

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

Submission # 7

This request has not been approved for oral testimony (11/03/16).

Gennrich, Jane

From: Sunovion Med Info <sunovionmedinfo@irmsonline.net>
Sent: Thursday, November 03, 2016 7:15 AM
To: Eide, Tamara J.
Cc: Kimberly.Laubmeier@sunovion.com
Subject: Requested Medical Information Regarding LATUDA - Case Number 2016-005776
Attachments: LATUDA Package Insert.pdf; Medical Information Letter Latuda.pdf

Dear Dr. Eide:

The enclosed information is being provided by Sunovion Pharmaceuticals Inc. on Latuda® (lurasidone HCl) for the Idaho Medicaid Pharmacy & Therapeutics Committee Review on November 18, 2016.

Should you have questions or need additional information, please contact us directly at 1-800-739-0565, email us at minfo@sunovion.com, or visit us at www.SunovionMedical.com.

Sincerely,
Sunovion Medical Information

October 24, 2016

Tami Eide, PharmD
3232 Elder Street
Boise, ID 83705

Dear Idaho Medicaid Pharmacy and Therapeutics Committee:

Thank you for your interest in Latuda® (lurasidone HCl) tablets. The enclosed information is in response to your request prepared for the Idaho Medicaid Pharmacy and Therapeutics Committee Review on November 18th, 2016. This was forwarded by your Health Economics and Outcomes Research Liaison, Kimberly Laubmeier, regarding:

- Latuda Tablets – MSL-HEOR Responsive Testimony for Idaho Medicaid

LATUDA is indicated for the treatment of patients with schizophrenia. The efficacy of LATUDA in schizophrenia was established in five 6-week controlled studies of adult patients with schizophrenia.

LATUDA is indicated as monotherapy and as adjunctive therapy with either lithium or valproate for the treatment of patients with major depressive episodes associated with bipolar I disorder (bipolar depression). The efficacy of LATUDA was established in a 6-week monotherapy study in adult patients with bipolar depression and in a 6-week study in adult patients with bipolar depression who were treated with lithium or valproate.

Please see the attached package insert for important safety information, including the following **Boxed Warning**:

WARNINGS: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS; AND SUICIDAL THOUGHTS AND BEHAVIORS
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death [see **WARNINGS AND PRECAUTIONS**]. LATUDA is not approved for use in patients with dementia-related psychosis [see **WARNINGS AND PRECAUTIONS**]. Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults in short-term studies. These studies did not show an increase in the risk of suicidal thoughts and behavior with antidepressant use in patients over age 24; there was a reduction in risk with antidepressant use in patients aged 65 and older [see **WARNINGS AND PRECAUTIONS**]. In patients of all ages who are started on antidepressant therapy, monitor closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber [see **WARNINGS AND PRECAUTIONS**].

The enclosed information is provided as a professional courtesy in response to your unsolicited request for information. This information is intended to provide pertinent data that may assist you in forming your own conclusions and making your own decisions based on your professional judgment. This information is not intended to advocate any indication, dosage, or other claim that is not covered in the enclosed package insert.

Should you have any questions or need additional information, please contact us directly at 1-800-739-0565, email us at minfo@sunovion.com, or visit our Medical Information website at www.sunovionmedical.com.

Thank you again for your interest in LATUDA.

Sincerely,

Sunovion Pharmaceuticals Inc.
Medical Information Department

Sunovion Pharmaceuticals Inc. (Sunovion) is a wholly-owned U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

2016-005776

MSL-HEOR Responsive Testimony for Idaho Medicaid

November 18, 2016

MSL

Hello everyone. My name is Dr. Lyle Laird, and I am a PharmD, Director, and Medical Science Liaison with Sunovion Pharmaceuticals, Inc. Thank you for the opportunity to address the committee today on lurasidone HCL (Latuda). I will briefly review the key clinical information for the product and then my colleague, Dr. Kim Laubmeier, will be utilizing the remainder of our allotted time to review new comparative health economic and outcomes data.

Lurasidone is indicated for the acute treatment of both schizophrenia and bipolar depression in adults and is the only agent in this class with an indication as both monotherapy and adjunctive therapy with lithium or valproate for the acute treatment of bipolar depression.¹ In addition, lurasidone and clozapine are the only atypical antipsychotics with a pregnancy category B rating. Also, lurasidone has no clinically relevant impact on the QT interval and smoking is not expected to have an effect on its pharmacokinetics.

The safety and efficacy of lurasidone has been established in numerous clinical trials.¹ In these trials, patients, on average, did not experience significant increases in weight or other metabolic parameters, which is important consideration, given that patients with serious mental illness have an increased risk of developing diabetes, obesity, and cardiovascular disease.

In fair balance, I refer you to the lurasidone full prescribing information for a complete list of warnings, precautions and adverse events.

