

Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 11-18-2016.

Submission # 1

This request has not been approved for oral testimony (10/25/16).

## Gennrich, Jane

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**From:** Eide, Tamara J.  
**Sent:** Friday, October 07, 2016 4:16 PM  
**To:** Gennrich, Jane  
**Subject:** FW: Idaho Medicaid P & T Committee Meeting November 18, 2016  
**Attachments:** ADH-9-00221-1 Feld- Aptensio XR Testimony.pdf

### **Tami Eide, Pharm.D., BCPS**

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**From:** Tim Hopkins [<mailto:THopkins@guidemarkhealth.com>]  
**Sent:** Thursday, October 06, 2016 11:44 AM  
**To:** Eide, Tamara J.  
**Subject:** Idaho Medicaid P & T Committee Meeting November 18, 2016

Hi Tami,

I am attaching the written testimony from our speaker Dr. Michael Feld that we plan on giving testimony at the Boise, ID Medicaid P & T Committee Meeting November 18, 2016. I understand that the registration is 30 minutes prior the meeting for a speaker to give testimony on behalf of a pharmaceutical company.

I did not see an agenda but is the time slot 9 AM to 5 PM? Sorry for the questions but I am kind of new to this and just trying to understand.

Tim

**Tim Hopkins**  
Director, Meeting Operations  
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My name is Michael Feld; I am a practicing pediatric and adult psychiatrist with 24 years of experience. In my practice I treat approximately 300–350 patients, ages 3 through 65, of whom about 25% are children, about 40% are adolescents and about 35% are adults. The patient population at my practice includes a mix of approximately 30% Medicaid insured patients and 70% commercially insured patients. As a physician with experience using Aptensio XR® (methylphenidate HCl extended-release), I would like to provide, for the committee's consideration, the clinical benefits that I have observed with Aptensio XR in my practice that have been consistent with results demonstrated in clinical trials. I do so on behalf of Rhodes Pharmaceuticals L.P.

Aptensio XR can be prescribed for children and adults, as it is indicated in patients aged 6 and above, allowing for continued therapy into adulthood. Furthermore, because Aptensio XR is supplied in 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, and 60 mg capsules, it allows dosing customization to meet the patient's need.

Moreover, Aptensio XR would meet the definition of a sprinkle-dosage form of methylphenidate. As demonstrated by its pharmacokinetic (PK) profile, capsules may be swallowed whole or opened and the entire contents sprinkled onto applesauce, as the plasma concentration-time curve is nearly identical in both cases. Each capsule of Aptensio XR contains multilayered beads, in which each bead is composed of an immediate-release (IR) layer that contains ~40% of the methylphenidate dose and a sustained-release layer that contains ~60% of the methylphenidate dose, which is delayed for absorption later in the patient's day. This results in a biphasic PK curve. It has been shown in clinical studies in both pediatric and adult patients that the plasma concentration of methylphenidate increases rapidly (from the ~40% IR), reaching an initial maximum concentration at about 2 hours post dose administration, after which it gradually decreases over the next 4-6 hours and then gradually starts to increase again, reaching a second peak at approximately 8 hours post dose (from the sustained release of the remaining ~60% methylphenidate).

Each capsule of Aptensio XR is designed to have a 12-hour duration of effect. In my practice, patients have responded well to Aptensio XR; my clinical experience is consistent with the results of Rhodes Pharmaceuticals' clinical studies. Aptensio XR has proven symptom improvement after 1 week of treatment, as shown in a clinical study that measured change from baseline in ADHD-RS-IV total score. In addition, an analog classroom clinical study showed that once-daily treatment with Aptensio XR led to fewer ADHD symptoms related to classroom behavior, written work, and overall behavior (as measured by lower Swanson, Kotkin, Agler, M-Flynn, and Pelham [SKAMP] rating scale total scores) compared to placebo, demonstrating statistically significant efficacy from hour 1 to hour 12 post dose. The SKAMP rating scale is a validated 13-item classroom assessment tool used to determine impairment of specific classroom behaviors related to both inattentiveness and impulsivity, in which lower SKAMP scores represent an improvement in ADHD symptoms. In this study, Aptensio XR demonstrated statistically-significant reduction of SKAMP scores as compared to placebo at every time point tested post dose: 1, 2, 3, 4.5, 6, 7.5, 9, 10.5, and 12 hours. My clinical experience has also been consistent with published clinical study safety and tolerability data. The discontinuation rate in my practice has been consistent with the 1.6%–4.4% discontinuation rate observed in Rhodes' clinical studies.

