Pharmacy and Therapeutics (P&T) Committee Meeting Record

Date: November 20, 2015

Time: 9:00 a.m. – 3:15 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

Moderator: Perry Brown, M.D.

Committee Members Present: Perry Brown, MD-Chair; Tami Eide, PharmD; David Calley PharmD; Kevin Ellis, PharmD; Mark Turner, MD; Troy Geyman, MD; Stephen Carlson, PharmD; Christopher Streeter, MD; Brian K. Crownover, MD; Kali Bradfield, PA-C

Committee Members Absent: Alex Adams, PharmD, Leigh Morse, MD

Others Present: Sarah Martinez, PharmD, Magellan Health Services; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Tammy Haugland, Division of Medicaid; Wendy Estrellado, Division of Medicaid; Mark England, PharmD, Magellan Medicaid Administration; Jeffrey Berlant, MD, Optum Idaho

AGENDA ITEMS	PRESENTER	OUTCOME/ACTIONS
CALL TO ORDER	*Perry Brown, MD*	*Dr. Brown called the meeting to order.*
Committee Business		
➢ *Roll Call*	*Perry Brown, MD*	Dr. Brown completed the roll call and welcomed the P&T Committee members. Committee members introduced themselves to new member Kali Bradfield who has replaced Jeff Johnson as the physician assistant member of the committee.
➢ *Reading of Confidentiality and Mission Statements*	*Perry Brown, MD*	Dr. Brown read the Confidentiality and Mission Statements.
➢ *Approval of Minutes from October 16, 2015 Meeting*	*Perry Brown, MD*	The October 16, 2015 minutes were reviewed. The minutes were accepted as proposed.
➢ *Second Generation Antipsychotics in children*	*Tami Eide, PharmD*	**Second Generation Antipsychotics (SGA) in Children** Dr. Eide presented information from the OIG report that came out in March of this year which

		studied second generation antipsychotic drug use in Medicaid enrolled children. The study looked at five states and addressed quality of care concerns, non-medically accepted indications and drugs being prescribed for conditions described in the black box warnings on these medications. The findings of the study reported that 67% of the claims had quality of care concerns. The recommendations to CMS by the OIG were to work with States to implement measures that include the following: • Performing utilization reviews of SGAs prescribed to children • Conduct periodic reviews of medical records associated with claims for SGAs prescribed to children • Consider other methods of enhanced oversight of SGAs prescribed to children, such as implementing peer review programs Dr. Eide presented information on the utilization data of these drugs for this age group in Idaho. Dr. Eide also discussed suggestions that were received from the DUR board who recommended that there be a focus on utilization of children ages 0-6 and on low doses of quetiapine which may be used for sleep. The DUR Board also recommended partnering with Optum.
➢ *Methadone and Chantix follow up from last meeting*	*Christopher Johnson, PharmD*	**Methadone and Chantix follow up** Previous meeting follow up for recommended changes to the prior authorization requirements for Chantix were discussed. Chantix is now preferred but has clinical requirements including follow up counseling of treatment and adverse effects. New proposed criteria for methadone were also discussed. Dr. Johnson review PA criteria for cardiac arrhythmia monitoring while on methadone and the risks associated with prescribing methadone. New PA forms with new criteria for both were reviewed.
➢ *Immune Globulin Follow up From October Meeting*	*Sarah Martinez, PharmD*	**Immune Globulin update from last meeting** Dr. Martinez gave an update on Hyqvia from the last meeting and clarified previous comments. She stated that there are differences between Hyqvia and other subcutaneous immune globulin formulations including a difference in dosing among the products.
Public Comment Period	*Perry Brown, MD* *Tammy Haugland*	**Public Comment Period** Six (6) people signed up to speak during the public comment period. Three manufacturer representatives were pre-approved to provide testimony. Public testimony was received from the following speakers:

Speaker	Representing	Agent	Class
Deborah Rush, NP	Self /Patient	Aristada	Antipsychotics
Christine Sugg	Self/family member	Mental Health Drugs	Mental Health Drugs
Kathie Garrett	NAMI	Mental Health Drugs	Mental Health Drugs
Greg Broutman, PhD	Sunovian	Aptiom	Anticonvulsants
Laura Litzenberger, Pharm.D.	Janssen	Invega Sustenna	Antipsychotics
Samantha Min Pharm.D.	Otsuka	Abilify Maintena	Antipsychotics

➢ *Pharmacologic Treatments for Attention Deficit Hyperactivity Disorder*	*Marian McDonagh, PharmD* *Pacific Northwest Evidence-based Practice Center*	**<u>Pharmacologic Treatments for Attention Deficit Hyperactivity Disorder</u>** Dr. McDonagh presented the drug class review for pharmacological treatment in ADHD. This is update number five for this DERP class review. New studies were presented comparing effectiveness, harms (including tolerability, serious adverse events, abuse/misuse/diversion) and differences in subgroups between ADHD agents. New drugs added to this review included Quillivant XR extended release methylphenidate suspension and Nuvugil (armodafinil). Eight (8) new head-to-head trials and three (3) observational studies were included in this update. Strength of evidence on comparative effectiveness and serious harms was insufficient in children and adults to show any differences. Comparative evidence on abuse, misuse, and diversion continues to be limited.
Drug Class Reviews and Committee Recommendations	*Perry Brown, MD*	**Drug Class Reviews and Committee Recommendations** Committee members were asked to base their recommendations for each drug class on the answers to the following questions: 1. Is there evidence to support clinically significant differences in efficacy or 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?
➢ *Stimulants and Related Agents*	*Sarah Martinez, PharmD*	**<u>Stimulants and Related Agents</u>** Dr. Martinez reported that there were two new products on the market in this class. Evekeo (amphetamine) is indicated for the treatment of narcolepsy, ADHD, and exogenous obesity.

		Aptensio (methylphenidate) XR is indicated for the treatment of attention deficit hyperactivity disorder in patients six years and older. She reviewed dosing, contraindications, warnings, adverse effects and drug interactions for both agents. There are no comparative studies for either product. Dr. Martinez announced that Intuniv and Methylin chewable tablets are now available generically and that Vyvanse is now also indicated for the treatment of moderate to severe binge eating disorder. She also reported that Daytrana patch now contains a warning regarding potential permanent skin color loss that can range up to eight inches in diameter. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that clonidine and guanfacine extended release generic formulations be considered for preferred status. It was also recommended that the Daytrana patch dermatological warning be added to the PA form for provider education.
➢ *Antipsychotics, Atypical (Second Generation)*	*Sarah Martinez, PharmD*	**<u>Antipsychotics, Atypical (Second Generation)</u>** Dr. Martinez reported that there are two new products in this class. Invega Trinza (paliperidone) is an intramuscular injection indicated for the treatment of schizophrenia in patients who have been adequately treated with Invega Sustenna for at least four months. It is administered every three months by a health care professional in a clinic setting. Rexulti (brexpiprazole) is indicated for the treatment of schizophrenia and as adjunctive therapy to antidepressants for the treatment of major depressive disorder. Dr. Martinez reviewed dosing, administration, adverse effects, and warnings associated with Rexulti. Dr. Martinez also provided four product updates. Invega Sustenna is now indicated in patients with schizoaffective disorder as monotherapy or in combination with mood stabilizers or antidepressants. Abilify administered orally is now indicated for the treatment of Tourette's disorder. Saphris is now indicated as monotherapy for the acute treatment of mania or mixed episodes associated with bipolar I disorder in patients 10–17 years of age (previously indicated only in adults). Abilify (aripiprazole) tablets and suspension are now available generically. Dr. Martinez also reported on the Paliperidone Palmitate Research in Demonstrating Effectiveness (PRIDE) Study which compared long acting injectable paliperidone palmitate and oral antipsychotic medication in 450 subjects with schizophrenia. The results demonstrated superiority of once-monthly IM paliperidone compared to oral antipsychotics in delaying the onset of treatment failure in schizophrenic patients. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness

		or safety between the agents.
➢ *Antipsychotics, Typical*	*Sarah Martinez, PharmD*	**Antipsychotics, Typical** There were no new agents and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Antidepressants, SSRI*	*Sarah Martinez, PharmD*	**Antidepressants, SSRI** Dr. Martinez reported that there are no new products on the market in this class and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Antidepressants, Other*	*Sarah Martinez, PharmD*	**Antidepressants, Other** Dr. Martinez reported that there are no new products on the market in this class and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents. The committee recommended all MAO-I agents have prior authorization requirements due to safety concerns.
➢ *Sedative Hypnotics*	*Sarah Martinez, PharmD*	**Sedative Hypnotics** Dr. Martinez reported that there is one new product in this class, Belsomra (suvorexant). Indications, dosing and administration guidelines, contraindications, warnings, and drug interactions were reviewed. No comparative studies have been done. **Committee Recommendations** The committee concluded that although there is some degree of differences between agents there was not comparative evidence to support differences in efficacy, effectiveness or safety between the agents in this class to prefer one over another. It was recommended that prior authorization criteria be added that would require the trial and failure of Rozeram and Lunesta before Belsomra

		could be approved.
➢ *Anticonvulsants*	*Sarah Martinez, PharmD*	**Anticonvulsants** There were no new agents to report on in this class. Dr. Martinez reviewed five product updates. Lamictal (lamotrigine) ODT is now available generically. Banzel is now indicated for the adjunctive treatment of seizures associated with Lenox-Gastaut syndrome in patients one year and older (previously for four years and older). Qudexy XR is now indicated as initial monotherapy in patients two years and older with partial onset or primary generalized tonic-clonic seizures (previously 10 years and older). Fycompa is now indicated as an adjunctive treatment for primary generalized tonic-clonic seizures in patients 12 years and older (previously indicated only for the treatment of partial onset seizures in this population). Aptiom is now indicated for treatment of partial onset seizures as monotherapy (previously indicated only as adjunctive therapy). Dr. Eide read comments received from Dr. Wechsler who was unable to attend the meeting concerning his clinical experience with these agents for epilepsy indications. The comments included Dr. Wechsler's preferences and reasoning for first line and second line treatments in this drug class. Specifically, he recommended once a day drugs that could be administered at night to minimize dose-dependent side effects causing day time disability; using Aptiom as a preferred sodium channel agent over less effective agents with safety concerns such as carbamazepine, oxcarbazepine or phenytoin and limiting lamotrigine, topiramate, zonisamide and Fycompa to second line or add-on therapy. **Committee Recommendations** The committee concluded that there are differences in efficacy, effectiveness and safety between the agents in this class. With the newer agents now available for treating epilepsy, the committee recommended that phenytoin be blocked as a first-line agent for new patients for safety reasons. They recommended that Aptiom be considered for preferred status.
➢ *Colony Stimulating Factors*	*Sarah Martinez, PharmD*	**Colony Stimulating Factors** Dr. Martinez reported that there is one new product in this class, Zarxio (filgrastim-sndz), which was approved in March 2015 and is the first FDA approved biosimilar product**.** She reviewed the indications, contraindications, warnings, adverse effects, and drug interactions for filgrastim-sndz which are similar to those for Neupogen. She also reviewed the National Comprehensive Cancer Network (NCCN) Myeloid Growth Factor Guidelines for the role of biosimilars. Dr. Martinez presented information on the 2015 updated guidelines issued by The American Society of Clinical

