at making sure that those stay available for the clients that need them. Any questions?

Committee
The patients that have been denied this, we actually don't deny that many injectables when people need them, but we do not allow injectables and orals to be given at the same time. Are those the patients that you're talking about?

Michael Larocco
No, it's actually been more because of the Vivitrol in just the past few months because of the switch with the Optum, so we're having real struggles with that one

right now.

Committee
Okay, that's a physician-administered drug, so it doesn't come through the pharmacy side, but we could work on that.

Michael Larocco
Excellent, thank you so much.

Committee
Thank you. That concludes the public testimony and other testimony.