I hope that the Department will consider the benefit of adding Aptensio XR to the preferred drug list. Thank you for your time and consideration.

Michael Lee Feld, MD  
Board Certified, American Board of Psychiatry and Neurology  
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Please see Important Safety Information below. Please see Full Prescribing Information, including Boxed Warning, available at <http://www.aptensioxr.com/resources/full-prescribing-information.pdf>.

## INDICATION

Aptensio XR<sup>®</sup> (methylphenidate HCl extended-release) is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

## IMPORTANT SAFETY INFORMATION

### **WARNING: ABUSE AND DEPENDENCE**

**CNS stimulants, including Aptensio XR, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing and monitor for signs of abuse and dependence while on therapy.**

- Aptensio XR is contraindicated:
  - In patients known to be hypersensitive to methylphenidate or other components of Aptensio XR. Hypersensitivity reactions, such as angioedema and anaphylactic reactions, have been reported
  - During treatment with monoamine oxidase inhibitors (MAOIs) and within 14 days following discontinuation of treatment with an MAOI because of the risk of hypertensive crisis
- Prior to treating pediatric patients and adults with CNS stimulants including Aptensio XR, assess for the presence of cardiac disease (ie, perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam). Educate patients about abuse, monitor for signs of abuse and overdose, and periodically reevaluate the need for Aptensio XR use
- Sudden death, stroke, and myocardial infarction have occurred in adults treated with CNS stimulants at recommended doses. Sudden death has occurred in children and adolescents with structural cardiac abnormalities and other serious cardiac problems, as well as in adults taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during Aptensio XR treatment
- CNS stimulants cause an increase in blood pressure (mean increase approximately 2 to 4 mm Hg) and heart rate (mean increase approximately 3 to 6 bpm). Individuals may have larger increases. Monitor all patients for hypertension and tachycardia
- Exacerbation of preexisting psychosis: CNS stimulants may exacerbate symptoms of behavior disturbance and thought disorder in patients with a preexisting psychotic disorder
- Induction of a manic episode in patients with bipolar disorder: Prior to initiating treatment, screen patients for risk factors for developing a manic episode (eg, comorbid or history of depressive symptoms or a family history of suicide, bipolar disorder, or depression)

- New psychotic or manic symptoms: CNS stimulants, at recommended doses, may cause psychotic or manic symptoms (eg, hallucinations, delusional thinking, or mania) in patients without a prior history of psychotic illness or mania
- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed
- Patients who are not growing or gaining height or weight as expected may need to have their treatment interrupted
- Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud's phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with ADHD stimulants
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Closely monitor growth (weight and height) in pediatric patients treated with CNS stimulants, including Aptensio XR
- Based on accumulated data from other methylphenidate products, the most common ( $\geq 2\%$  and twice the rate of placebo) adverse reactions are decreased appetite, decreased weight, nausea, abdominal pain, dyspepsia, dry mouth, vomiting, insomnia, anxiety, nervousness, restlessness, affect lability, agitation, irritability, dizziness, vertigo, tremor, blurred vision, increased blood pressure, increased heart rate, tachycardia, palpitations, hyperhidrosis, and pyrexia. There is limited experience with Aptensio XR in US double-blind, placebo-controlled trials. Because of very different study designs, adverse events following Aptensio XR treatment were not merged between studies. Adverse events following treatment with placebo were, however, merged. At least 5% of patients in any treatment group reported abdominal pain (combined preferred terms abdominal pain and abdominal pain upper), decreased appetite, headache, and insomnia
- The long-term efficacy of methylphenidate in pediatric patients has not been established. The safety and effectiveness of Aptensio XR in pediatric patients under 6 years have not been evaluated
- Limited published studies report on the use of methylphenidate in pregnant women; however, the data are insufficient to inform any drug associated risks. The background risk of major birth defects and miscarriage for the indicated population are unknown
- Patients should be advised to tell their physicians if they are pregnant or plan to become pregnant. It is not known if Aptensio XR will harm their unborn baby
- Nursing mothers should be advised to discontinue drug or discontinue nursing, taking into consideration the importance of the drug to the mother because methylphenidate is present in human milk