		Oncology (ASCO) for the use of white blood cell growth factors. Dr. Martinez also reviewed a comparative study between Figrastrim –sndz and filgrastrim which showed filgrastim-sndz met the noninferiority requirement. Dr. Martinez announced that Neupogen is now indicated to increase survival in short–term exposure to myleosupressive doses of radiation. Zarxio does not have this indication. **Committee Recommendations** The committee concluded that there is not any evidence to support differences in efficacy, effectiveness and safety between the agents in this class.
➢ *Erythropoiesis Stimulating Proteins*	*Sarah Martinez, PharmD*	**<u>Erythropoiesis Stimulating Proteins</u>** There were no new agents and no recent clinically significant information in this class to report on**.** **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *NSAIDS*	*Sarah Martinez, PharmD*	**<u>NSAIDS</u>** Dr. Martinez reported that there is one new product in this class, Tivorbex (indomethacin), which is indicated for the treatment of mild to moderate acute pain in adults. She reviewed contraindications, warnings, adverse effects and drug interactions which are similar to those for Indocin. She reviewed contraindications, warnings, adverse effects and drug interactions which are similar to those for Indocin. Dr. Martinez provided two product updates. Celebrex (celecoxib) and Naprelan (naproxen) are both now available generically. The FDA has strengthened the existing label warning that non-aspirin NSAIDs increase the chance of heart attack or stroke. **Committee Recommendations** The committee concluded that there is no evidence to support differences in efficacy, effectiveness or safety between the agents in this class.
➢ *Pain Drugs, Other*	*Sara Martinez, Pharm D*	**<u>Pain Drugs, Other</u>** Dr. Martinez reported that there is one new product in this class, Irinka (duloxetine), which is indicated for the treatment of major depressive disorder, generalized anxiety disorder, diabetic peripheral neuropathy, and chronic musculoskeletal pain. She stated that contraindications, warnings, adverse effects and drug interactions are similar to those for other duloxetine products.

		The only difference being that Irinka's available dosage strength is 40 mg. Irinka is also now available generically. No comparative data is available between Irinka and other duloxetine products. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They felt prior authorization criteria should remain as it is currently.
➢ *Antihyperuricemics, oral*	*Sarah Martinez, PharmD*	**Antihyperuricemics, oral** There were no new agents and no recent clinically significant information in this class to report on. Dr. Martinez reported that there are once again colchicine generics available. **Committee Recommendations** The committee concluded that there is no evidence to support differences in efficacy, effectiveness or safety between the agents in this class.
➢ *Antiparkinson Agents/Restless Leg Syndrome*	*Sarah Martinez, PharmD*	**Antiparkinson Agents/Restless Leg Syndrome** Dr. Martinez reported that there was one new product in the class, Rytary, an extended release levodopa/carbidopa product which is indicated for the treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide or manganese intoxication. Dr. Martinez also presented information on contraindications, warnings and adverse effects as well as a comparative study between levodopa/carbidopa IR versus levodopa/carbidopa ER (Rytary). This study showed Rytary had less off-time and less dyskinesia drug waking hours, but the final daily dose was approximately double the final daily dosage for the immediate release formulation. Dr. Martinez also announced that Mirapex ER (pramipexole) and Tasmar (tolcapone) are both now available generically. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents within the subclasses. They supported keeping all prior authorization criteria the same.
➢ *Alzheimer's Agents*	*Sarah Martinez, PharmD*	**Alzheimer's Agents** Dr. Martinez reported that there is one new product in this class, Namzaric, a combination of memantine XR and donepezil, which is indicated for the treatment of moderate to severe Alzheimer's dementia in patients already stabilized on both of the component drugs. Dr. Martinez also reported that Namenda (memantine) IR tablets and solution are now available generically.

		Committee Recommendations The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Otic Antibiotics*	*Sarah Martinez, PharmD*	**<u>Otic Antibiotics</u>** There were no new agents and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents.
➢ *Otic Anti-infectives and Anesthetics*	*Sarah Martinez, PharmD*	**<u>Otic Anti-infectives and Anesthetics</u>** There were no new agents and no recent clinically significant information in this class to report on. **Committee Recommendations** The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended removing "anesthetics" from the drug class name as there are no FDA approved anesthetic otic products.
➢ *Other Committee Business*	*Tami Eide, PharmD*	Dr. Eide announced Dr. Geyman's contract will end prior to the next meeting and thanked him for his four years of service. She also announced that Dr. Browns term as committee chair will also end prior to the next meeting. She thanked him for the eight years of excellent and committed service he had provided, first as a committee member and then as chair. The public meeting adjourned at 12:53 p.m.