HEOR

Hello everyone. My name is Dr. Kim Laubmeier, and I am a clinical psychologist and a Director of Health Economics and Outcomes Research with Sunovion Pharmaceuticals, Inc. Again, thank you for the opportunity to address the committee today.

In addition to the favorable clinical trial outcomes, lurasidone has also consistently demonstrated favorable comparative health outcomes and cost-effectiveness in adult patients with schizophrenia and bipolar disorder. I will highlight examples across 4 key outcomes: hospitalization, adherence, number needed to treat, and total medical costs.

Starting with hospitalization outcomes, in real-world claims analyses from Medicaid and commercial databases, lurasidone initiation was associated with an ~50% decrease in both all-cause and mental-health related hospitalization for patients with schizophrenia, and a 36% to 39% reduction for patients with bipolar disorder in the 6-month follow-up period.²⁻³ Similarly, in another 6-month analysis of Medicaid patients with schizophrenia, hospital length of stay was significantly shorter for patients switching to lurasidone compared to those switching to quetiapine.⁴

Turning to adherence outcomes, in real-world claims analyses of patients with schizophrenia and bipolar disorder in Medicaid, patients on lurasidone experienced significantly higher adherence rates compared to patients on aripiprazole, olanzapine, quetiapine, and risperidone.⁵⁻⁶

Looking at number needed to treat outcomes, in a comparison of the only 3 approved agents for bipolar depression, lurasidone yielded substantially more favorable relative number needed to treat and number needed to harm compared to quetiapine and the olanzapine-fluoxetine combination.⁷

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Finally, in terms of economic outcomes, in an independent Humana claims database analysis, patients on lurasidone were observed to have substantially lower total medical costs when compared with those on aripiprazole, quetiapine, risperidone, olanzapine, and paliperidone; and, this study was recently published in the *Journal of Managed Care and Speciality Pharmacy*.⁸

In conclusion, lurasidone addresses the need for safe and cost-effective agents to manage adult patients with schizophrenia and bipolar depression. And, importantly, in the most recently published Medicaid treatment guidelines, lurasidone is positioned as a 1st-line treatment for both schizophrenia and bipolar depression, with a specific footnote indicating that lurasidone has a better metabolic profile than quetiapine in treatment of bipolar depression.⁹

Thus, on behalf of Sunovion Pharmaceuticals, Inc., I respectfully request that lurasidone be retained on the preferred drug list for the Medicaid beneficiaries in the state of Idaho. I thank you for the opportunity to speak today, and I am happy to address any questions.

MSL-HEOR Responsive Testimony for Idaho Medicaid

November 18, 2016

References

1. Latuda® (lurasidone HCl) tablets [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.
2. Hassan M *et al.* Inpatient admissions among schizophrenia patients before and after initiating lurasidone in a multi-state Medicaid population. Poster presented at the US Psychiatric and Mental Health Congress, Las Vegas, NV, Sept. 30–Oct. 3, 2013.
3. Hassan M *et al.* Six-month evaluation of changes in inpatient admissions among patients with bipolar disorder who switched to lurasidone in a commercial health plan population. Poster presented at Academy of Managed Care Pharmacy (AMCP), Tampa, FL, April 2-4.
4. Ng-Mak D, *et al.* Comparative outcomes of patients switching to lurasidone or quetiapine: a real world analysis of Medicaid-insured schizophrenia patients. Podium presentation at International Conference on Schizophrenia Research (ICOSR), March 28 - April 1, 2015; Colorado Springs, Colorado.
5. Hassan M, *et al.* Comparison of treatment adherence among new-start patients on Latuda vs other atypical antipsychotics: results from a multi-state Medicaid population among adults with schizophrenia. Poster presented at US Psychiatric and Mental Health Congress (USPMHC); September 30 - October 3, 2013, Las Vegas, NV.
6. Hassan M, *et al.* Treatment adherence among patients initiated on Latuda vs other atypical antipsychotics: results from a multi-state Medicaid population among adults with bipolar disorder. Poster presented at US Psychiatric and Mental Health Congress (USPMHC); September 30 - October 3, 2013, Las Vegas, NV.
7. Citrome L, *et al.* Clinical assessment of lurasidone benefit and risk in the treatment of bipolar I depression using number needed to treat, number needed to harm, and likelihood to be helped or harmed. *J of Affect Disord.* 2014;155:20-27.
8. Jiang Y, Ni W. Health Care Utilization and Treatment Persistence Associated with Oral Paliperidone and Lurasidone in Schizophrenia Treatment. *J Manag Care Spec Pharm.* 2015;21(9):780–792.
9. 2015 Florida Best Practice Psychotherapeutic Medication Guidelines for Adults (2015). The University of South Florida, Florida Medicaid Drug Therapy Management Program sponsored by the Florida Agency for Health Care Administration.