Pharmacy and Therapeutics Committee Meeting
Public Comment

<u>Deborah Rush, PMHNP</u>

My name is Deborah Rush. I am a psychiatric mental health nurse practitioner, a graduate of Gonzaga University. I am practicing in my own practice. I have a partner, so we provide evaluation and medication management, as well as counseling, and that is at Renewed Hope

Counseling & Wellness in Meridian, Idaho. I don't have any connection; I am not being paid for what I am here to talk about today. I am here today because the majority of my practice is Medicaid. I have about 89% Medicaid, some Medicare and then a handful of private clients. I am also the psychiatric provider for the Canyon County free clinic in Caldwell, so they send me their uninsured clients requiring psychiatric oversight or medication prescriptions, and we work with them as well, doing a lot of the patient assistance programs with them for medications. One of my clients, my patient that has been with me since she was seventeen, and I have worked with her, she has schizoaffective disorder. She came to me after failing Invega Sustenna, and after hospitalization where she was placed on that. So over the years, we have gradually gotten her into therapy, gotten her on some aripiprazole, oral aripiprazole, and in the last year, has been on the higher dose of the Abilify Maintena. She still has some shortcomings, and I was hoping to be able to attempt to put her on the 882 Aristada LAI because it may offer her a little more medicine, and it will also offer her the security of not having to show up on her four-week medication compliance, because at times, she does miss that. However, she is compliant, she does show up for her appointments most of the time, and doesn't really miss her shot that often, but is sometimes late. She is no good with oral compliance. She will not take medicine. I have tried oral supplementation to get her at the dose where I need to control all of her symptoms, and I have been unable to do that. She is on only this medication because we've tried a little Strattera for her, it works, but she just won't take it. So usually what's happening with this medication that she's currently on; she starts to wane a bit in the third week, we see some exacerbation of behaviors. She is a big concern for me; she's been able to stay out of the hospital since I've had her. She has a supportive family that holds her accountable. She is not yet able to live on her own. She can't work. She has tried, but she just is missing something there. She has, just her whole life ahead of her. She has some really good goals. My biggest concern for her is pregnancy. Whenever she lapses, she will come in and need a pregnancy test. We have that talk every time we meet, about the importance of her being cautious, and that's a cost to the state, as well as a cost to the child if they come into the world not wanted. She does a lot better right after her injection. That first couple of weeks, she shows up for everything and she's thinking more clearly. It is amazing, the difference, when everything is on board and everything is working. She's just done a lot of things that are good for her. She was institutionalized in a girls' home for a while. Her mother has tried very hard with her growing up, so she just seemed like a prime candidate to try Aristada because it may very well offer her that extra medicine, and it will certainly keep her safer in that 1-2-week period that she is often late on her injection. She is young enough that she hasn't yet had the deterioration of her brain that will happen if she continues on and off medicine. She has a trusting relationship with me, which has continued for now three years, she's kind of grown up in my office. She used to attend with her mother all the time and now we have her on transport. She comes by herself. She's making an effort to move closer to my office to not miss counseling appointments, so there's good, but it's just missing something. So the opportunity for her to use this medication that just might be the answer to getting her some further education, a job, being able to have a normal life and maybe have children one day. I think she deserves this option, and I am so proud to be in a state where 90% of the time, when I want a medication that isn't formulary, I am able to get it because the patient does matter in this state, and I really appreciate that. I have a patient who...

Committee
I'm sorry to interrupt, but if I can just have you wrap it up in the next minute or so, that would be great.

Deborah Rush, PMHNP
That was what I was going to do. That one example I want to leave is that Vyvanse is something I have to get a prior authorization for, and it has proven to be very effective as a prodrug compared to Adderall, so that I seldom use Adderall anymore. Adderall is highly abused, and when I don't have to use it, I feel good, and my patients have done well without Adderall, now having that prodrug as an option, so I appreciate the time. Thank you very much.

Committee
Thank you. Are there any questions?

Committee
I have one question? So you don't have to go into great detail, but when you had decided that the other long-acting was a clinical failure, was that due to side effects, or was that because the patient didn't respond?

Deborah Rush, PMHNP
No, the patient is responding well, it's just not enough. She needs an oral supplementation, which I cannot get her to take. I have tried and tried. We have been on this medication now for nearly a year. She does show up for her injection, but she's sometimes late. So my goal for her is maybe a little more medication, maybe this will be her PGT test or genotype would work that this medication is one that works, where risperidone and olanzapine are not. Her PGT test shows me that. So that's my hope, is that this would be workable for her, to give her that security if she's late for her shot, and keep her safer, and give her some more opportunity for growth, as she's such a young gal.

Committee
I guess the question I was asking was how long did you have the patient on the previous Invega Sustenna before you considered it treatment failure.

Deborah Rush, PMHNP
She came to me on Invega Sustenna out of the hospital. She had been on it for two months, the injection. She was flat, unhappy and refusing treatment. Her mother had to drag her in, and only because I worked with her and agreed to take her off that medicine, do I still have her in care today.

Committee
All right, so one thing I was realizing that I neglected to mention before our first speaker, is that we ask that those giving testimony to try to limit their testimony to about three minutes or so, and then we would have some time for questions. So next up, we're going to go ahead and do private citizens. The first one I have signed up is Christine Sugg, and Christine, if you can kind of state the same things in terms of name, degree and if you happen to be representing anyone or receiving compensation.

Christine Sugg
My name is Christine Sugg. I don't have a degree. I'm not a professional. I have a brother who has schizophrenia, and I'm not being paid for today and I don't have any financial ties with anybody. I'm just going to read something. I urge you to support all medications as possible used for persons with mental illness. I have a brother with schizophrenia and depression who is 64 years old. Our family has seen the various effects of medications he has used over the past 45 years and know how important options are. One medication causes damage to his liver, another causes damage to his kidneys. Another causes weight gain, and he's developed diabetes along the way, which when changed to a new medication he loses weight again and is able to control his diabetes. Some make him shake very badly. Some cause him to have OCD-like symptoms. Some have been effective in controlling his symptoms, and others have not. One medication cannot suit all, and without choices and alternatives to rotate with, our citizens with mental health issues may have the option... I misread that. I think you know what I mean, though... and will require additional medical care and prescriptions as they develop other types of illnesses as a result, such as liver and/or kidney damage. Mental illness was not my brother's choice, or anything he caused himself. He has been its victim virtually his entire adult life. It's precluded or severely limited nearly every normal experience and pleasure most of us take for granted. So I just urge you to keep as many medications available as possible. My brother's always been on Medicaid and now he's on Medicare/Medicaid, and we just appreciate your consideration. Thank you.

Kathie Garrett
My name is Kathie Garrett and I'm here on behalf of NAMI Idaho. NAMI Idaho is the State organization chartered by the National Alliance on Mental Illness to serve people impacted by mental illness. Thank you for granting this opportunity to present testimony regarding access to psychiatric medications. NAMI supports full and open access to psychiatric medications for all persons living with mental illness. Now, I changed by written testimony when I listened to your presentation earlier. I wasn't aware that we were going to be looking at some children's mental health issues. Yesterday, I was on a conference call with NAMI National, and we were discussing some issues, and part of the report had to do with some facts that I think I will present to you. Half of all mental health emerges by age fourteen. Three-fourths of all mental health emerges by age 24. Research shows that early intervention can prevent mental health crisis and prepare children to thrive. Despite this, in the United States, there is an average of 8-10 years between onset of mental health condition and the

start of treatment. While one in five American youth will live with a mental health condition, less than half receive any services. We call this "the lost years". Families and parents end up with more kids with disabilities, more delays in their development, they lose out on their education opportunity. For us, children's mental health and for the State of Idaho, children's mental health should be a priority, and I encourage you to take that into consideration. Medications are a powerful tool. In my own life, with cancer and some other things, I always say "better living through chemistry", and for people with mental illness, appropriate treatment, the success rate for people with mental illness who have the appropriate treatment is 60-80%. It exceeds the treatment success for heart disease, and that's been publicized a lot, and we know that. Medication adherence is often key to experience recovery. Barriers to getting effective and well tolerated medications, such as prior authorization, can result in poor outcomes for persons with mental illness. Based on the experience of many of the NAMI members and our families, NAMI Idaho supports full and open access to psychiatric medication and opposes policies, such as restrictive formularies and "fail first" policies. We believe that the best decisions are made between the patient and the doctor, and I have brought you some copies of, this is NAMI Idaho's position paper, and some other information for the Committee. And I forgot to tell you, I'm not getting paid, and I have a Master's Degree in Public Administration, not mental health, and I'm just here as a citizen. Thank you.

Committee
Thank you very much. Does anybody have any questions? Okay, thank you. We will now go on to [inaudible] I just remind you to please stick to the testimony that was approved for today. The first person that I have up is, and I'm hoping I'm saying this right, Greg Broutman from Sunovion?

Greg Broutman, PhD
So I have a prepared statement that our legal department has approved. Thanks for the opportunity, everyone, to give testimony today. My name's Greg Broutman, I'm a Medical Science Liaison with Sunovion. It's a nice opportunity to be able to present today, because I really think there is a need for patients with epilepsy to have access to all the medications that they may need. Epilepsy is a serious neurological condition, characterized by unpredictable seizures, which can be difficult to manage. In a seminal case study, 36% of patients with epilepsy continue to experience seizure despite adequate trials of one or more AEGs. This is an article by [inaudible]. Today, there continues to be medical need for additional medications to help patients to control their seizures. In August of 2015, the FDA approved Aptiom, or eslicarbazepine acetate, for use as monotherapy treatment of partial-onset seizures. Two monotherapy studies were conducted in patients taking one or two AEDs, but still experiencing seizures. The results showed, am I speaking into this? The results showed that patients who converted to Aptiom monotherapy were less likely to exit the trial, due to worsening of seizures versus historical controls. The 1600 mg and 1200 mg groups in both trials, separately and combined, met the pre-specified criteria for efficacy. Aptiom was first approved by the FDA for adjunctive treatment of partial-onset seizures in November of 2013, wherein clinical studies with patients with partial-onset seizures who had not responded adequately to one, two or three other AEGs, experienced significantly lower seizure with the

addition of Aptiom relative to placebo. So, patient exposure to eslicarbazepine acetate since it was first marketed worldwide in 2009, where it's been approved in Europe since 2009, so the overall worldwide exposure has totaled over 75,000 patients. Aptiom is a new molecular entity; eslicarbazepine acetate is metabolized extensively to eslicarbazepine, resulting in final plasma levels of 94% eslicarbazepine and minimal amounts of (R)-licarbazepine of 5%, and 1% of circulating oxcarbazepine. Although the mechanism of action is not definitely known, eslicarbazepine is believed to be responsible for the pharmacological effects of Aptiom. Aptiom is dosed once daily, it is not an extended-release formulation, and it can be taken crushed or whole, and it's not a controlled substance. So, in closing, for patients with partial-onset seizures who are not controlled, despite taking other AEG medications, there clearly is a need for additional therapeutic doses and choices. Aptiom is an additional option as adjunctive or monotherapy treatment for these patients. We respectfully request that Aptiom is added to the preferred drug list. Thank you.

Committee
Any questions? Thank you very much. Next up, I have Laura Litzenberger from Janssen, talking about Invega Sustenna.

Laura Litzenberger, Pharm D, MBA
Good morning, I'm Laura Litzenberger with the Outcomes Research Group at Janssen Scientific Affairs. Invega Sustenna is an atypical antipsychotic, indicated for the treatment of schizophrenia. In addition, Invega Sustenna is the only long-acting atypical antipsychotic indicated for the treatment of schizoaffective disorder as either monotherapy or adjunct to mood stabilizers or antidepressants. The data supporting the schizoaffective indication was recently published and is not part of the therapeutic clinical review provided by Magellan. In this study, patients with schizoaffective disorder experiencing acute exacerbation of psychotic or depressive or manic symptoms were stabilized on Invega Sustenna and then randomized either to continue on Invega Sustenna, or were switched to a placebo for a 15-month, double-blind, relapse prevention phase. The primary outcome of the study was time to relapse, and relapse, briefly, was defined as psychiatric hospitalization, any intervention to prevent hospitalization, or worsening of clinical symptoms on two consecutive visits within seven days. A total of 334 patients were evaluated. Invega Sustenna significantly delayed time to relapse for psychiatric, depressive or manic symptoms compared to placebo. The relapse rate was lowered by 2.4 times in the Invega Sustenna group compared to the placebo group. Overall relapse rate was 33% for placebo, 15% for Invega Sustenna. For monotherapy, the relapse rate was 3.3 times greater for placebo and, for adjunct therapy, the relapse rate was two times greater for placebo. The duration for exposure was six months longer in the Invega Sustenna group. The most common adverse events were increased weight, insomnia and headache. Invega Sustenna as monotherapy or as adjunct therapy with mood stabilizers or antidepressants, significantly delays time to relapse in schizoaffective patients, and these results support that Invega Sustenna should be used for maintenance therapy in patients with schizoaffective disorder. Any questions?

Samantha Min

Good morning, my name is Samantha Min. I'm a Managed Market Liaison with Otsuka America Pharmaceutical, and I also have a legally approved document that I must read, so please bear with me. Thank you for the opportunity to provide new information about Abilify Maintena. I believe you have all received the full prescribing information, so I'd like to highlight just the following key clinical points from two publications. The first is by Naber et al, who published a head-to-head, randomized, open-label, rater-blinded study to evaluate the efficacy and safety of Abilify Maintena to paliperidone palmitate long-acting injectable, also known as Invega Sustenna in adult patients with schizophrenia. The primary efficacy endpoint using the Heinrichs-Carpenter Quality of Life Scale, showed a statistically significant improvement on total scores from baseline to week-28 with Abilify Maintena compared to Invega Sustenna. Adverse events were the most frequent reason for discontinuation; 11% in the Abilify Maintena group and 20% in the Invega Sustenna group. The incidence of treatment-emergent adverse events occurring in 5% or greater of Abilify Maintena treatment group was weight gain, and in the Invega Sustenna group were weight gain, insomnia, and psychotic disorder. The next publication was by Caine et al, where they published a phase-3b, multicenter, open-label, mirror image study in a naturalistic setting of patients with schizophrenia. It was conducted to compare total psychiatric hospitalization rates between retrospective treatment with oral standard of care antipsychotics and prospective treatment with Abilify Maintena. The primary efficacy outcome reported the rate of at least one psychiatric hospitalization for retrospective oral standard of care as 27%, and for the prospective Abilify Maintena treatment to be 2.7% treatment-emergent adverse events with incidence of 5% or greater in the prospective treatment phase included insomnia and akathisia. Discontinuation due to adverse events during the prospective phase was about 9%. As a reminder, Abilify Maintena for extended-release injectable suspension is an atypical antipsychotic indicated for the treatment of schizophrenia. It is administered by intramuscular injection in the deltoid or gluteal muscle by a health care professional. For convenience, a single dose, pre-filled dual-chamber syringe was FDA approved in July of this year. In fair balance, please note the box warning for Abilify Maintena, which is increased mortality in elderly patients with dementia-related psychosis, and of course you have the full prescribing information if you need any further information on that. So, in closing, Otsuka respectfully asks that Abilify Maintena be included on the Preferred Drug List in Idaho Medicaid, and if you have any questions, I'd be happy to entertain them right now. Thank you.